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编号	**项目**	**咨询包含内容**
1	**ISO 13485(医疗器械质量体系认证)**	质量手册（一级文件）、程序文件（二级文件）、操作规程/管理制度/技术要求模板（三层文件）、确认或验证\记录（四层文件）
2	**ISO 9001（质量体系认证QMS）**	质量手册（一级文件）、程序文件（二级文件）、操作规程/管理制度/技术要求模板（三层文件）、确认或验证\记录（四层文件）
3	**德国**	质量手册（一级文件）、程序文件（二级文件）、操作规程/管理制度/技术要求模板（三层文件）、确认或验证\记录（四层文件）
4	**ISO 13485(医疗器械质量体系认证)和ISO9001**	质量手册（一级文件）、程序文件（二级文件）、操作规程/管理制度/技术要求模板（三层文件）、确认或验证\记录（四层文件）
5	**ISO 13485(医疗器械质量体系认证)**	质量手册和程序文件，协助完成第三层和第四层文件的完善
6	**CE(IIa)**	全套文件
7	**CE(IIb)**	全套文件
8	**CE(III)**	全套文件
9	**国内注册（二类）**	全套文件
10	**国内三类**	全套文件除临床
11	**灭菌确认**	灭菌确认方案、报告（安装鉴定IQ\运行鉴定OQ\性能鉴定PQ）、记录、不合格项的整改
12	**包装确认**	包装确认包括热封确认、加速老化确认
13	**模拟运输确认**	按照astmD4169出具包括方案、检测报告、确认报告
14	**生物学评价**	生物学评价报告
15	**临床评价报告**	方案报告
16	**上市后产品监督计划（PMCF）**	
17	**上市后产品报告**	上市后产品报告
18	**易用性（可用性）报告**	IEC_62366-可用性报告
19	**风险管理报告（CE）**	符合ISO 14971要求的风险分析报告
20	**风险管理报告（国内）**	
21	**工艺用水确认报告**	符合国内医疗器械规范（医疗器械gmp）的方案报告等
22	**飞行检查符合性（国内）**	检查符合性、不合格整改，让企业符合gmp规范，避免停产
23	**确认培训（灭菌、包装、工艺用水、热封、CE法规）**	培训ppt，课程1-2天
24	**国内医疗器械飞检培训**	课程1-2天
25	**降解方案及报告**	编写降解方案（符合国内、ce、FDA要求），检测报告

EUROPEAN COMMISSION
DG Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies

Health technology and Cosmetics

备注：中文翻译中的临床调查=临床研究，评估=评价、设备=器械、数据=资料

MEDDEV 2.7/1 revision 4

June 2016

GUIDELINES ON MEDICAL DEVICES 医疗器械指南

CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

Note

The present Guidelines are part of a set of Guidelines relating to questions of application of EC-Directives on medical Devices. They are legally not binding. The Guidelines have been carefully drafted through a process of intensive consultation of the various interested parties (competent authorities, Commission services, industries, other interested parties) during which intermediate drafts where circulated and comments were taken up in the document. Therefore, this document reflects positions taken by representatives of interest parties in the medical devices sector. These guidelines incorporate changes introduced by Directive 2007/47/EC amending Council Directive 90/385/EEC and Council Directive 93/42/EEC.

本指南为一系列与CE—医疗器械指令应用问题相关的指南中的一部分。并不具有法律约束力。该指南在经过与各个利益方（主管当局、服务委员会、行业委员会、其他利益相关团体）进行深入协商之后谨慎拟定而成，期间对中期草案进行了传阅，而且部分意见还为本文件所采纳。因此，本文件反映出了来自医疗器械行业的利益团体代表所持的立场。本指南包含了指令 2007/47/EC对90/385/EEC和 93/42/EEC修正中的变更

（没规定实施时间）

MEDICAL DEVICES DIRECTIVES
CLINICAL INVESTIGATION

CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

Index

1. Introduction 介绍

Pursuant to 依据

- section 6a of Annex I to Directive 93/42/EEC (amended by Directive 2007/47/EC) and to
- section 5a of Annex 1 to Directive 90/385/EEC (amended by Directive 2007/47/EC),

the demonstration of conformity with Essential Requirements for a medical device must include a clinical evaluation, which is conducted in accordance with Annex X to Directive 93/42/EEC or with Annex 7 to Directive 90/385/EEC.

MDD 指令93/42/EEC (amended by Directive 2007/47/EC) 附录I的6a部分和

MDD指令90/385/EEC (amended by Directive 2007/47/EC) 附录I的5a部分

和医疗器械的基本要求一致性的证明必须包含临床评价，根据Directive 93/42/EEC的附录10和Directive 90/385/EEC的附录7来指导。

This document promotes a common approach to clinical evaluation for medical devices regulated by directives 90/385/EEC and 93/42/EEC. It does not concern in vitro diagnostic devices.

The depth and extent of clinical evaluations should be flexible and appropriate to the nature, intended purpose, and risks of the device in question. Therefore, this guidance is not intended to impose device-specific requirements.

这个文件提供了按directives 90/385/EEC and 93/42/EEC规定开展医疗器械临床评价的一般途径，不包含体外诊断试剂。

This document uses the terms "must", "shall", "have to" where these terms are used in the Directives. "Should" is used in other instances.

本文档使用了术语“必须”、“应当”、“必须”这些术语使用的指令。“应该”在其他情况下使用。

2. Scope范围

This guide is not legally binding; only the text of the Directives is authentic in law. It is recognised that under given circumstances, for example as a result of scientific developments, an alternative approach may be possible or appropriate to comply with the legal requirements.

本指南不具有法律约束力，只有在指令的文本是法律约束的。在给定的情况下是被承认的，例如作为科学发展的结果，另一种方法可能或适当的符合法律要求。

Nevertheless, due to the participation of interested parties and of experts from national Competent Authorities, it is anticipated that this guide will be followed within the Member States, thereby supporting uniform application of relevant provisions of EU Directives and common practices.

然而，由于有利害关系人和国家主管部门的专家参与，预计本指南将在成员国跟从，从而支持欧盟相关指令的统一应用和一般做法。

On certain issues not addressed in the Directives, national legislation may be different from this guide.

在指令中，某些问题不能被解决，国家法规可能不同于本指南。

This guide is regularly updated according to regulatory developments. The latest version of the guide should always be used. This version is a complete revision of the previous texts.

The medical device legislation in Europe is currently being significantly revised. A new Regulation of the European Parliament and of the Council on medical devices will be published, which may result in changes to important concepts or definitions relating to clinical evaluation. Parts or all of this document are likely to be revised. Some contents (such as contents about notified bodies) are likely to be removed and integrated in other series of documents.

本指南将根据监管发展而定期更新，指南的最新版本总是被使用。本版本完全修订了之前的文本。

欧洲的医疗器械法规目前正在大幅修订。一项新规定的欧洲议会和理事会的医疗设备将发布，这可能导致临床评估相关的重要概念或定义发生变化。部分或全部本文档可能会修订。某些内容(如关于NB的内容)可能会被删除和综合其他系列文档中。

3. References 参考文献

European Legislation: 欧盟法规

- Council Directive 90/385/EEC of 20 June 1990 relating to active implantable medical devices

AIMDD 90/385/EEC

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

MDD 93/42/EEC

- Commission Regulation 722/2012 of 8 August 2012 concerning active implantable medical devices and medical devices manufactured utilising tissues of animal origin

（有源植入器械和含动物源组织器械的法规）

- Commission Implementing Regulation 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices

Harmonised and International standards: 协调标准和国际标准

- EN ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good clinical practice

EN ISO 14155:2011 人体用医疗器械的临床调查—优良的临床规范

- EN ISO 14971:2012 Medical devices – application of risk management to medical devices

EN ISO 14971:2012 医疗器械 – 风险管理对医疗器械的应用

European guidance documents: 欧盟指南文件

- MEDDEV 2.12/1 Guidelines on a medical devices vigilance system

MEDDEV 2.12/1 医疗器械警戒系统指南

- MEDDEV 2.12/2 Guidelines on post market clinical follow-up studies: a guide for manufacturer and notified body

MEDDEV 2.12/2 上市后的临床跟踪指南

- MEDDEV 2.4/1 Classification of medical devices

MEDDEV 2.4/1 医疗器械的分类

- MEDDEV 2.7/2 Guidelines for competent authorities for making a validation/assessment of a clinical investigation application under directives 90/385/EEC and 93/42/EC

MEDDEV 2.7/2 主管部门进行临床研究应用的验证/评估指南

- Manual on borderline and classification in the Community regulatory framework for medical devices

人工边界和分类，医疗器械在社区的监管架构

- NBOG BPG 2006-1 Change of notified body

NBOG BPG 2006-1 公告机构的变更

- NBOG BPG 2009-1 Guidance on design-dossier examination and report content

NBOG BPG 2009-1 设计档案检查和报告内容的指南

- NBOG BPG 2009-4 Guidance on notified body‘s tasks of technical documentation assessment on a representative basis

NBOG BPG 2009-4 公告机构技术文件评估指南

- NBOG BPG 2010-2 Guidance on audit report content

NBOG BPG 2010-2 审计报告内容指南

- NBOG BPG 2014-1 Renewal of EC design-examination and type-examination certificates: Conformity assessment procedures and general rules

NBOG BPG 2014-1 EC设计审核和型式检验认证：符合性评估程序和一般规则

- NBOG BPG 2014-2 Guidance on the information required for notified body medical device personnel involved in conformity assessment activities

NBOG BPG 2014-2 公告机构医疗设备人员参与合格评定活动所需信息的指南

- NBOG BPG 2014-3 Guidance for manufacturers and notified bodies on reporting of design changes and changes of the quality system

NBOG BPG 2014-3 制造商和公告机构报告设计变更和质量体系变更的指南

Other guidance documents:其他指南文件

- GHTF SG5 N1R7:2007: Clinical evidence - Key definitions and concepts

GHTF SG5 N1R7:2007 临床证据—关键定义和概念

- GHTF SG5 N2R8:2007: Clinical evaluation 临床评价

- GHTF SG5 N41R9:2005: Essential principles of safety and performance

GHTF SG5 N41R9:2005: 安全和有效的基本原则

This list contains documents available at the time this MEDDEV document was published. In general, the most recent versions of standards and legal texts should be used.

这个列表包含文件时可用MEDDEV文档发表。一般来说，应当使用最新版本的标准和法律文本。

4. Definitions 定义

4.1 Adverse event: any untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons whether or not related to the investigational medical device.

不良事件：任何不幸的医疗事件，非预期的疾病或伤害，或任何不幸的临床症状（包括反常的试验检查）在受试者、使用者、或无论是否与临床实验的医疗设备相关的其他人员。

NOTE 1: This includes events related to the investigational device or the comparator.

包括 相关的调查设备和对照设备

NOTE 2: This includes events related to the procedures involved.

NOTE 3: For users or other persons this is restricted to events related to the investigational medical device.对使用者或其他人员仅限于调查器械相关的事件。

[EN ISO 14155:2011]

4.2 Bias: bias is a systematic deviation of an outcome measure from its true value, leading to either an overestimation or underestimation of a treatment's effect. It can originate from, for example, the way patients are allocated to treatment, the way treatment outcomes are measured and interpreted, and the way data are recorded and reported. [Adapted from GHTF SG5/N2R8:2007]

偏见：偏见是一个从它的真正价值和测量结果之间的系统性偏差，导致一个高估或者低估治疗的效果。可能来源于，例如病人分配给治疗的方式，治疗结果的测量和解释方式，数据记录和报告的方式。

4.3 Clinical data: the safety and/or performance information that is generated from the clinical use of a device. Clinical data are sourced from:

由医疗器械的临床使用生成的安全和/或性能信息，临床数据包括：

- clinical investigation(s) of the device concerned; or设备有关的临床调查，或

- clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or临床调查或科学文献的研究报告，或者类似设备的等价性问题可以被证明，或

- published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.公开发表或未公开发表的相同设备或者等价性问题可以被证明相似设备的临床经验报告

[derived from Article 1.2.k MDD and Art. 1.2.k AIMDD]

4.4 Clinical evaluation: a methodologically sound ongoing procedure to collect, appraise and analyse clinical data pertaining to a medical device and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer's Instructions for Use.

临床评价：不间断收集、评价和分析适合于医疗器械的临床数据，评价是否足够充分的临床

证据来确认在根据制造商的使用说明书使用设备时，符合相关安全和性能相关的基本要求。

Note: In exceptional cases where an instruction for use is not required, the collection, analysis and assessment are conducted taking into account generally recognised modalities of use. 在一个不需要使用说明书的特殊情况下，收集、分析和评估考虑采用普遍认可的使用形式。

4.5 Clinical evidence: the clinical data and the clinical evaluation report pertaining to a medical device. [GHTF SG5/N2R8:2007]

临床证据: 适合于医疗器械的临床数据和临床评价报告

4.6 Clinical investigation: systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device.

临床调查： 在一个或多个人体受试者上进行的任何系统调查, 用于评估医疗器械的安全和/或性能。

Note: 'clinical trial' or ' clinical study' are synonymous with ' clinical investigation'. [EN ISO 14155:2011] clinical trial 等同于 clinical study

4.7 Clinical investigation plan: document that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation. [EN ISO 14155:2011]

临床调查方案： 陈述基本原理，目标，设计和建议的分析、方法论、监测、进行和记录临床调查的文件

4.8 Clinical performance: behaviour of a medical device or response of the subject(s) to that medical device in relation to its intended use, when correctly applied to appropriate subject(s). [EN ISO 14155:2011]

临床性能: 医疗器械正确应用于合适的受试者，医疗器械的行为或者响应达到预期用途

4.9 Device registry: an organised system that uses observational study methods to collect defined clinical data under normal conditions of use relating to one or more devices to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves predetermined scientific, clinical or policy purpose(s).

器械登记：一个组织系统，采用观察性研究方法来收集定义的临床数据，在正常使用情况下有关指定一个或多个设备评估结果，为一个特定的疾病、条件定义的人口或暴露和预定服务科学、临床或政策目的(s)。

Note: The term “device registry” should not be confused with the concept of device registration and listing.

[MEDDEV 2.12/2 rev2]

4.10 Clinical safety: freedom from unacceptable clinical risks, when using the device according to the manufacturer’s Instructions for Use. [MEDDEV 2.7/2 revision 2]

Note: In exceptional cases where an instruction for use is not required, the collection, analysis and assessment are conducted taking into account generally recognised modalities of use.

临床安全: 当根据说明书使用器械时，没有不可接受的临床风险。

4.11 Clinical use: use of a medical device in or on living human subjects.

Note: Includes use of a medical device that does not have direct patient contact.

临床使用： 医疗器械在人类活体上使用

4.12 Equivalent device: a device for which equivalence to the device in question can be demonstrated. [Derived from Art. 1.2.k MDD]

等价器械：一个器械的等同性问题能被证明的器械。

4.13 Feasibility study: a clinical investigation that is commonly used to capture preliminary information on a medical device (at an early stage of product design) to adequately plan further steps of device development, including needs for design modifications or parameters for a pivotal study. [MEDDEV 2.7/2 revision 2]

可行性研究：临床调查通常用于获取医疗设备初步信息 (在产品设计的早期阶段)而充分计划设备开发的未来步骤，包括需要设计修改或一个关键参数研究。

4.14 Harmonised standards: standards whose references have been published in the Official Journal of the European Communities. [Derived from article 5 of Directive 90/385/EEC and article 5 of Directive 93/42/EEC]

协调标准：已经发表在欧洲共同体的官方杂志上的应用标准。

4.15 Hazard: potential source of harm. [EN ISO 14971:2012]

危险：潜在的伤害。

4.16 Hazard due to substances and technologies: for the purpose of this MEDDEV document, a hazard that is seen with products that share specific characteristics.

危险物质和技术：为了MEDDEV文档的目的，看作分担特定特征的产品的风险。？

Note: This includes products that contain the same materials and substances, material combinations, use the same technologies, produce similar abrasion, are used with the same

type of surgical approach, share the same manufacturing procedures or impurities, or share other characteristics.

4.17 Incident: any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. [MEDDEV 2.12/rev 8]

事件：任何设备的品质和/或性能的故障或恶化，以及标签或使用说明书中的任何不足，直接或间接，可能导致或可能已经导致病人或使用者或他人的死亡，或他们的健康状况严重恶化。

4.18 Information materials supplied by the manufacturer：for the purpose of this document, this refers to the labelling, instructions for use and the manufacturer's promotional materials for the device under evaluation. [Derived from MDD Art. 1.2.g, MDD Annex I section 13, AIMDD Art. 1.2.f, AIMDD Annex I sections 14 and 15]

制造商提供的信息材料：本文件的目的是指的是设备标签、使用说明书和制造商的宣传材料应该评估。

4.19 Intended purpose: the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials. [MDD Art. 1.2.g, AIMDD Art. 1.2.f]

预期目的：设备的使用是根据制造商提供的数据标签、说明书和/或促销材料

4.20 Investigator: individual member of the investigation site team designated and supervised by the principal investigator at an investigation site to perform critical clinical-investigation-related procedures or to make important clinical investigation-related decisions. [EN ISO 14155:2011]

研究者：

4.21 PMCF plan: the documented, proactive, organised methods and procedures set up by the manufacturer to collect clinical data based on the use of a CE-marked device corresponding to a particular design dossier or on the use of a group of medical devices belonging to the same subcategory or generic device group as defined in Directive 93/42/EEC. The objective is to confirm clinical performance and safety throughout the expected lifetime of the medical device, the acceptability of identified risks and to detect emerging risks on the basis of factual evidence. [MEDDEV 2.12/2 rev.2]

PMCF计划：

4.22 PMCF study: a study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a

device when used in accordance with its approved labelling. [MEDDEV 2.12/2 rev.2]

PMCF研究：

4.23 Risk: combination of the probability of occurrence of harm and the severity of that harm. [EN ISO 14971:2012]风险：危害发生的概率和危害严重性的组合。

4.24 Risk management: systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk. [EN ISO 14971:2012]

风险管理：系统应用管理政策、程序和实践来分析、评价、控制和监控风险的工作。

4.25 Serious adverse event: adverse event that 严重不良事件

a) led to death,

b) led to serious deterioration in the health of the subject, that either resulted in

1) a life-threatening illness or injury, or

2) a permanent impairment of a body structure or a body function, or

3) in-patient or prolonged hospitalization, or

4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

c) led to foetal distress, foetal death or a congenital abnormality or birth defect.

a) 导致死亡;

b) 导致病人，使用者或他人的健康恶化:

(1) 导致威胁生命的疾病或伤害;

(2) 导致人体结构或身体机能永久的损伤;

(3) 要求病人住院治疗或延长住院时间

(4) 导致医疗或手术的介入从而阻止对人体结构或身体机能的永久损失;

c) 导致胎儿宫内窒息，胎儿死亡或先天不健全

NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the CIP [Clinical Investigation Plan], without serious deterioration in health, is not considered a serious adverse event. [EN ISO 14155:2011] 在于其存在的情况下计划住院，或一个CIP(临床研究计划)过程所需的，没有严重的健康恶化，并不被视为严重不良事件。

4.26 Sufficient clinical evidence: an amount and quality of clinical evidence to guarantee the scientific validity of the conclusions.

足够的临床证据：临床证据的数量和质量保证结论的科学有效性。

5. Abbreviations 缩写词

AIMDD: Active implantable medical device directive (Council Directive 90/385/EEC amended by Directive 2007/47/EC) 有源植入医疗器械

CEAR: Clinical Evaluation Assessment Report 临床评价评估报告

CER: Clinical Evaluation Report 临床评价报告

ER: Essential Requirement 基本要求

IFU: Instructions For Use 使用说明书

MDD: Medical Device Directive (Council Directive 93/42/EEC amended by Directive 2007/47/EC) 医疗器械指令

PMS: Post Market Surveillance 上市后的监督

PMCF: Post Market Clinical Follow-Up 上市后的随访

6. General principles of clinical evaluation 临床评价的一般原则

6.1. What is clinical evaluation? 什么是临床评价

Clinical evaluation is a methodologically sound ongoing procedure to collect, appraise and analyse clinical data pertaining to a medical device and to analyse whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer's instructions for use.

临床评价是一种方法论，是持续的收集、评价和分析临床数据适合医疗器械的过程，和在根据制造商的使用说明书使用设备时，分析是否有足够的临床证据来证实符合相关安全和性能的基本要求。

In exceptional cases where an instruction for use is not required, the collection, appraisal, and analysis are conducted taking into account generally recognised modalities of use.

在不需要使用说明书的特殊情况下，进行收集、评价和分析考虑普遍认可的使用形式。

The requirements for clinical evaluation apply to all classes of medical devices. The evaluation should be appropriate to the device under evaluation, its specific properties, and its intended purpose.

临床评估的要求适用于所有类别的医疗设备。评价应适合设备评估它的特定属性和预期目的。

Benefits and risks should be specified, e.g. as to their nature, probability, extent, duration and frequency. Core issues are the proper determination of the benefit/risk profile in the intended target groups and medical indications, and demonstration of acceptability of that profile based

on current knowledge/ the state of the art in the medical fields concerned.

应该定收益和风险，例如他们的种类、概率、范围、持续时间和频率。核心问题是在目标群和医学指征众测定适当效益/风险预测，和基于医疗领域现有知识/科学技术下的状况证明是可接受性，。

Clinical evaluation is a responsibility of the manufacturer and the clinical evaluation report is an element of the technical documentation of a medical device.

临床评估是制造商的责任和临床评估报告是医疗设备技术文档的一部分。

For compliance with European medical device directives 需要遵守以下欧盟的医疗器械指令

- the clinical evaluation addresses the following Essential Requirements:

临床评价满足下述基本原则

- Annex 1 sections 1, 2, 5 of AIMDD (for active implantable medical devices), or

AIMDD附录1的1、2、5，或

- Annex I sections 1, 3, 6 of MDD (for medical devices); MDD附录1的1、3、6

see Appendix A7 (Analysis of the clinical data - compliance to specific Essential Requirements);见附录A7（临床数据分析-符合特定的基本要求）

- the evaluation must follow defined and methodologically sound procedures as described in: 评价必须遵从下述的定义和方法论

- Annex 7 of AIMDD (for active implantable medical devices), or AIMDD附录7 或

- Annex X of MDD (for medical devices); MDD附录10

- where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, an adequate justification has to be given. The justification is included in the clinical evaluation report with contents according to:

与临床数据的基本要求相符合的证明认为不合适，必须要有充足的理由。理由包含在临床评估报告中，内容根据：

- Annex 7 section 1.5 of AIMDD (for active implantable medical devices), or

AIMDD附录7的1.5部分，或

- Annex X section 1.1d of MDD (for medical devices). MDD附录10的1.1d部分

Conformity to the Essential Requirements can only be assumed when the following items are aligned with each other: 符合基本要求只能假定，当下面的项目互相对准的时候？

- the information materials supplied by the manufacturer (the labelling, instructions for

use, available promotional materials, including accompanying documents foreseen by the manufacturer)

制造商提供的信息（标签、说明书、促销资料，包括补充资料）

- the clinical evaluation (the device description used for the clinical evaluation, other contents of the clinical evaluation report)

临床评价（设备描述用于临床评价，临床评价报告的其他内容）

- the available clinical data (such as results of Clinical Investigations, publications, PMS studies, etc.). 获得的临床数据（临床调查结果、出版物、PMS研究等）

Particularly, evaluators should address if the following points are adequately supported by sufficient clinical evidence:

尤其是，评价者应该解决以下几点是否充分足够的临床证据来支持:

- the intended purpose described in the information materials supplied by the manufacturer (including for all medical indications);

制造商提供信息材料里描述的预期目的（包括所有的医学特征）

- the clinical performance and benefits described in the information materials supplied by the manufacturer (including, for example, any claims on product performance and safety);

制造商提供信息材料里描述的临床性能和收益（包括产品性能和安全的任何要求）

- measures for risk avoidance and risk mitigation described in the information materials supplied by the manufacturer (including, for example the declaration of the residual risks, contraindications, precautions, warnings, instructions for managing foreseeable unwanted situations);

制造商提供信息材料里描述的避免风险和降低风险的措施 (包括,例如宣称的剩余风险、禁忌症、预防措施、警告、管理可预见的意外情况的说明);

- the usability of the device for the intended users and the suitability of the information materials supplied by the manufacturer for the intended users (including, if applicable, for lay or disabled persons);

对目标用户来说，器械的可用性和制造商提供的信息资料的适用性 (包括，如果适用，外行或残疾人)

- instructions for target population groups (including, for example, pregnant women, paediatric populations).

说明目标人群(包括孕妇、婴幼儿)。

6.2. When is clinical evaluation undertaken and why is it important?

什么时候开展临床评价和它为什么重要？

Clinical evaluation is conducted throughout the life cycle of a medical device, as an ongoing process.Usually, it is first performed during the development of a medical device in order to identify data that need to be generated for market access. Clinical evaluation is mandatory for initial CE-marking and it must be actively updated thereafter.

临床评价是在医疗器械使用生命周期内持续进行的过程。它首先是在医疗器械研发期间执行，以便识别市场准入需要的数据。首次获得CE-marking时，临床评价是强制要求的，在随后需要积极更新。

Clinical evaluation is necessary and important because it ensures that the evaluation of safety and performance of the device is based on sufficient clinical evidence throughout the lifetime that the medical device is on the market. This ongoing process enables manufacturers to provide notified bodies and competent authorities with sufficient clinical evidence for demonstration of conformity of the device with the Essential Requirements throughout its lifetime (for example for CE marking, fulfilment of post-market surveillance and reporting requirements, or during surveillance procedures).

临床评价是必须的和重要的，因为确保器械的安全性和有效性得到评价，通过器械在市场上整个生命周期获得的充足的临床数据。这种持续的过程使制造商提供NB和通知主管当局有足够的临床证据来证明设备在整个生命周期满足基本要求（例如CE marking，实现上市后的监测和报告的要求，或在监测过程中)。

6.2.1. Clinical evaluation undertaken for the development of a medical device

临床评价用于医疗设备的开发

Premarket research and development are guided by clinical evaluation and risk management. Typically, manufacturers carry out clinical evaluations to

上市前的研究和开发应遵循临床评估和风险管理。通常，制造商进行临床评价

- define needs regarding clinical safety and clinical performance of the device;

  定义关于器械的临床安全性和临床性能的需要

- in case of possible equivalence to an existing device, evaluate if there are clinical data available and determine equivalence; for additional information, see Appendix A1 (Demonstration of equivalence);

尽可能的等效到现有设备，评价是否有用的临床数据和确定等效性，更多信息请参阅附录A1(等效性证实)

- carry out a gap analysis and define which data still need to be generated with the device under evaluation, whether clinical investigations are necessary and if so, to define the study

design; for additional information, see Section 10 (Analysis of the clinical data) and Appendix A2 (When should additional clinical investigations be carried out?).

执行差距分析和定义评估器械生成的数据，临床调查是否是必要的，如果是，定义研究设计；有关更多信息请参见10节(临床数据的分析)和附录A2(应当执行附加的临床调查?)。

As the initial clinical evaluation identifies the questions to be answered by a clinical investigation, the clinical evaluation process should generally commence in advance of any clinical investigation[1].

作为初始临床评价确定临床调查需要回答的问题，临床评估过程通常临床调查前开始[1]。

6.2.2. Clinical evaluation for initial CE-marking 首次CE-marking的临床评价

Clinical evaluation is required to be carried out for the conformity assessment process leading to the CE-marking and placing on the market of a medical device. The purpose is to:

临床评估需要执行获得CE-marking和医疗设备在市场上出售的合格评定过程。其目的是:

• document that there is sufficient clinical evidence to demonstrate conformity with the Essential Requirements covering clinical performance and clinical safety;

文档中有足够的临床证据证明符合临床表现和临床安全的基本要求

• identify aspects that need to be addressed systematically during post-market surveillance (PMS), e.g. in post market clinical follow-up studies (PMCF Studies) required under the medical device directives. Typically, these aspects include estimation of residual risks and uncertainties or unanswered questions (such as rare complications, uncertainties regarding long-term performance, safety under wide-spread use).

识别方面，需要与系统的处理上市后监督(PMS)，如在医疗器械指令中的上市市场临床随访研究(PMCF研究)的要求。通常，这些方面包括剩余风险的评估和不确定性或悬而未决的问题(如罕见的并发症、不确定的长期性能、大规模使用下的安全性)。

6.2.3. Updating the clinical evaluation临床评价的更新

a. Frequency of updates 更新频率

The manufacturer should define and justify the frequency at which the clinical evaluation needs to be actively updated. 制造商需要定义和判断临床评价更新的频率

When doing so, the manufacturer should typically consider: 制造商需要重点考虑以下情况

• whether the device carries significant risks (e.g. based on design, materials, components, invasiveness, clinical procedures, high-risk anatomical locations, high-risk target populations (e.g. paediatrics, elderly), severity of disease/ treatment challenges).

设备是否有重大风险(例如基于设计、材料、组件、侵袭性、临床过程、高风险的解剖位置、高

风险的目标人群(如儿科、老年)、疾病严重程度/治疗的挑战性)。

• whether the device is well established, taking into consideration: 设备是否良好，应考虑

- innovation; 创新

- relevant changes in clinical sciences, materials sciences or other sciences related to the device under evaluation; 评估器械相关的临床科学、材料科学或其他科学的变化

- the current level of confidence in the evaluation of clinical performance and clinical safety of the device; the manufacturer should consider

目前器械在临床性能和临床安全评价中的置信水平和设备，制造商应该考虑

- the data available from clinical investigations, PMCF studies, registries or other systematic studies (including the number of devices used, if that usage was representative of the usage in the market, the results to date);

有用数据来自临床调查、PMCF研究、注册或其他系统的研究(包括使用设备的数量、设备在市场上的代表性用法、到目前为止的结果);

- the total number of devices used so far in the market, and expected reporting rates under the vigilance system.

目前在市场上使用的设备总数，和在警戒系统中预期的报告率

• whether there are risks and uncertainties or unanswered questions, in the medium or long-term, that would influence the frequency of updates.

是否有风险和不确定性或悬而未决的问题，在中或长期会影响更新的频率

• design changes or changes to manufacturing procedures (if any).

设计变更或制造工艺变更（如有）

The clinical evaluation is actively updated: 临床评价应积极更新：

• when the manufacturer receives new information from PMS that has the potential to change the current evaluation;

当制造商从PMS收到新信息，有可能改变目前的评估

• if no such information is received, then 如果没有这种信息收到，则：

-at least annually if the device carries significant risks or is not yet well established; or

每年一次，如果设备带有重大风险或不是良好运行，或

-every 2 to 5 years if the device is not expected to carry significant risks and is well established, a justification should be provided.

每隔2-5年一次，如果设备没有重大风险，和运行良好，需要提供一个理由。

When involvement of notified bodies is required, updates are usually coordinated with the notified body. Typically, they are aligned with the timetable for surveillance audits and the renewal of the certificates.

当NB的参与被要求时，更新通常与公告机构协调。通常，他们确定监督审核的时间表和证书更新。

b. General considerations on updating the clinical evaluation 临床评价更新的总则

Manufacturers are required to implement and maintain a PMS system that routinely monitors the clinical performance and clinical safety of the device as part of their quality management system[2]. The scope and nature of such PMS should be appropriate to the device and its intended purpose.

制造商要求实施和维护一个PMS系统，定期地监控设备的临床表现和临床安全的质量管理系统[2]。PMS的范围和种类应该与设备和其预期的目的相适合。

PMS regularly generates new data (e.g. safety reports, results from published literature, registries, PMCF studies, and other data about device usage). Those data need to be evaluated for information that has a potential to change the evaluation of the risk/benefit profile, and the clinical performance and clinical safety of the device. Those data are required to be fed into the clinical evaluation process in a timely manner.

PMS定期生成新的数据(例如安全报告、文献发表的结果、注册、PMCF研究和设备使用的数据)。这些数据需要评估的信息有可能改变风险/效益评估，以及设备的临床性能和临床安全。这些数据需要及时输入到临床评估过程。

In accordance with the Directives, the clinical evaluation and the clinical evaluation report must be actively updated with data obtained from post-market surveillance[3].

根据指令，临床评价和临床评估报告必须从上市后监测获取的数据来积极更新。

When updating the clinical evaluation, the evaluators should verify:

更新临床评价，评价者应当核实

•if the benefit/risk profile, undesirable side-effects (whether previously known or newly emerged) and risk mitigation measures are still

如果效益/风险，不良的副作用(无论之前所知或新出现的)和风险降低措施仍在

-compatible with a high level of protection of health and safety and acceptable according to current knowledge/ the state of the art;

兼容高水平的健康、安全和可接受的保护，根据目前的知识/科技状态

-correctly addressed in the information materials supplied by the manufacturer of the device;

正确处理由设备制造商提供的信息资料

- correctly addressed by the manufacturer's current PMS plan;

正确处理由设备制造商提供的PMS计划

- if existing claims are still justified; 如果现有声明仍然是合理的;
- if new claims the manufacturer intends to use are justified.

如果制造商打算使用的新的声明是有合理的

While clinical evaluation requires data from PMS activities, it also generates new information that have to be fed into the PMS and risk management process. Clinical evaluation can therefore result in changes to the manufacturer's risk management documents, instructions for use (IFU) and PMS activities.

当临床评估需要的数据来自PMS活动，产生的新信息必须输入PMS和风险管理过程。因此临床评估可能导致改变制造商的风险管理文档，使用说明 说(IFU)和FMS活动。

If the manufacturer concludes there is not sufficient clinical evidence to be able to declare conformity with the Essential Requirements, the manufacturer will need to :

如果制造商认为没有足够的临床证据能够宣称符合基本要求，制造商需要

- stop placing the devices on the market until conformity is restored, and

停止设备在市场上出售，直到符合性被修复，和

- take necessary corrective and preventive action. 采取必要的纠正和预防措施

6.3. How is a clinical evaluation performed? 如何进行临床评价

The clinical evaluation is based on a comprehensive analysis of available pre- and post-market clinical data relevant to the intended purpose of the device in question, including clinical performance data and clinical safety data.

临床评估基于上市前和上市后，相关设备的预期目的临床数据，包括临床性能数据和临床安全数据的综合分析。

There are discrete stages in performing a clinical evaluation: 执行临床评价有下述独立阶段

•Stage 0: Define the scope, plan the clinical evaluation (also referred to as scoping and the clinical evaluation plan).定义范围、临床评价计划（也称范围和临床评价计划）

- Stage 1: Identify pertinent data. 识别相关数据

• Stage 2: Appraise each individual data set, in terms of its scientific validity, relevance and weighting. 评价每一个数据集，其科学性、相关性和权重

- Stage 3: Analyse the data, whereby conclusions are reached about 分析数据，得出结论

-compliance with Essential Requirements (including ER1, ER3, ER6) on performance and safety of the device, including its benefit/risk profile,

符合设备性能和安全基本要求（ER1, ER3, ER6），包括利益/风险预测

-the contents of information materials supplied by the manufacturer (including the label, IFU of the device, available promotional materials, including accompanying documents possibly foreseen by the manufacturer),

制造商提供的信息资料的内容(包括标签、IFU、可用宣传材料，包括制造商可能预见的补充文件)

-residual risks and uncertainties or unanswered questions (including on rare complications, long term performance, safety under wide-spread use), whether these are acceptable for CE-marking, and whether they are required to be addressed during PMS.

剩余风险、不确定性或悬而未决的问题(包括罕见的并发症、长期性能、大规模使用的安全性)，是否这些都可被CE-marking接受，是否要求在PMS期间处理。

- Stage 4: Finalise the clinical evaluation report 完成临床评价报告

The clinical evaluation report summarises and draws together the evaluation of all the relevant clinical data documented or referenced in other parts of the technical documentation. The clinical evaluation report and the relevant clinical data constitute the clinical evidence for conformity assessment.

临床评估报告汇总和聚焦在所有相关临床数据文件的评估或技术文档的其他部分中引用。临床评估报告及相关临床数据构成符合性评估的临床证据。

Each of these stages is covered in separate sections later in this document (see the figure below). During the course of a clinical evaluation the stages are often iterative. Indeed, the appraisal and analysis stage may uncover new information and raise new questions, with a need to widen the scope of the evaluation, refine the clinical evaluation plan, and to retrieve, appraise and analyse additional data.

每一个阶段都被单独章节覆盖，在本文的后面部分(见下图)。临床评价过程中，各阶段往往迭代。事实上，评估和分析阶段可能会发现新的信息和提出新的问题，需要扩大评估范围，完善临床评估计划,和检索、评价和分析附加的数据。

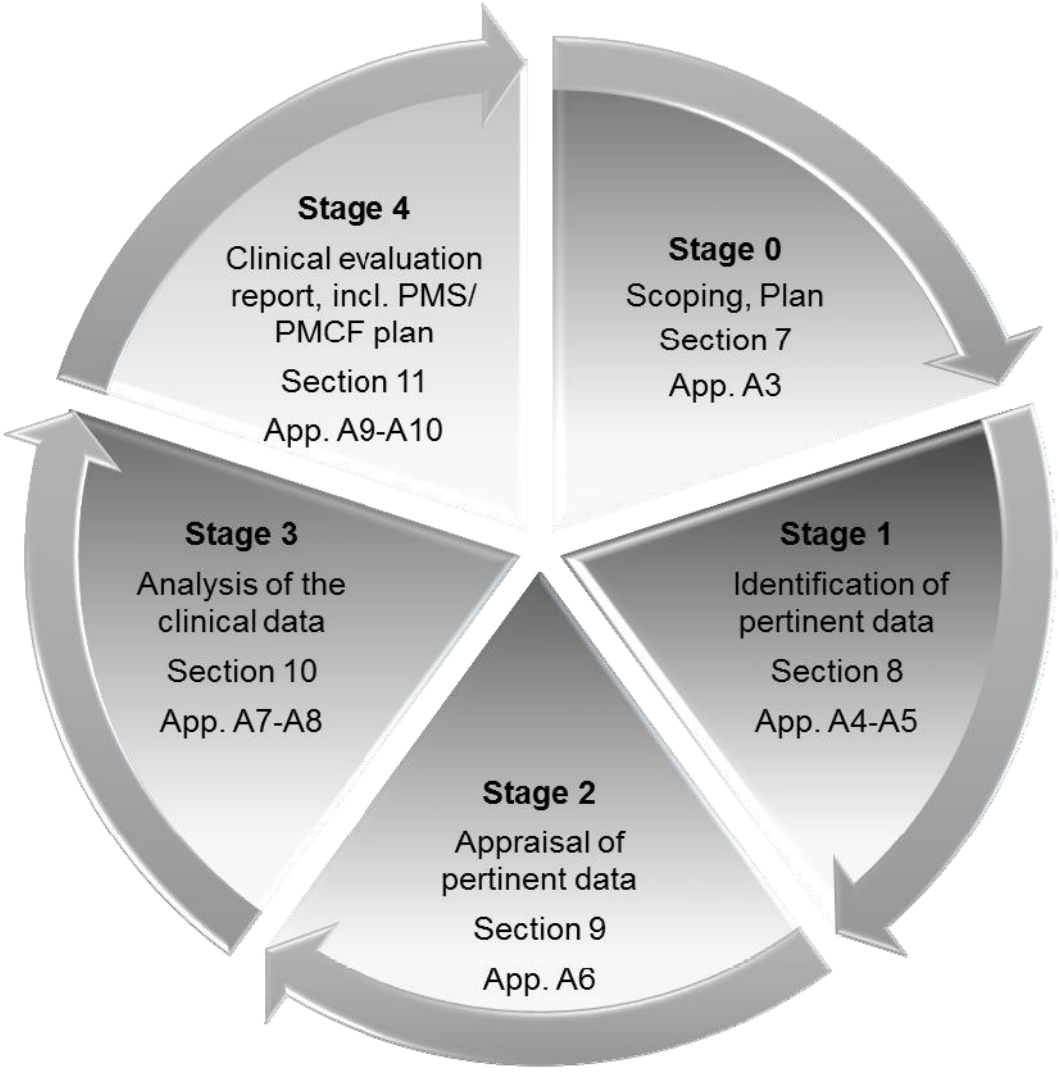

Figure: Stages of a clinical evaluation and references to sections and appendices of this document. 临床评价的步骤和参考的章节以及附录

Stage 0: 范围和计划 见章节7 附录A3

Stage 1: 数据识别 见章节8 附录A4、A5

Stage 2: 数据评估 见章节9 附录A6

Stage 3: 临床数据分析 见章节10 附录A7、A8

Stage 4: 临床评价报告含PMS、PMCF计划 见章节11 附录A9、A10

6.4. Who should perform the clinical evaluation? 谁做临床评价

The clinical evaluation should be conducted by a suitably qualified individual or a team. The manufacturer should take the following aspects into consideration:
临床评价应由有资质的个人或团队进行。制造商应考虑以下方面：

•The manufacturer defines requirements for the evaluators that are in line with the nature of the device under evaluation and its clinical performance and risks.

制造商提出评价者的要求，评价者与评价设备的性质，临床表现和风险一致。

•The manufacturer should be able to justify the choice of the evaluators through reference to their qualifications and documented experience, and to present a declaration of interest for each evaluator.

制造商必须通过参考任职资格和书面经验证明选择的评估员是合理的。

•As a general principle, the evaluators should possess knowledge of the following:

一般原则，评价者应当掌握下列知识：

-research methodology (including clinical investigation design and biostatistics);

研究方法论（包括临床调查设计和生物学统计）

-information management (e.g. scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline);

信息管理（科学背景或图书管理资格，数据库相关经验，如Embase and Medline）

-regulatory requirements; and 法规要求

-medical writing (e.g. post-graduate experience in a relevant science or in medicine; training and experience in medical writing, systematic review and clinical data appraisal).

医学写作（医学或相关专业研究生，医学写作的培训和经验，系统的文献搜索和数据评估）

•With respect to the particular device under evaluation, the evaluators should in addition have knowledge of: 对特定设备的评估，评估者应另外的知识

-the device technology and its application; 设备技术和应用

-diagnosis and management of the conditions intended to be diagnosed or managed by the device, knowledge of medical alternatives, treatment standards and technology (e.g. specialist clinical expertise in the relevant medical specialty).

诊断和管理条件下预期做诊断或管理的设备，医学知识的选择，治疗标准和技术(如相关医学专业专家临床经验)

•The evaluators should have at least the following training and experience in the relevant field:

评价者应当有下述相关领域的培训和经验

-a degree from higher education in the respective field and 5 years of documented professional experience; or相关领域的高等教育学位，5年的专业经验，或

-10 years of documented professional experience if a degree is not a prerequisite for a given task. 如果学位不是一个给定任务的先决条件，需要十年的专业经验记录。

There may be circumstances where the level of evaluator expertise may be less or different; this should be documented and duly justified.

可能有的情况下，评估者的专业知识水平可以减少或不同，这应该被记录和适当的调整。

7. Definition of the scope of the clinical evaluation (Stage 0) 定义临床评价的范围

Before a clinical evaluation is undertaken the manufacturer should define its scope, based on the Essential Requirements that need to be addressed from a clinical perspective and the nature and history of the device. This is also referred to as scoping.

制造商应在临床评估之前定义它的范围，根据基本要求，需要从临床的角度处理设备的性质和历史。这也称为范围。

The scope serves as a basis for further steps, including the identification of pertinent data. The manufacturer sets up a description of the device under evaluation, and a clinical evaluation plan.

范围服务于进一步措施，包括相关数据的识别。制造商建立了一个评估设备的描述，和临床评估计划。

A clinical evaluation is required to be critical[4]. Therefore, it needs to identify, appraise and analyse both favourable and unfavourable data.

临床评价是紧急要求的。因此，它需要识别、评价和分析都有利和不利的数据

Depending on the stage in the lifecycle of the product, considerations for setting up a clinical evaluation plan should include different aspects. Typical examples are listed below.

根据产品生命周期的阶段，考虑建立一个临床评估计划应包括不同的方面。下面列出了典型的例子。

Aspects (not an exhaustive list) 方面（不是详细清单）	前	后
•The device description.设备描述 For additional information, see Appendix A3 (Device description - typical contents) 附加信息附录A3	X	X
•Whether there are any design features of the device, or any indications or target populations, that require specific attention. The clinical evaluation should cover any design features that pose special performance or safety concerns (e.g. presence of medicinal, human or animal components), the intended purpose and application of the device (e.g. target treatment group and disease, proposed warnings, contraindications, precautions, and method of application) and the specific claims made by the manufacturer about the clinical performance and clinical safety of the device. 是否有设备的任何设计特点、适应症或目标人群,需要特别关注。临床评估应包括构成特殊性能或安全的任何设计特点(如含药、人类或动物源)，设备的目的和应用(如目标试验组和疾病、警示、禁忌症、预防措施、和应用方法)，设备临床性能和临床安全由制造商具体声明。	X	X
•Information needed for evaluation of equivalence, if equivalence may possibly be claimed. 如果等同性被声明，等同信息需要评价	X	
•The risk management documents of the device, e.g. the hazard identification list, clinical risks identified from the risk analysis. The scope of the clinical evaluation will need data from and cross references to the manufacturer's risk management documents. The risk management documents are expected to identify the risks associated with the device and how such risks have been addressed. The clinical evaluation is expected to address the significance of any clinical risks that remain after design risk mitigation strategies have been employed by the manufacturer. 设备的风险管理文档，如危害鉴定列表，,临床风险识别从风险分析确定。临床评估需要的数据范围和交叉引用制造商的风险管理文档。预计风险管理文档识别与该设备相关的风险以及这些风险已经解决。临床评估的意义在处理任何临床风险，设计风险降低措施后还有的风险。	X	X

•The current knowledge/ state of the art in the corresponding medical field, such as applicable standards and guidance documents, information relating to the medical condition managed with the device and its natural course, benchmark devices, other devices and medical alternatives available to the target population. 在相应的医学领域当前知识/科学水平，如适用的标准和指南文件，设备的医疗状况管理的信息和和它的自然进程、基准设备，其他设备和医疗选择提供给目标人群。	X	X
•Data source(s) and type(s) of data to be used in the clinical evaluation.临床评价的数据源和数据类型 Data relevant to the clinical evaluation may be generated and held by the manufacturer or available from scientific literature.临床评价的数据可能是制造商生成和持有，或来自科技文献，附加信息见8.1和附录A4 For additional information, see Section 8.1 (Data generated and held by the manufacturer), and Appendix A4 (Sources of literature).	X	X
•Whether the manufacturer has introduced/ intends to introduce any relevant[5] changes, including制造商是否介绍或引入任何变更，包括 -design changes, 设计变更 -changes to materials and manufacturing procedures, 材料和工艺变更 -changes to the information materials supplied by the manufacturer (label, IFU, available promotional materials including accompanying documents possibly foreseen by the manufacturer) or other claims,信息材料变更（标签、说明书、宣传资料等） -and whether the claim of equivalence to an existing device is still appropriate.声明的等效设备是否还合适		X
•Whether there are any specific clinical concerns that have newly emerged and need to be addressed. 是否有任何新出现和需要解决的特定的临床关注点		X
•PMS aspects that need[6] regularly updating in the clinical evaluation report: 临床评价报告需要定期更新PMS		X

-new clinical data[7] available for the device under evaluation;评价设备出现新的临床数据 -new clinical data available for the equivalent device (if equivalence is claimed); 声明的等效设备出现新的临床数据 -new knowledge about known and potential hazards, risks[8], performance, benefits[9] and claims[10], including出现已知或潜在的危害、风险、性能、收益和投诉的新知识，包括 -data on clinical hazards seen in other products (hazard due to substances and technologies); 其它产品发现的临床危害数据 -changes concerning current knowledge/ the state of the art, such as changes to applicable standards and guidance documents, new information relating to the medical condition managed with the device and its natural course, medical alternatives available to the target population;目前的只是和科学技术方面的变化，如应用标准和指南文件等 -other aspects identified during PMS. PMS期间识别出来的其他方面		
•Needs for planning PMS activities. 需要计划PMS活动		X

It is important to recognise that there is considerable diversity in the types and history of technologies used in medical devices and the risks posed by them. Many devices are developed or modified by increments, so they are not completely novel. It may be possible to draw on the clinical experience and literature reports of the safety and performance of an equivalent device to establish the clinical evidence, thereby reducing the need for clinical data generated through clinical investigation of the device under evaluation. Similarly, it may be possible to use compliance with harmonised standards to satisfy the clinical evidence requirements for devices based on technologies with well established safety and performance characteristics.

重要的是要认识到，有相当大的多样性和历史类型的技术用于医疗设备，及其带来的风险。许多设备都是后来的人开发或修改，所以他们并不是全新的。可以根据同等设备临床经验和文献报告得出安全性和性能的临床证据，从而减少评估设备通过临床调查生成临床数据的需要。同样，尽可能按照协调标准的要求来满足设备基于技术的良好安全和性能的临床证据。

8. Identification of pertinent data (Stage 1) 识别数据

8.1 Data generated and held by the manufacturer 制造商生成或持有的数据

Data generated and held by the manufacturer typically include the following items (not a complete list): 制造商生成或持有的数据主要包括下述项目（未完全列出）)

•All pre market clinical investigations 所有上市前的临床调查

•All clinical data generated from risk management activities and the PMS programmes which the manufacturer has implemented in Europe and in other countries, including the following items (not a complete list): 所有临床数据生成于制造商在欧洲和其他国家实施的风险管理活动和PMS程序，包括下列事项(未完全列出):

-PMCF studies, such as post market clinical investigations and any device registries sponsored by the manufacturer PMS研究，如制造商支持的上市后的临床调查和设备登记

- PMS reports, including vigilance reports and trend reports PMS报告（警戒报告和趋势报告）

- the literature search and evaluation reports for PMS PMS的文献检索和评价报告

- incident reports sent to the manufacturer (including the manufacturer's own evaluation and report) 发送给制造商的事故报告（包括制造商自己的评价和报告）

- complaints regarding performance and safety sent to the manufacturer, including the manufacturer's own evaluation and report 发送给制造商的关于安全和性能的投诉

- analysis of explanted devices (as far as available) 移植设备的分析

- details of all field safety corrective actions 安全领域纠正措施的细节

- use as a custom made device 作为定制设备使用

- use under compassionate use/ humanitarian exemption programs 捐助使用?

- other user reports 其他使用报告

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6 Requirement according to letter 1.1.c of Annex X MDD, and section 1.4 AIMDD: "The Clinical Evaluation and its documentation must be actively updated with data obtained from the post-market surveillance…."

7 References: Annex 1, Essential Requirements 1, 2, 5, 5a, and Annex 7 AIMDD; and Annex I, Essential

Requirements 1, 3, 6, 6a, and Annex X MDD.

8 For further detail, refer to standard EN ISO 14971 and other harmonised standards.

9 For further detail, refer to standard EN ISO 14971 and other harmonised standards.

10 Claims made by the manufacturer on the clinical performance and clinical safety of the device under evaluation.

•Relevant pre-clinical studies (e.g. bench test reports including verification and validation data) With regard to those data:

关于数据的临床前研究（实验室测试报告包括验证和验证数据）

•All data generated and held by the manufacturer need to be identified.

制造商生成或持有的需要识别的所有数据

•Complete data need to be entirely disclosed and made available to the evaluators; this includes data from Europe and other countries; it includes clinical studies as well as use data. 完整的数据需要完全披露和提供给评估者，包括来自欧洲和其他国家的数据，包括临床研究和使用数据

•All data sets should be documented (adequately summarised[11], appraised, analysed and referenced) in the clinical evaluation report.

临床评价报告中的所有数据应当文件化（一般是总结、评估、分析和应用）

8.2 Data retrieved from literature 文献数据

Literature searching is used to identify data not held by the manufacturer that are needed for the clinical evaluation.文献搜索用于识别制造商不持有的数据，需要用于临床评价。

Literature searching identifies potential sources of clinical data for establishing:

文献搜索识别潜在的来源来建立临床数据

•Clinical data relevant to the device under evaluation, which are data that relate either to the device under evaluation or to the equivalent device (if equivalence is claimed).

相关设备评价的临床数据，无论是评估设备还是等效设备(如果声称等效)的数据

•Current knowledge/ the state of the art. 目前的知识和科学水平

Includes applicable standards and guidance documents, data that relate to benchmark devices, other devices, critical components and medical alternatives or to the specific medical conditions and patient populations intended to be managed with the device. The data are typically needed in order to

包括适用的标准和指南文件，基准设备、其他设备、关键部件和医疗替代或特定的医疗条件、管理患者群体的设备的数据。数据通常是为了

-describe the clinical background and identify the current knowledge/ state of the art in the corresponding medical field, 描述临床背景和识别当前医学领域的知识/科学技术

-identify potential clinical hazards (including hazards due to substances and technologies, manufacturing procedures and impurity profiles), 识别潜在的临床危害(包括危险物质和技术、

制造工艺和杂质概况)

-justify the validity of criteria used for the demonstration of equivalence (if equivalence is claimed), 证明用于验证的等效(如果声明等效)标准的有效性

- justify the validity of surrogate endpoints (if surrogate endpoints are used). 证明替代终点(如果使用替代终点)的有效性。

The following aspects should be considered for literature searching:

文献搜索应考虑以下几方面

•The searching strategy should be thorough and objective, i.e. it should identify all relevant favourable and unfavourable data. For some devices, clinical data generated through literature searching will represent the greater part (if not all) of the clinical evidence. Thus, when conducting a literature review a comprehensive search should be conducted. If a comprehensive search is not deemed necessary, reasons should be documented.

搜索方法要全面和客观，应识别所有相关有利的和不利的数据。对于某些设备，通过文献搜索生成的临床数据将产生大部分(如果不是全部)临床证据。因此，当进行文献综述时，应进行全面搜索。如果没有采取全面的搜索，原因应该记录。

•Several searches with different search criteria or focus are usually necessary to obtain the necessary data. For additional information, see Appendix A4 (Sources of literature).

运用多个不同搜索条件或关键词的搜素对获得数据是必须的。有关的更多信息，请参阅附录A4(文献的来源)

•A literature search and other retrieval of data are carried out based on a search protocol.

文献检索和其他数据检索是基于检索方案来进行。

The search protocol documents the planning of the search before execution. For additional information, see Appendix A5 (Literature search and literature review protocol, key elements) and Appendix A6 (Appraisal of clinical data - examples of studies that lack scientific validity for demonstration of adequate clinical performance and/or clinical safety).
执行搜索计划前需要有搜索方案。有关的更多信息，请参阅附录A5(文献检索和文献检索方案、关键词)和附录A6(临床数据的评估-缺乏足够科学有效性的临床表现和/或临床安全的研究实例)。

•Once the searches have been executed, the adequacy of the searches should be verified and a literature search report should be compiled to present details of the execution, any deviations from the literature search protocol, and the results of the search.

一旦执行搜索，搜索的充分性应被验证和编写详细的文献检索报告，文献搜索方案的任何偏离，搜索的结果。

•It is important that the literature search is documented to such degree that the methods

can be appraised critically, the results can be verified, and the search reproduced if necessary.

重要的是文献检索记录到可以挑剔评价的程度，搜索结果是可以验证的，必要时搜索复制。

Abstracts lack sufficient detail to allow issues to be evaluated thoroughly and independently, but may be sufficient to allow a first evaluation of the relevance of a paper. Copies of the full text papers and documents should be obtained for the appraisal stage.

摘要缺乏允许问题彻底、独立评估足够的细节，但对第一次评价论文的相关性是足够的。在评价阶段论文和文件全文应获得。

The literature search protocol(s), the literature search report(s), and full text copies of relevant documents, become part of the clinical evidence and, in turn, the technical documentation for the medical device.

文献检索方案、文献检索报告和有关文件的全文，成为临床证据的一部分，依次，成为医疗设备的技术文档。

9. Appraisal of pertinent data (Stage 2) 数据评估

9.1 General considerations总则

In order to determine the value of the data identified in stage 1, the evaluators should appraise each individual document in terms of its contribution to the evaluation of the clinical performance and clinical safety of the device.

为了确定第一阶段识别数据的价值，评估者应评价每个文档对评价设备的临床性能和临床安全的贡献。

Uncertainty arises from two sources: the methodological quality of the data, and the relevance of the data to the evaluation of the device in relation to the different aspects[12] of its intended purpose. Both sources of uncertainty should be analysed to determine a weighting for each data set.

不确定性有两个来源：数据的质量和数据与设备评估的预期目的不同方面的相关性。这两个不确定性的来源应该分析来确定每个数据集的权重。

The evaluators should therefore:以下方面应评价

•identify information contained in each document, 包含每个文件的识别信息

•evaluate the methodological quality of work done by the authors and from that, the scientific validity of the information,评价 作者工作质量和信息的科学有效性

•determine the relevance of the information to the clinical evaluation, and 确定临床评价信息的相关性

•systematically weight the contribution of each data set to the clinical evaluation.数据的权重分配

9.2. The appraisal plan 评估计划

To ensure systematic and unbiased appraisal of the data, the evaluators should set up an appraisal plan that describes the procedure and the criteria to be used for the appraisal.

确保系统和公正的评价数据，评价者应该建立一个评估计划，描述了程序和用于评估的标准

•The appraisal plan typically includes: 评估计划包括

-criteria for determining the methodological quality and the scientific validity of each data set. 确定方法质量和数据科学有效性的标准

-criteria for determining the relevance to the clinical evaluation (relevance to the device and to the different aspects of its intended purpose). 确定临床评价相关性的标准（设备和预期用途的不同方面的相关性）

-criteria for weighting the contribution of each data set to the overall clinical evaluation.

全部临床评价数据的权重标准

•The appraisal should be thorough and objective, i.e. it should identify and attribute adequate weighting both to favourable and unfavourable contents of each document.

应全面和有目的的评估，应识别和划分每个文件有利和不利内容的权重

•The criteria adopted for the appraisal should reflect the nature, history and intended clinical use of the device. They should be documented and justified on the basis of current knowledge / the state of the art, applying accepted scientific standards.

评估采用的标准应该反映设备的性质、历史和临床使用。他们应该被记录和证明在现有知识的基础上/科学水平，为公认的科学标准。

•There are many acceptable ways, both qualitative and quantitative, by which the appraisal can be carried out[13]. For many well established devices and lower-risk devices, qualitative data may be adequate to fulfil the requirements of the MDD and AIMDD. The evaluation criteria should be adjusted accordingly.

有许多可以接受的定性和定量方法，用来进行评估。对于许多良好的设备和较低风险的设备，定性数据可能足以满足MDD和AIMDD的要求。评估标准应相应调整。

•The appraisal plan should be documented in the clinical evaluation report.

评估计划应该记录在临床评估报告中。

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11 to the extent that it can be critically reviewed by others

12 For example different medical indications, target populations, intended users.

9.3 Conduct of the appraisal 进行评估

The evaluators should 评价者应当

•follow the pre-defined appraisal plan strictly and apply its criteria consistently throughout the appraisal; 在整个评估过程中，严格按照预先确定的评估计划和应用标准

•base their appraisal on the full text of publications and of other documents (not abstracts or summaries), so as to review all of the contents, the methodology employed, the reporting of results, the validity of conclusions drawn from the investigation or report, and evaluate any limitations and potential sources of error in the data;

评估是基于文献全文和其他文件(不是摘要或概要)，以便回顾调查或报告的所有内容、使用方法、报告结果、得出结论的有效性，并评估任何限制和错误数据的潜在来源;

•document the appraisal in the clinical evaluation report to the extent that it can be critically reviewed by others.

在临床评估报告中，评估文件在某种程度上可以由其他人批判性的评价。

9.3.1. How to evaluate methodological quality and scientific validity

如何评价方法质量和科学有效性

The evaluators should examine the methods used to generate/ collect the data and evaluate the extent to which the observed effect (performance or safety outcomes) can be considered to be due to intervention with the device or due to

评价者应该检查用于生成/收集数据的方法和评估观察效果(性能或安全结果) 的程度可以被认为是由于设备或由于

-confounding influences (e.g. the natural course of the underlying medical condition / regression to the mean, concomitant treatments)

混淆影响（自然进程、趋势回归、联合治疗）

- bias偏差
- random error 偶然误差
- inadequate disclosure of information 不充分的信息
- misinterpretation 误解

Some papers considered unsuitable for demonstration of adequate performance because of poor elements of the study design or inadequate analysis may still contain data suitable for safety analysis or vice versa.

一些论文被认为不适合充分证明性能，因为可怜的研究设计因素或分析不充分可能仍然包含适用于安全分析的数据，反之亦然。

Examples of aspects that can be taken into consideration for evaluating the methodological quality and the scientific validity of the evidence are detailed below.

例子可以考虑到评价的方法学质量和科学有效性方面的证据在下面会详细进行介绍。

a. Study design of pre-market and post-market clinical investigations 上市前的研究设计和上市前的临床调查，注意事项应包含：

Considerations may need to include:

- adequacy of the sample size and power calculation 充足的样本规模和功率计算
- adequacy and relevance of endpoints (including validity of surrogate endpoints, if used)

终点的充分性和相关性 (包括替代终点的有效性，如果使用)

- adequacy of applied controls (including choice of the study type and of comparators, if applicable)应用控制的充分性（包含研究类型的选择、对照）
- prospective randomisation of patients (in case of multiple treatment arms) 患者随机
- adequacy of inclusion and exclusion criteria, and of stratification of patients (e.g. in respect to age, medical indication, severity of the condition, gender, other prognostic factors)入组和排除标准的充分性，和病人分组(如考虑年龄、医学特征、严重的状况、性别、其他后期因素)
- distribution of prognostic factors (in case of multiple groups, were the groups comparable for these factors?) 后期因素分布（假设多组，组间对比因素？）
- blinding of patients (may include use of sham devices or sham surgery), professional users, outcome assessors (blinded endpoints)

患者不知情(可能包括使用虚假的设备或虚假的手术)，专业用户，结果评估(不知情的终点)

- adequacy of the follow-up period, including if follow-up was long enough for outcomes to occur, and if follow-up was frequent enough to detect temporary side effects and complications (such as prolonged wound healing)

足够的随访时间，包括为了得到结果的长期随访和发现暂时性的副作用和并发症的定期随访 (如延长伤口愈合)

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13 For an example, refer to Appendix D of the GHTF SG5 document N2R8:2007 on Clinical Evaluation (Appendix D: A Possible Method of Appraisal)

• reliability of the methods used for quantifying symptoms and outcomes (including validation of the methods)用于量化症状的方法和结果的可靠性(包括方法的验证)

• adequate recording and reporting of serious adverse events and device deficiencies

充分记录和报告严重不良事件和设备不足

• adequate handling of medications and concomitant interventions

适当处理药物和伴随的干预措施

• adequacy of procedures for retrieving complete information (e.g. procedures to be applied when contacts with patients are lost, disclosure of reasons for patients leaving the study, conduct of sensitivity analysis for determining if missing data affect conclusions)

程序的充分性，用于检索完整信息(例如：用于联系患者的程序丢失、患者离开研究的原因披露，决定进行灵敏度分析，如果丢失的数据影响结论)

The evaluators should verify whether clinical investigations have been defined in such a way as to confirm or refute the manufacturer's claims for the device; and whether these investigations include an adequate number of observations to guarantee the scientific validity of the conclusions.

评价者应该验证临床调查是否已经以证实或驳斥为设备制造商的声明的方式确定，以及这些调查是否包含足够数量的观察来保证结论的科学有效性。

b. Additional aspects for appraisal of the quality of clinical investigations generated and held by the manufacturer

制造商生成和持有的临床调查质量的其他方面的评价

Where a clinical investigation has been carried out by or on behalf of a manufacturer, it is expected that documentation relating to the design, ethical and regulatory approvals, conduct, results and conclusions of the investigation needed for the clinical evaluation will be available for consideration, as appropriate. These may include:

临床调查已由制造商或其代表执行，预期文件有调查设计、伦理和监管机构的批准、执行、结果和结论，临床评估所需的都可以适当的考虑。包括：

-the clinical investigation plan; 临床调查计划

-clinical investigation plan amendments and the rationale for these changes; 计划的修正和论据变化

-case report form templates, monitoring and audit records; 病理报告范本，监察和审计记录

-the relevant ethics committee documentation; 伦理委员会的证明文件

-regulatory authority approvals as required by applicable regulations; 监管机构的批准文件

-the signed and dated clinical investigation report (for investigations that are terminated);

临床调查报告要有签字和日期（调查终止）

-the latest intermediate report available and the latest collation on serious adverse events (for investigations that are ongoing); 最新的中期报告和严重不良事件(对正在进行的调查);

-when a clinical investigation is conducted outside of the EU, an analysis whether the results are transferable to the European population; 当在欧盟以外进行临床研究，分析结果是否能转移到欧洲人口;

-a gap analysis, when a clinical investigation is conducted to standards different from EN ISO 14155; the gap analysis should contain sufficient information to be read and understood by an independent party.

当临床调查没按EN ISO 14155标准进行时，进行差距分析，差距分析应包含独立第三方可以阅读和理解的足够信息。

The clinical investigation plan sets out how the study was intended to be conducted. It contains important information about the study design such as the selection and assignment of participants to treatment, masking (blinding of participants and investigators) and measurement of responses to treatment, which may be important sources of bias that can be assessed and possibly discounted when trying to determine the actual performance of the device. In addition the clinical investigation plan sets out the intended participant follow-up, approaches to statistical analyses and methods for recording outcomes, which may impact on the quality, completeness and validity of results obtained for performance and safety outcomes.

临床研究计划制定了这项研究的目的是如何进行。它包含关于研究设计的重要信息，如参与者治疗的选择和分配等，掩蔽(不知情的参与者和调查人员)和对治疗反应的测量，这可能是偏差的重要来源，能被评估和确定设备的实际性能的折扣。另外，临床调查计划制定了预期的参与者随访、统计分析方法和记录结果的方法，这可能影响性能和安全结果的质量、完整性和有效性。

Also, by having the clinical investigation plan, its amendments and the clinical investigation report available, the evaluators will be able to assess the extent to which the investigation was conducted as planned and, where deviations from the original plan have occurred, the impact those deviations had on the veracity of the data generated and the conclusions that can be drawn from the investigation about the performance and safety of the device.

通过临床研究计划以及修订和临床调查报告，评估者将能够评估按计划进行调查的程度，与原计划发生的偏差，这些偏差影响从调查设备的性能和安全得出的数据和结论的真实性。

The clinical investigation report should be signed by the sponsor and the coordinating or principal investigator to provide assurance that the report is an accurate reflection of the conduct and results of the clinical investigation.

临床调查报告应有研究者和助手的签字，负责人提供保证报告是临床研究行为和的结果的真实反应。

Another important consideration of the evaluation will be to assess whether the conduct of the investigation was in accordance with applicable regulations, and in accordance with the current applicable ethical standards that have their origin in the Declaration of Helsinki. Clinical investigations not in compliance with applicable ethical standards, medical device standards (for example EN ISO 14155 or comparable standards) or regulations should not be used for demonstration of performance and/or safety of the device. The reasons should be noted in the report.

另一个重要的评价考虑因素是评估调查的行为是否符合国家有关规定，并依照当前适用的源自《赫尔辛基宣言》的伦理标准。临床调查不符合适用的道德标准、医疗器械标准(例如EN ISO 14155或类似的标准)、法规不应该用于证实设备的性能和/或安全。原因在报告中应注释。

c. Information derived from vigilance data, device registry data, case series, patient dossiers, and other use data

信息来源于警戒数据、设备注册数据、案例系列、病人档案和其他使用数据

Evaluators need to consider significant differences between sources of information in respect to: 评价者需要考虑信息来源之间的显著差异，以下方面的：

- procedures used for retrieving information about outcomes用于检索结果信息程序
- quality aspects of registers and patient dossiers 登记和病人档案的质量方面

In case of information based on vigilance reporting, evaluators should consider that expected undesirable side-effects and complications of devices are not reportable under the vigilance reporting system. Under-reporting or lack of reporting of expected side effects or complications by users is common. Therefore, the vigilance system does not typically deliver adequate information about the true frequency of expected undesirable side-effects and complications. Systematic scientific data are needed for such purposes. Vigilance data, including trend analysis, should be used for identification of unexpected risks.

基于警戒报告的信息，评估者应考虑在警戒系统中没有报告的设备不良的副作用和并发症。漏报或缺乏使用者预期的副作用或并发症的报告是常见的。因此，警戒系统通常不真实频率的提供足够预期不良副作用和并发症的信息。达到目的需要系统科学数据，警戒数据包括趋势分析，应该用于识别意外的风险。

In case of information based on device registries, case series, retrospective analyses of patient dossiers, and other use data, the retrieval of information about outcomes may be incomplete and unreliable (have all the patients been considered? are the patients representative of the use of the device? did the register/ professional lose contact with patients if they moved on to different professionals? was there a passive or active follow-up of patients by the professionals involved? for how long?). Significant differences may exist between device registries. For instance, they may offer an important or limited coverage of a country. The evaluators should take into account the possibility of patients leaving the coverage of a registry or the follow-up of a professional when experiencing serious adverse outcomes. In routine practice, there are also significant differences in the duration of the follow-up of patients by surgeons and other professionals, and in the quality of patient dossiers and data retrieval.

根据设备的注册信息、病例系列、病人档案的回顾性分析和其他使用数据，源于结果信息的检索可能不完整的和不可靠的(所有的病人被考虑了吗？使用设备的患者有代表性吗? 注册/专业人员失去同患者的联系，如果他们换成不同的专业人士? 专业人士被动或主动参与病人的随访?多长时间?) 在设备注册之间可能存在显著差异。例如，他们可能会提供一个重要的或有限的国家。评估者应考虑患者离开的注册或专业随访的可能性，经历严重不良后果时。在日常实践中，外科医生和其他专业人士的病人随访时间，和病人档案和数据检索的质量也存在着很大差异。

For clinical experience data it is important that any reports or collations of data (e.g. the manufacturer's PMS reports) contain sufficient information for the evaluators to be able to undertake a rational and objective evaluation of the information and make a conclusion about its significance with respect to the performance and safety of the device in question.

任何报告或收集的临床经验数据是很重要的(如制造商的PMS报告)，包含评价者能够进行合理、客观评价的足够信息，得出结论关于设备的性能和安全问题的重要意义。

Reports of clinical experience that are not adequately supported by data, such as anecdotal reports or opinions, may contribute to the evaluation, e.g. for the identification of unexpected risks, but should not be used as proof of adequate clinical performance and clinical safety of the device.

不被充分的数据支持的临床经验报告，比如趣闻报告或意见，可能促成评估，例如意外风险的识别，但不应该被充分证明设备的临床性能和临床安全。

d. Data processing and statistics数据处理和统计

Aspects to consider may include:考虑的方面包括

•suitability of methods for data processing (transforming data that are suitable for analysis), converting data to a consistent format, reconstructing missing statistics from other statistics, dealing with missing data;

合适的数据处理方法 (转换数据是合适的分析方法)，将数据转换成统一的格式，重建丢失的数据、处理缺失数据

•exclusions from the analysis and their implications (including disclosure and adequacy of the intention-to-treat and per-protocol populations, disclosure of results from both the intention-to-treat and the per-protocol populations);

排除分析及其影响(包括披露、意向处理和方案数量，按方案数量和意向处理的披露结果)

- adequacy of statistical methods. 统计方法的合适性

e. Quality assurance 质量保证

• compliance with Good clinical practice (GCP), such as EN ISO 14155 or equivalent standards; 符合GCP，如EN ISO 14155或等同标准

- compliance with the clinical investigation plan, independent monitoring and auditing;

符合临床调查计划、独立监察和审计

- compliance with legal requirements. 符合法规要求

While a publication in a renowned peer reviewed scientific journal is generally accepted as an indicator of scientific quality, such publication is not considered an acceptable reason for bypassing or reducing appraisal activities.

当一个出版物是著名同行评议的科学期刊是公认的科学质量的指标，不认为是避开或减少评估活动可以接受的理由。

f. Report quality 报告质量

Evaluators should consider:评估者应考虑

- adequacy of disclosure of methods used 使用适当的披露方法
- adequacy of disclosure of data, including适当的披露数据，包含

-completeness of the reporting of adverse events and outcomes 不良事件和结果的完整报告

-sufficient description about the distribution of prognostic factors in the study population and in different study arms充分描述关于人口研究和不同的武器研究后期因素的分布规律

-disclosure of all the results the study was originally designed to generate

披露原始设计产生的所有研究结果

•validity of conclusions drawn by the authors (example: conclusions not in line with the results section of the document)

作者得出的结论的有效性(例如：结论不符合部分文档的 结果)

Possible conflicts of interest of the authors of the publications should also be taken into consideration.

可能的出版物的作者利益冲突也应考虑。

It is recognised that, where manufacturers source clinical investigation data reported in the scientific literature, the documentation readily available to the manufacturer for inclusion in the clinical evaluation is likely to be no more than the published paper itself. In case of missing information, the rating of the methodological quality of a publication may need to be downscaled.

承认制造商原文临床研究数据在科学文献中报道，包含在临床评估中制造商现成的文档不超过发表的论文。在信息缺失的情况下，出版物的方法学质量的比率可能需要缩减规模。

For additional information see Appendix A6 (Appraisal of clinical data - examples of studies that lack scientific validity for demonstration of adequate clinical performance and/or clinical safety). 更多信息参见附录A6

9.3.2. How to determine the relevance of a data set for the clinical evaluation

如何确定数据的相关性

When evaluating the relevance of collected data it is important to consider whether the data are intended to directly demonstrate adequate clinical performance and clinical safety of the device (often referred to as pivotal data), or whether the data serves an indirect supportive role. 评估收集的数据的相关性是很重要的，考虑到数据的目的是直接证实装置的临床性能和临床的安全 (通常被称为关键数据)的充分性，或是否数据提供间接的支持作用。

a. Pivotal data 关键数据

•Pivotal data must have the data quality necessary for demonstration of adequate clinical performance and clinical safety of the device under evaluation (see Appendix A6, Appraisal of clinical data - examples of studies that lack scientific validity for demonstration of adequate clinical performance and/or clinical safety);

关键数据必须有数据质量来用于证实评价设备的临床性能和临床安全的充分性（见附录A6））

•be generated either with the device under evaluation or with an equivalent device used in its intended purpose (for an equivalent device, equivalence must be demonstrated; see Appendix A1, Demonstration of equivalence).

生成评估设备或等效设备用于预期目的 (等效设备，必须证明等效，请参阅附录A1，等效证实)。

b. Other data 其他数据

Data that are not pivotal are generally appraised and weighted for their contribution for purposes such as: 数据不是关键

•identifying and defining the current knowledge/ state of the art in the corresponding medical field, so as to define acceptability criteria for the evaluation of the benefit/risk profile and of specific side-effects of the device under evaluation;

识别和定义相关医疗领域当前的知识/科学水平，定义评价设备可接受的风险/收益评价标准和特定的副作用

•identifying hazards (including hazards due to substances and technologies), individual case reports may be used for identification of new and previously unknown hazards that are associated with the device;识别危害（包含归于物质和技术的危害），个体事件报告可用于识别与设备相关的新危害和潜在未知的危害

•justifying the validity of criteria used for the demonstration of equivalence (if equivalence is claimed); 用于证实等效的证明有效性的标准 (如果声称等效)

- justifying the validity of surrogate endpoints (if surrogate endpoints are used).

证明替代终点的有效性

- providing input for the planning of pivotal studies. 为关键研究计划提供输入

The corresponding information is, in general, summarised in a literature review section of the clinical evaluation report. 相关信息是临床评估报告中文献回顾部分的总结

c. Aspects to consider when determining relevance 确定相关性需要考虑的几个方面

The table below shows examples of aspects that could be used for determining if and in what respect data are relevant to the clinical evaluation.给出实例用于考虑数据相关性

Description 描述	Examples 实例
To what extent are the data generated representative of the device under evaluation? 评价设备生成的数据的代表性程度？	-device under evaluation 评价设备 -equivalent device等效设备 -benchmark device 基准设备 -other devices and medical alternatives其他设备和医学迭代 -data concerning the medical conditions that are managed with the device关于设备医学状况被管理的数据

What aspects are covered? 哪些方面被覆盖	-pivotal performance data 关键性能数据 -pivotal safety data关键安全数据 -claims要求 -identification of hazards危害识别 -estimation and management of risks风险估计和管理 -establishment of current knowledge/ the state of the art建立当前的知识/科学水平 -determination and justification of criteria for the evaluation of the risk/benefit relationship确定风险/利益相关的评价标准 -determination and justification of criteria for the evaluation of acceptability of undesirable side-effects 确定可接受的不良副作用标准 -determination of equivalence 定义等效性 -justification of the validity of surrogate endpoints 判断代理终点的有效性
Are the data relevant to the intended purpose of the device or to claims about the device? 设备或声明的设备吗的预期目的相关性数据?	-representative of the entire intended purpose with all patient populations and all claims foreseen for the device under evaluation评价设备和声称已知设备代表所有患者群体的全部预期目的 -concerns specific models/ sizes/ settings, or concerns specific aspects of the intended purpose or of claims关注特定的型号/尺寸/设置，或关心预期目的某方面或要求 -does not concern the intended purpose or claims 不涉及预期目睹或要求

If the data are relevant to specific aspects of the intended purpose or claims, are they relevant to a specific -model, size, or setting of the device? 如果相关数据是特定目的或要求，特定型号、大小或设置?	-smallest / intermediate / largest size 最小/中间/最大尺寸 -lowest / intermediate / highest dose 最低/中间/最大剂量 -etc.
-user group?用户分组	-specialists专家 -general practitioners一般医师 -nurses护士 -adult healthy lay persons 健康成年人 -disabled persons 残疾人 -children儿童 -etc.等
-medical indication (if applicable)?医学特征	-migraine prophylaxis 偏头疼预防 -treatment of acute migraine严重偏头疼治疗 -rehabilitation after stroke 中风后复原 -etc.
-age group?年级分组	- pre-term infants / neonates / children /adolescents / adults / old age 早产的婴儿/新生儿/儿童/青少年/成年/老年
-gender?性别	- female/ male
-type and severity of the medical condition? 医疗状况类型和严重性	-early / late stage早期和晚期 -mild / intermediate / serious form轻度/中度/严重 -acute / chronic phase急性/慢性
-range of time?时间范围	-duration of application or use长期 -number of repeat exposures周期 -duration of follow-up随访期间

9.3.3. How to weight the contribution of each data set 如何分配权重

Based on their scientific validity and relevance, the data should be weighted according to their relative contributions. 基于科学有效性和相关性，数据应该根据相对贡献给予权重。

Due to the diversity of medical devices, there is no single, well established method for weighting clinical data: 由于医疗设备的多样性，没有单一、良好的加权方法

•the evaluators should identify appropriate criteria to be applied for a specific evaluation;

评价者应该确定用于具体评价的合适标准

•these pre-defined criteria should be followed strictly by the evaluators.

评价者应严格遵守预先确定的标准

Typically, clinical data should receive the highest weighting, when generated through a well designed and monitored randomized controlled clinical investigation (also called randomised controlled trial), conducted with the device under evaluation in its intended purpose, with patients and users that are representative of the target population.

通过精心设计和监控时生成的随机对照临床研究(也称为随机对照试验) 的临床数据应给予最高的权重，评估设备的目的、病人和目标人群的代表的使用者。

Note: It is acknowledged that randomized clinical investigations may not always be feasible and/or appropriate and the use of alternative study designs may provide relevant clinical information of adequate weighting.

随机临床调查可能并不总是可行的和/或适当的，和使用的替代研究设计可以提供足够权重的相关临床信息。

When rejecting evidence, the evaluators should document the reasons (both for studies and reports that have been generated and are held by the manufacturer, and for other documents identified during Stage 1).

当拒绝证据，评价者应给出书面原因（制造商生成或持有的研究和报告，和在第1阶段识别的文件）

10. Analysis of the clinical data (Stage 3) 临床数据分析

10.1. General considerations 总则

The goal of the analysis stage is to determine if the appraised data sets available for a medical device collectively demonstrate compliance with each of the Essential Requirements pertaining to the clinical performance and clinical safety of the device, when the device is used according to its intended purpose.

分析阶段的目的是确定评价数据集用于证实医疗设备符合临床性能和临床安全相关的基本要求，当设备根

据预期目的使用的时候。

In order to demonstrate compliance, the evaluators should 为证实符合性，评价者应当：

- use sound methods; 使用合理的方法
- make a comprehensive analysis; 综合分析
- determine if additional clinical investigations or other measures are necessary;

确定附加的临床调查和其他措施是必要的

- determine PMCF needs. 确定PMCF需求

10.2. Specific considerations 具体考虑

a. Use sound methods 合理方法

A literature review that describes current knowledge/ the state of the art should be prepared with relevant literature identified during Stage 1 and appraised during Stage 2.

描述了当前知识/科学水平的文献综述，相关文献的准备在第1阶段识别和第2阶段评价。

Weighting criteria developed and assigned during the appraisal stage can be used to identify those sets of data, which may be considered to be pivotal.

权重标准开发和分配在评估阶段可以用来识别这些数据集，被认为是关键的。

The methods available for analysing clinical data generally are either qualitative or quantitative. Depending on the nature of the medical device and the circumstances, it is likely that qualitative (i.e. descriptive) methods will need to be used for some devices. Reliance on qualitative methods should be justified. Generally, available clinical data such as numbers of incidents in the post market phase should be assessed quantitatively in relation to current knowledge/ the state of the art.

用来分析临床资料的可用方法是定性的或定量的。根据医疗设备的性质和环境，定性(即描述性)方法可能用于一些设备。依赖定性方法是合理的。一般说来，可用的临床数据，如上市后阶段事故数量用来定量评估当前的知识/科学水平。

The results of the pivotal datasets should be explored, looking for consistency of results across particular device performance characteristics and identified risks. If the different datasets report similar outcomes, confidence in the robustness increases. If different results are observed across the datasets, it will be helpful to determine the reason for such differences. Regardless, all data sets should be considered and included. The reviewers should take into account the weighting attributed to data sets during Stage 2 when addressing conflicting information. Where relevant, a rationale should be given for the lack of value of a data set to the evaluation.

关键数据结果的应该开发，通过特定设备的性能特征和识别风险来寻找一致性的结果。如果不同的数据报告相似的结果，信心暴增。如果观察到不同的结果，将有助于确定这些差异的原因。无论如何，所有的数据应考虑和包含。在处理冲突信息时，评论者应在第二阶段对数据进行权重分配。相关的，评估无价值的数据应给出理由。

In general, data that are not methodologically sound (such as single patient reports) should not be used for demonstration of adequate clinical performance and clinical safety of a device.

一般来说，方法上不合理的数据(如单个病人报告)不被用于充分证实装置临床性能和临床安全

For additional information, see Appendix A6 (Appraisal of clinical data - examples of studies that lack scientific validity for demonstration of adequate clinical performance and/or clinical safety).更多信息，参阅附录A6

In exceptional situations, when an evaluation is based on limited data, this shall be described and justified in the clinical evaluation report. See additional information and specific considerations in Appendix A8 (Devices for unmet medical needs - aspects to consider).

在特殊情况下，评价是基于有限的数据，将在临床评估报告中被描述和判断。更多的信息和具体参见附录A8(设备未满足的医疗需求方面的考虑)。

b. Make a comprehensive analysis 综合分析

The evaluators should: 评价者应：

•Determine compliance with each of the Essential Requirements pertaining to the clinical performance and clinical safety of the device. For detailed information concerning specific Essential Requirements, see Appendix A7 (Analysis of the clinical data - compliance to specific Essential Requirements).

确定适合设备临床安全和临床性能的基本要求，更多信息，参见附录A7

•The evaluation includes 评价包括：

-the adequacy of pre-clinical testing (e.g. bench testing, animal testing) to verify safety

足够的临床前测试来证明安全（实验室测试、动物试验）

-risks to patients, users or other persons associated with the intended purpose of the device 对患者、使用者或其他人员的风险

-benefits to patients 患者福利

-confirmation that the device achieves the performance(s) intended by the manufacturer, including all claims made by the manufacturer确认设备达到制造商预期的能，包括制造商的所有要求

-confirmation of usability, that the design adequately reduces the risk of use error as far as possible, and that the design is adequate for the intended users (lay, professional, disabled or other users, if applicable)

确认可用性，设计尽可能的减少使用错误的风险，设计是用于合适的预期使用者（外行、专业人员、残疾或其他人员

-adequacy of the information materials supplied by the manufacturer, including if risk mitigation measures are correctly addressed in the IFU (handling instructions, description of risks, warnings, precautions, contraindications, instructions for managing foreseeable unwanted situations)

制造商提供充足的信息资料，包括说明书中正确处理降低风险的措施（使用说明、风险描述、警示、预防、禁忌症、可预知的不期望状态的管理说明）

•Take into consideration all products covered by the clinical evaluation and all aspects of their intended purpose. Any gaps in evidence need to be identified, including in respect to information relevant to:

考虑覆盖临床评价和预期目的所有产品。需要确认证据偏差,包括对相关的信息:

- understanding the interaction between the device and the body; 明白人和设备之间互动

-the comprehensiveness of the available data, taking into account: 考虑所有数据的综合

-the entire range of products/ models/ sizes/ settings covered by the evaluation产品/型号/尺寸/设置全部范围

-the entire range of conditions of use and of the intended purpose 使用条件和预期目的的全部范围

-the estimated number of patients exposed to the device估计接触设备的病人数量

-the type and adequacy of patient monitoring 患者监护的合适性和类型

-the number and severity of adverse events 不良事件的数量和严重性

-the adequacy of the estimation of associated risk for each identified hazard

识别危害合适的风险评估

-the severity and natural history of the condition being diagnosed or treated

接受诊断和治疗的严重程度和自然历史条件

-current standards of care, including the availability and the benefit/risk profiles of other devices and medical alternatives

当前的治疗标准，包括设备和可选方案的可用性和风险/收益

•Assess if there is consistency and alignment between the clinical evaluation, the information materials supplied by the manufacturer, and the risk management documentation for the device under evaluation; any discrepancies should be identified in order to ensure that all the hazards and other clinically relevant information have been identified and analysed appropriately.

评估临床评价之间是否稳定和一致，制造商提供的信息材料和评价设备的风险管理文档的任何差异都应该确认，确保所有的危险和其他临床相关信息已确定并适当地分析。

•Assess if there is consistency between the documents mentioned above and current knowledge/ the state of the art.

评估上面提到的文件和当前的知识/科学水平之间的一致性。

c. Determine if additional clinical investigations or other measures are necessary

确定额外的临床调查和其他措施是否必要

The evaluators should identify additional clinical investigations or other measures that are necessary in order to generate any missing data and eliminate compliance issues.

评价者应识别额外的临床调查和其他措施是必要的，以便得到确实的数据和消除合规问题。

Data needed to address the identified gaps should be determined so that conclusions can be drawn with confidence in relation to conformity with the essential requirements, including:

需要处理识别偏差的数据应确定，有信心得出符合基本要求的数据，包括：

-evaluation of the safety, performance and the benefit/risk profile

性能、安全、风险/收益评估

-compatibility with a high level of protection of health and safety (that can be determined by considering current knowledge/ the state of the art, with reference to standards and available alternatives, risk minimisation, patient needs and preferences)

兼容健康和安全高风险水平（根据现有的知识/科技水平、参考标准、可选方案、风险最简化、患者需求和选择权）

-the acceptability of any undesirable side-effects 任何不良副作用的可接受性

-the risk of use error and the adequacy of the IFU to the intended users, 使用错误或给目标使用者不充分说明书的风险

-consistency between available information 可利用信息的一致性

See Appendix A2 for detailed information on when additional clinical investigations should be carried out. 参见附录A2

d. Determine PMCF needs 确定PMCF需求

In order to determine needs, the evaluators should describe residual risks and any uncertainties or unanswered questions. The evaluators should also include aspects such as rare complications, uncertainties regarding medium- and long-term performance, or safety under wide-spread use.

为了确定需求，评价者应描述剩余风险和任何未确定或为回答的问题。评价者应包括这些方面：较少发生的并发症、不确定的中-长期性能、大规模使用的安全性。

10.3. Where demonstration of conformity based on clinical data is not deemed appropriate 验证基础临床数据被认为不合适

Where demonstration of conformity with Essential Requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given:

验证基础临床数据的基本要求被认为不合适，充分判断给予排除：

•The justification must be based on the output of the risk management process. This should include an evaluation of background clinical data identified from the literature, and an appraisal of their relevance to the device under evaluation.

判断必须基于风险管理过程的输出。包括评价识别自文献的临床数据的背景，评估与评价设备的相关性。

•The device/body interaction, the clinical performances intended and the claims of the manufacturer have to be specifically considered.

人/设备交互作用，预期的临床性能和制造商声称的性能应被具体考虑

•Adequacy of demonstration of conformity with the Essential Requirements based on performance evaluation, bench testing and pre-clinical evaluation in the absence of clinical data has to be duly substantiated.

基本要求一致性验证的充分性基于性能评价，在却反临床数据前可以适当考虑实验室测试和临床前评价。

•A clinical evaluation is still required and the above information and evidence-based justification should be presented in the clinical evaluation report.

临床评价的静态需求、上述信息、基于证据的判断都应体现在临床评价报告中。

11. The clinical evaluation report (CER, Stage 4) 临床评价报告

A clinical evaluation report shall be compiled to document the clinical evaluation and its output.临床评价报告需要编辑成临床评价和输出文件。

The clinical evaluation report should contain sufficient information to be read and understood by an independent party (e.g. regulatory authority or notified body). Therefore, it should provide sufficient detail for understanding the search criteria adopted by the evaluators, data that are available, all assumptions made and all conclusions reached.

临床评价报告应包含充分信息，以便独立第三方阅读和理解（如监管建构和公告机构）。因此，应提供评价者使用的详细搜索条件、可供使用的数据、所有假设和得出的结论。

The contents of the clinical evaluation report shall be cross-referenced to the relevant documents that support them. It should be clear which statements are substantiated by which data, and which reflect the conclusions or opinions of the evaluators. The report should include references to literature-based data and the titles and investigational codes (if relevant and available) of any clinical investigation reports, with cross-references to the location in the manufacturer's technical documentation.

临床评估报告的内容要被相关文件交叉引用，应明确声明数据被证实，并反映评价者的结论或观点。报告应该包括基于数据的文献、标题和临床研究规则(如果相关和可用)的临床研究报告，与制造商交叉引用的技术文档的位置。

The amount of information may differ according to the history of the device or technology. Where a new device or technology has been developed, the report would need to include an overview of the developmental process and the points in the development cycle at which all clinical data have been generated.

根据设备的历史或技术，信息的数量会有差异。新的设备或技术在开发时，报告可能需要包括发展历程的综述和在研发周期中产生的所有临床数据的要点。

It is important that the report outlines the different stages of the clinical evaluation:

报告临床评价不同阶段的提纲是重要的

•Stage 0, scope of the clinical evaluation: 临床评价的范围

-explains the scope and context of the evaluation, including which products/ models/ sizes/ settings are covered by the clinical evaluation report, the technology on which the medical device is based, the conditions of use and the intended purpose of the device;

说明临床评价的范围和内容，包括临床评估报告覆盖的产品、型号、尺寸、设置，医疗设备的技术原理、设备的使用条件和预期使用目的。

-documents any claims made about the device's clinical performance or clinical safety.

任何关于设备性能和安全声明的文件

•Stage 1, identification of pertinent data: 识别数据

-explains the literature search strategy; 说明文献搜索的策略

-presents the nature and extent of the clinical data and relevant pre-clinical data that have been identified.

临床数据目前的性质和内容，已被识别的相关的临床前相关数据

•Stage 2, appraisal of pertinent data: 评估数据

-explains the criteria used by the evaluators for appraising data sets;

说明评价者用于评估数据的标准

-summarises the pertinent data sets (methods, results, conclusions of the authors);

有关数据的综述（方法、结果、作者的结论）

-evaluates their methodological quality, scientific validity, the relevance for the evaluation, the weighting attributed to the evidence, and any limitations;

评价他们的方法质量、科学有效性、评价的相关性、证据的权重分配、和任何受限

-presents justifications for rejecting certain data or documents.

提出判断拒绝文件和数据的标准

•Stage 3, analysis of the clinical data: 数据分析

-explains if and how the referenced information, such as confirmation of compliance with clinical data requirement from applicable harmonised standards and the clinical data, constitute sufficient clinical evidence for demonstration of the clinical performance and clinical safety of the device under evaluation;

说明如何和怎样参考信息，如从可用的危害标准和临床数据来确认符合临床数据要求，构成足够的临床证据来证实评价设备的临床表现和临床的安全。

-explains whether there are adequate data for all aspects of the intended purpose and for all products/ models/ sizes/ settings covered by the clinical evaluation.

说明临床评价覆盖的产品、型号、尺寸、设置等各方面都有充足的数据

-describes the benefits and risks of the device (their nature, probability, extent, duration and frequency);

描述设备的风险/收益（性质、可能性、程度、长期性和频率）

-explains the acceptability of the benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned, with reference to applicable standards and guidance documents, available medical alternatives, and the analysis and conclusions of the evaluators on fulfilment of all Essential Requirements pertaining to clinical properties of

the device (MDD ER1, ER3, ER6; AIMDD ER1, ER2, ER5);

根据医疗领域现有知识/科学水平，解释风险/收益的可接受性，参照适用的标准和指南文件，可用的医疗方案、和评价者对实现设备临床属性基本要求的分析和结论(MDD ER1、 ER3、ER6和AIMDD ER1、ER2、ER5)

-analyses if there is consistency between the clinical data, the information materials supplied by the manufacturer, the risk management documentation for the device under evaluation;

分析临床数据间，制造商提供的信息材料，评价设备的风险管理文档的一致性。

-whether there is consistency between these documents and the current knowledge/ the state of the art;文件和目前知识/科学技术水平的一致性

-identifies any gaps and discrepancies; 识别偏差和差异

-identifies residual risks and uncertainties or unanswered questions (such as rare complications, uncertainties regarding medium- and long term performance, safety under wide-spread use) that should be further evaluated during PMS, including in PMCF studies. 识别的剩余风险、未确定的和未回答的问题（很少发生的并发症、未确定的中-长期性能、大规模使用的安全性）应在PMS中长期评价，包含PMCF研究

The evaluators should check the clinical evaluation report, provide verification that it includes an accurate statement of their analysis and opinions, and sign the report. They should provide their CV and their declaration of interests to the manufacturer.

评价者应检查临床评价报告，提供证实分析和结论的准确声明，签署报告。 他们应提供CV和制造商的利益声明。

The clinical evaluation report should be dated and version controlled.

临床评价报告应进行日期和版本控制。

A suggested format for the clinical evaluation report is located at Appendix A9 (Clinical evaluation report - proposed table of contents, examples of contents).

附录A9提供了一个临床评价报告的模板。

Suggestions for aspects that should be checked for the release of a clinical evaluation report are summarised in Appendix A10 (Proposed checklist for the release of the clinical evaluation report).

附录A10提供放行临床评估报告的建议检查表（建议的临床评价报告放行检查表）

Information on declaration of interests can be found in Appendix A11 (Information on declarations of interests).

利益声明的信息见附录A11（利益声明信息）

12. The role of the notified body in the assessment of clinical evaluation reports

公告机构在临床评价报告评估中的作用

The notified body plays a key role in the assessment and verification of clinical evaluation reports and supporting documentation provided by medical device manufacturers to support demonstration of conformity of a device with the Essential Requirements of the relevant Directive.

在评估和确认制造商提供的临床评估报告和支持文件时，公告机构起着关键作用，以证明临床评价报告符合相关指令的基本要求。

Detailed recommendations for notified bodies are given in Appendix A12 (Activities of notified bodies). These include: NB的详细建议见附录A12，包括：

•guidance for notified bodies on the assessment of clinical evaluation reports provided by medical device manufacturers as part of technical documentation (including design dossiers) and

指导NB评估医疗设备制造商提供的技术文件一部分的临床评估报告(包括设计档案)

•guidance for notified body in development of their internal procedures for assessment of clinical aspects relating to medical devices.

指导NB公告机构在内部研发程序中评估医疗器械有关的临床方面。

In addition, documents of the Notified Bodies Operations Group (NBOG) should also be consulted. NBOG documents include best practice guides, checklists and forms.

另外，应当咨询NBOG的文件，NBOG文件包括最佳实践指南、检查表和表格。

Pursuant to section 6a of Annex I MDD and to section 5a of Annex 1 AIMDD, the demonstration of conformity with the Essential Requirements must include a clinical evaluation conducted in accordance with Annex X of Directive 93/42/EEC or with Annex 7 AIMDD. This is applicable for all classes of medical device.

按照MDD附录I的6a，AIMDD附录1的5a，基本要求检查表一致性的证实必须包括临床评价来符合Annex X of Directive 93/42/EEC or with Annex 7 AIMDD。所有类别的器械都适用。

Where demonstration of conformity with Essential Requirements based on clinical data is not deemed appropriate this must be adequately justified by the manufacturer and based on the output of the risk management process. The device-body interaction, the intended

purpose and the claims of the manufacturer have to be specifically considered. The adequacy of demonstration of conformity based on performance evaluation, bench testing and pre-clinical evaluation in the absence of clinical data must be duly substantiated. The notified body must review the manufacturer's justification, the adequacy of data presented and whether or not conformity is demonstrated. Nevertheless a clinical evaluation is still required and the above information and an evidenced justification should be presented as the clinical evaluation for the device in question.

证实符合基本要求的制造商需要充分判断认为不合适的临床数据和风险管理的输出过程。必须特别考虑设备/人交互作用、预期目的和制造商的要求。基于性能评估、实验室测试和临床前评价来证实一致性，在缺乏临床数据时必须适当的证实。公告机构必须审查制造商的理由，资料的充分性和是否合格。然而临床评估仍是需要的，在设备讨论中上面的信息和证据理由应作为临床评价在设备讨论中提交。

Appendices 附录

A1. Demonstration of equivalence A1 证实等效性

Pursuant to Annex X of Directive MDD and Annex 7 AIMDD, the evaluation of clinical data (i.e. the clinical evaluation), where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

根据MDD指令附录10和AIMDD指令附录7，临床数据的评价（临床评价），适当采用相关协调标准、必须遵守合理程序的定义和方法论：

1. either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:科学文献的评价标准，可能相关的安全、性能、设计参数、预期目的

-there is demonstration of equivalence of the device to the device to which the data relates, and 验证设备与等效设备相关的数据

- the data adequately demonstrate compliance with the relevant Essential Requirements.

充分验证符合基本要求的数据

2. or a critical evaluation of the results of all clinical investigations made.

达到临床调查结果的评价标准

3. or a critical evaluation of the combined clinical data provided from 1 and 2.

结合1和2提供的临床数据的评价标准

Clinical, technical and biological characteristics shall be taken into consideration for the demonstration of equivalence: 临床的、技术的、生物学特征等考虑用于等效验证

• Clinical:临床的

-used for the same clinical condition (including when applicable similar severity and stage of disease, same medical indication), and

用于相似的临床环境（包括相同疾病的阶段和严重性、相同的医学特征）

- used for the same intended purpose, and 相似的预期目的
- used at the same site in the body, and相似患者部位

-used in a similar population (this may relate to age, gender, anatomy, physiology, possibly other aspects), and 相似人群（年龄、性别、解剖、生理、可能的其他方面）

-not foreseen to deliver significantly different performances (in the relevant critical performances such as the expected clinical effect, the specific intended purpose, the duration of use, etc.).不可预知的显著差异性能（临床性能如预期临床效应、特定预期目的、持续时间）

•Technical:技术的

- be of similar design, and设计相似
- used under the same conditions of use, and 相似的使用条件

-have similar specifications and properties (e.g. physicochemical properties such as type and intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, surface texture, porosity, particle size, nanotechnology, specific mass, atomic inclusions such as nitrocarburising, oxidability), and有相似的规格和属性（物理属性如能量强度和类型、拉伸强度、粘度、表面特性、波长、表面结构、多孔性、粒径、纳米技术、密度、原子内部结构如氮化物、氧化物）

- use similar deployment methods (if relevant), and相似的部署（加工？）方法
- have similar principles of operation and critical performance requirements.

相似的工作原理和关键性能要求

•Biological: Use the same materials or substances in contact with the same human tissues or body fluids.

生物的：相似的材料和物质，接触人体组织和体液的

Exceptions can be foreseen for devices in contact with intact skin and minor components of devices; in these cases risk analysis results may allow the use of similar materials taking

into account the role and nature of the similar material. Different aspects of equivalence and compliance to different Essential Requirements can be affected by materials. Evaluators should consider biological safety (e.g. in compliance to ISO 10993) as well as other aspects necessary for a comprehensive demonstration of equivalence. A justification explaining the situation should be provided for any difference.

例外的，可以预知与完好皮肤接触的设备，和设备的微小部件，在这些情况下风险分析结果可能允许使用相似的材料考虑类似材料的作用和性质。等效的不同方面和符合不同的基本要求可能受材料的影响。评估者应考虑生物学安全(如符合ISO 10993)以及其他方面全面证实等效的必要条件。任何的差异需要提供理由说明

For assuming equivalence, 评价等效

•equivalence can only be based on a single device[14]; 等效仅基于单个设备

•all three characteristics (clinical, technical, biological) need to be fulfilled;

3个特性（临床、技术、生物学）都需要满足

•similar means that no clinically significant difference in the performance and safety of the device would be triggered by the differences between the device under evaluation and the device presumed to be equivalent;

相似意味着设备没有显著的差异，在评价设备和等效设备之间的临床性能和安全上

•the differences between the device under evaluation and the device presumed to be equivalent need to be identified, fully disclosed, and evaluated; explanations should be given why the differences are not expected to significantly affect the clinical performance and clinical safety of the device under evaluation;

评价设备和假定等效设备之间的差异需要识别，全面公开和评估。为什么说这些差异对评价设备没有显著影响，需要给出说明。

•the manufacturer should investigate if the medical device presumed to be equivalent has been manufactured via a special treatment (e.g. a surface modification, a process that modifies material characteristics); if this is the case, the treatment could cause differences in respect to technical and biological characteristics; this should be taken into account for the demonstration of equivalence and documented in the CER;

如果假定等效设备具有特殊处理的加工渠道（表面改性、材料特性修饰过程），那么制造商需要调查；如果这种情况发生，需要处理导致技术和生物学特性方面的差异；这应该考虑等效验证和在CER中记录。

•if measurements are possible, clinically relevant specifications and properties should be measured both in the device under evaluation and the device presumed to be equivalent,

and presented in comparative tabulations;

如果可以测量，临床的相关规范和属性应被测量，包括评价设备和假定等效设备，形成比较表格

•comparative drawings or pictures should be included in order to compare shapes and sizes of elements that are in contact with the body;

比较应包含图纸和图片，以便比较与身体有联系的形状和尺寸

•the manufacturer is expected to:制造商期望：

-include the supporting non-clinical information (e.g. pre-clinical study reports) in the technical documentation of the device, and

在设备技术文档中包括支持非临床的信息（临床前研究报告）

-in the clinical evaluation report, summarise the information and cite its location in the technical documentation;在临床评估报告中，概括在技术文件中的信息和引用位置

•for the evaluation of the technical characteristics, devices that achieve the same therapeutic result by different means cannot be considered equivalent;

对技术参数的评价，设备通过不同的手段达到相同的治疗效果不能被认为是等效

•for the evaluation of the biological characteristics:对生物学参数的评价

-when a detailed chemical characterisation of materials in contact with the body is needed, ISO 10993-18 Annex C can be used to show toxicological equivalence but this is just a part of the evaluation of the biological criteria;

与人体接触的材料的详细化学特性描述是需要的，ISO 10993-18附录C可用于表明毒理学等效，只是生物学标准评价的一部分。

-sourcing and manufacturing procedures may adversely affect impurity profiles; analytical methods chosen to characterise medical devices should appropriately take into consideration knowledge concerning expected impurity profiles (tests may have to be repeated when production methods or sourcing are changed);

采购和制造过程可能影响杂质分布，选择描述医疗器械特性的分析方法应适当考虑杂质分布有关的知识(生产方法或采购变化后，需要重新测试)

-it may be necessary to show from histopathological studies that the same host response is achieved in vivo in the intended application and the intended duration of contact;

从组织病理学研究表明相同的宿主响应是实现体内预期应用和接触时间是必要的。

-for animal tests, differences between species may limit the predictive value of the test; the choice of the test and its predictive value should be justified;

动物试验，物种之间的差异可能会限制测试的预测价值，测试的选择和预期价值应被判断。

-abrasion, if relevant, and host response to particles may also need to be considered.

磨损，和主机反应微粒子也需要考虑。

•the only clinical data that are considered as relevant are the data obtained when the equivalent device is a CE-marked medical device used in accordance with its intended purpose as documented in the IFU.

当等效设备是按照说明书的预期使用目的使用的CE-marked设备时，获得的数据认为相关的临床数据。

Note: Exceptions can be considered. When the equivalent device is not a CE-marked device, information concerning the regulatory status of the equivalent device and a justification for the use of its data should be included in the clinical evaluation report. The justification should explain if the clinical data is transferrable to the European population, and an analysis of any gaps to good clinical practices (such as ISO 14155) and relevant harmonised standards

注意：免责条款能被承认。当等效设备ce标记设备时，关于等效设备的食品法规管理信息和使用数据的理由应该包括临床评估报告中。理由应说明临床数据可以转移到欧洲人和良好的临床实践的差异分析(如ISO 14155)和相关协调标准。

A2. When should additional clinical investigations be carried out?

什么时候执行额外的临床调查

a. How should manufacturers and evaluators decide if there is sufficient clinical evidence?

制造商和评价者如何确定足够的临床证据？

When clinical data are required in order to draw conclusions as to the conformity of a device to the Essential Requirements, the data need to be in line with current knowledge/ the state of the art, be scientifically sound, cover all aspects of the intended purpose, and all products/ models/ sizes/ settings foreseen by the manufacturer.

临床数据要求得出满足设备基本要求的结论，数据需要符合当前的知识/科学技术，科学合理的覆盖制造商所有产品/型号/尺寸/设置的所有目的。

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14 Evaluators may wish to refer to several devices that are equivalent. In such a situation, equivalence of every single device to the device under evaluation should be fully investigated, demonstrated, and described in the clinical evaluation report.

If gaps are present that cannot be addressed by other means, clinical investigations should be planned and carried out.

如果存在差异，不能通过其他方式处理，临床调查应该计划和实施。

.b. Considerations 考虑

Implants and high-risk devices, those based on technologies where there is little or no experience, and those that extend the intended purpose of an existing technology (i.e. a new clinical use) are most likely to require clinical investigation data.

植入和高风险的设备，哪些基于很少或没有经验的技术，和那些扩展现有技术的预期目的(新的临床使用)最有可能需要临床研究数据

For compliance with Annex X section 1.1.a MDD and Annex 7 AIMDD, clinical investigations with the device under evaluation are required for implantable and class III devices unless it can be duly justified to rely on existing clinical data alone.

符合MDD附录10的1.1a和AIMDD附录7，植入或III类评价设备需要临床调查，除非能被现存的临床数据充分说明。

The need for clinical investigations depends on the ability of the existing data to adequately address the benefit/risk profile, claims, and side-effects in order to comply with the applicable Essential Requirements. Clinical investigations may therefore also be required for other devices, including for devices in class I and class IIa, and for class IIb devices that are not implantable.

临床调查的必要性取决于现有数据的能力充分处理利益/风险、要求和副作用，以便符合适用的基本要求。其他设备也可能要求临床调查，包括费植入的I类、IIa类和IIb类设备。

When deciding if additional clinical investigations need to be carried out, the manufacturer should perform a detailed gap analysis. The gap analysis should determine whether the existing data are sufficient to verify that the device is in conformity with all the Essential Requirements pertaining to clinical performance and clinical safety.

如果决定额外的临床调查需要执行时，制造商需要执行详细的偏差分析。偏差分析应确定现有数据是否足以验证设备符合所有的临床表现和临床安全有关的基本要求。

Special attention should be given to aspects such as:特别注意的方面：

- new design features, including new materials,新的设计特点、包含新材料

-new intended purposes, including new medical indications, new target populations (age, gender, etc.),新的预期目的、包含新的医学特征、新的而目标人群

- new claims the manufacturer intends to use,制造商要求新的预期用途

- new types of users (e.g. lay persons), 新的使用者类型（外行）
- seriousness of direct and/or indirect risks, 严重的直接/间接风险
- contact with mucosal membranes or invasiveness, 粘膜接触或侵袭性
- increasing duration of use or numbers of re-applications,增加持续时间和重复使用次数
- incorporation of medicinal substances,合并药用物质
- use of animal tissues (other than in contact with intact skin),使用动物组织

-issues raised when medical alternatives with lower risks or more extensive benefits to patients are available or have become newly available[15],

当较低风险的医学方案，或可供患者使用的更多利益，或成为新可用问题升高

-issues raised when new risks are recognised (including due to progress in medicine, science and technology)

认识到新的风险（包括医疗、科学和技术的进展）

-whether the data of concern are amenable to evaluation through a clinical investigation, etc.

重要数据是否经得起临床研究评价检验，等等。

Data on the safety and performance of other devices and alternative therapies, including benchmark devices and equivalent devices, should be used to define the state of the art or identify hazards due to substances and technologies. This will allow the clinical data requirements to be established more precisely in relation to the intended purpose of a device. Precision in this analysis and the choice of selected medical indications and target populations may reduce the amount of clinical data needed from additional clinical investigations.

其他设备和替代疗法（包括基准设备和等效设备）的安全和性能数据，应用于定义科学水平或识别物质和技术危害。这将允许临床数据需求建立更准确设备预期目。分析精度，医学特征和目标人群的选择可能减少的大量来自额外临床调查的临床数据。

A3. Device description - typical contents 设备描述-典型内容

The description should be detailed enough to allow for a valid evaluation of the state of compliance with Essential Requirements, the retrieval of meaningful literature data and, if applicable, the assessment of equivalence to other devices described in the scientific literature:

描述应该足够详细，用来允许符合基本要求的有效评估，有意义的文献数据的检索，如果适用，等效的评估科学文献中描述的其他设备：

- name, models, sizes, components of the device, including software and accessories

设备名称、型号、尺寸、部件，包括软件和附件

- device group to which the device belongs (e.g. biological artificial aortic valve)

属于设备的设备组（生物人工主动脉瓣）

- whether the device is being developed/ undergoing initial CE-marking/ is CE-marked

设备是否已经研发、正在申请CE-marking，已取得 CE-marked

•whether the device is currently on the market in Europe or in other countries, since when, number of devices placed on the market

设备目前是在欧盟市场还是其他国家，指已上市的设备

- intended purpose of the device设备达到预期目的

-exact medical indications (if applicable) 准备的医学特征

-name of disease or condition/ clinical form, stage, severity/ symptoms or aspects to be treated, managed or diagnosed

疾病或环境名称/临床型式、阶段、严重性/症状、治疗方面、管理或诊断

-patient populations (adults / children / infants, other aspects)患者人群

-intended user (use by health care professional / lay person)预期使用者

-organs / parts of the body / tissues or body fluids contacted by the device

器官/身体的一部分/组织或设备接触的流体

-duration of use or contact with the body持续使用时间或接触身体

-repeat applications, including any restrictions as to the number or duration of re-applications重复使用，包括限制使用的次数和重复使用时间

-contact with mucosal membranes/ invasiveness/ implantation粘膜接触/侵袭性/植入

-contraindications禁忌症

-precautions required by the manufacturer预防措施

-single use / reusable一次性使用/重复使用

-other aspects其他方面

• general description of the medical device including 医疗设备描述的总则包括：

- a concise physical and chemical description简洁的物理和化学描述
- the technical specifications, mechanical characteristics技术参数、机械特征
- sterility 灭菌
- radioactivity 放射性
- how the device achieves its intended purpose 怎样达到设备的预期目的
- principles of operation 工作原理
- materials used in the device with focus on materials coming in contact (directly or indirectly) with the patient/ user, description of body parts concerned

设备使用材料，关注与 (直接或间接)与患者/使用者接触的材料，描述关注的身体部位

- whether it incorporates a medicinal substance (already on the market or new), animal tissues, or blood components, the purpose of the component

药用物质的组成（已上市的或新的），动物组织、血液成分、组分的用途

- other aspects其他方面

• whether the device is intended to cover medical needs that are otherwise unmet/ if there are medical alternatives to the device / if the device is equivalent to an existing device, with a description of the situation and any new features

设备是否打算覆盖未满足的医疗需求/如果有医疗设备的替代品/如果设备等效于现有设备，状况的描述和任何新特性

• if the device is intended to enter the market based on equivalence:

如果设备打算基于等效设备上市

- name, models, sizes, settings components of the device presumed to be equivalent, including software and accessories

假定等效设备的名称、型号、尺寸、设置，包括软件和辅件

- whether equivalence has already been demonstrated 等效是否已经被证实

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15 See Appendix A7.2 (Conformity assessment with requirement on acceptable benefit/risk profile)

- Intended performance, including the technical performance of the device intended by the manufacturer, the intended clinical benefits, claims regarding clinical performance and clinical safety that the manufacturer intends to use

预期性能，包括制造商预期的技术性能、预期的临床利益、关于临床性能的要求和临床安全

- For devices based on predecessor devices: Name, models, sizes of the predecessor device, whether the predecessor device is still on the market, description of the modifications, date of the modifications.

基于前代设备：前代设备名称、型号、尺寸、如果前代设备还在上市，描述修改、修改日期

- The current version number or date of the information materials supplied by the manufacturer (label, IFU, available promotional materials and accompanying documents possibly foreseen by the manufacturer).

制造商提供的信息材料(标签、IFU、宣传材料和相应的文档) 的当前版本或日期。

A4. Sources of literature 文献搜索

There are different sources of clinical literature that can be searched for clinical evaluation. A comprehensive search strategy is required, normally involving multiple databases. The search strategy should be documented and justified. Important sources include the following:

临床文献的不同来源可被搜索用于临床评价。需要综合的搜索策略，通常涉及多个数据库。搜索策略应记录和合理的。包括以下重要来源：

- Scientific literature databases科技文献数据库

-MEDLINE or Pubmed can provide a good starting point for a search. However, with possibly incomplete coverage of European Journals and reduced search features, comprehensiveness may not necessarily be guaranteed.

-Additional databases may need to be used to ensure adequate coverage of devices and therapies in use in Europe, to identify relevant clinical trials and publications of user experience16, and to facilitate searches by device name and manufacturer (e.g. EMBASE/Excerpta Medica, the Cochrane CENTRAL trials register, etc.).其他数据库

-Information coverage and search features available in scientific databases can change with time. Criteria for selecting adequate databases therefore need to be defined and re-evaluated on a regular basis. 信息覆盖在科学数据库和搜索特性可能随着时间的推移而改变。因此选择适当数据库的标准需要经常的重新定义和评估

- Internet searches 互联网搜索

Searches provide important data, examples include information on: 互联网提供重要数据

- harmonised standards and other standards applicable to the device in question and containing information on clinical performance and clinical safety.

设备讨论中可用的协调标准和其他标准，包含临床安全和临床性能的信息

- Field safety corrective actions for the equivalent and/or other devices. These can be found on manufacturer's web sites, internet sites of European Competent authorities, the U.S. Food and Drug Administration (FDA), possibly other sites.

等效和/或其他设备的现场安全纠正措施。这些可以在制造商的网站、欧洲主管部门的网站、美国食品和药物管理局(FDA)、其他网站找到。

- Implant registry reports.植入类的注册报告

- Documents available in systematic review databases (e.g. the Cochrane Database of Systematic Reviews, Prospero international prospective register of systematic reviews).

文档可以在系统综述数据库(例如Cochrane的系统评价数据库、Prospero国际前瞻性系统评价登记)。

-Expert documents produced by professional medical associations that are important for assessment of current knowledge/ the state of the art, including clinical practice guidelines and consensus statements.

专业医学协会的专家文档，评估当前的知识/科学水平是重要的,包括临床实践指南和一致同意声明

-Meta-analyses and reviews of health technology assessment (HTA) institutes and networks.HTA结构和网络的Meta分析和评论

- Identification of studies via the WHO International Clinical Trials Registry Platform (ICTRP) and ClinicalTrials.gov.

通过世卫组织国际临床试验注册平台(ICTRP)和ClinicalTrials.gov的研究识别

16 Studies yielding negative results or user experience (such as publications about risks that are based on a case or a case series) may not qualify for publication in high impact medical journals. Low impact journals available to European users and other sources may therefore need to be searched.

• Non-published data 未公开的数据

Non published data are important for many devices and retrieval of such data should be considered, including for monitoring of any changes, e.g.非公布的数据对许多设备是重要的，和这些数据的检索应该考虑，包括任何变化的监控，如：

- The label and IFU of the equivalent device (if equivalence is claimed by the manufacturer) and/or of benchmark devices and other devices.

等效设备的标签和说明书

- Data provided to manufacturers from implant registries.制造商从植入类登记提供的数据

- Data presented at congresses.会议展示的数据

•Citations referenced in cientific literature can be important and should be screened.

科学文献中引用的参考是很重要的，应检查。

Literature found to be relevant is likely to cite other literature that is of direct interest to the manufacturer. Additionally, it may be necessary to retrieve some of the referenced literature in order to appraise the scientific quality of a document.

文献可能引用与制造商有直接利益的其他文献。另外，检索参考文献来评价文献的科学质量是必要的。

A5. Literature search and literature review protocol, key elements

文献搜索和文献综述方案，关键因素

The output of the literature search and literature review are:文献搜索和文献综述的输出：

•Literature on the device in question and the equivalent device. 等效设备和讨论设备的文献

Note: If the manufacturer holds own clinical data for the device in question (e.g. own pre-market clinical investigations, PMCF Studies, other PMS data), the literature is considered together with those data for consistent appraisal and overall analysis.

注意:如果制造商拥有自己讨论设备的临床数据 (如自己的上市前临床调查、PMCF研究、其他PMS数据)，文献将和这些数据一起做一致性评估和全面分析。

•A review of the current knowledge/ the state of the art needed for the proper conduct of the appraisal and analysis of the clinical data of the device under evaluation and the equivalent device (i.e. applicable standards and guidance documents, information on the medical conditions that are relevant to the clinical evaluation, therapeutic/ management/ diagnostic options available for the intended patient population, etc.).

审查目前的知识/艺术的状态所需的适当行为的评价和临床资料的分析评价和设备相当于设备(即适用的标准和指导文档,信息相关的医疗条件的临床评估、治疗/管理/诊断选择预期患者人群,等等)。

The literature collected may relate directly to the device in question (e.g. publications of clinical investigations of the device in question that have been performed by third parties, its side effects or complications, incidence reports) and/or to equivalent device, benchmark devices, other devices and medical alternatives available to the intended patient population.

讨论设备收集的文献可以直接叙述(如由第三方执行的，讨论设备的临床调查出版物，其副作用或并发症、事故报告)和/或等效设备、基准设备、其他设备和医疗可用替代的预期患者人群。

The literature search and literature review protocol should address the background to and the objective of the review, specifying the literature review questions and the methods for identification, selection, collection and appraisal of the relevant publications needed to address them. It should include the literature search methodology (literature search protocol).

文献检索和文献评估方案应处理评估的背景和目的，文献综述问题和相关出版物识别、选择、收集和评估方法需要处理的问题。它应包括文献检索方法论(文献搜索方案)

The selection of literature should be objective and justified, i.e. include all relevant data, both favourable and unfavourable. With respect to the clinical evaluation, it is important that the clinical evaluators are able to assess the degree to which the selected papers reflect the intended application/ use of the device.

文献选择应客观和合理，包括所有的数据，有利和不利的。至于临床评价，重要的是临床评估者能够评估所选论文反映设备预期用途和使用的程度。

Objective, non-biased, systematic search and review methods should be used. Examples are:客观、无偏见、系统搜索和评估的方法应被使用，如：

-PICO (patient characteristics, type of intervention[17], control, and outcome queries)

PICO（病人特性、干预类型、控制和输出查询）

-Cochrane Handbook for Systematic Reviews of Interventions

Cochrane系统评价手册的干预措施

-PRISMA (The Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement

PRISMA（系统评价和Meta分析首选报告项目）陈述

-MOOSE Proposal (Meta-analysis Of Observational Studies in Epidemiology)

MOOSE建议（流行病学方面，观察研究的Meta分析）

The protocol should specify the elements described below, addressing the background, objective, and methods for identification, selection, and collection of the relevant publications to address the literature review questions.

下面描述的方案应有能具体原理、处理背景、目标和方法用于识别、选择、和收集相关出版物来处理文献综述问题。

A5.1. Background to the literature search and the literature review 搜索和评估背景

This section documents the importance of and rationale for the literature review and includes, but is not limited to:这个部分说明文献评估的重要性和原理，但不限于：

- Device name/model 设备名称和型号
- Importance of literature review to risk management process. The literature review will provide data on current interventions[18] for the intended patient population (state of the art) in order to give input to the assessments of acceptable benefit/risk profiles, what is currently considered as providing a high level of protection of health and safety and what are considered acceptable side-effects.

文献评估对风险管理过程的重要性。文献综述将提供当前预期患者人群（当前科学水平）的干预措施数据，为了给输入评估可接受的利益/风险概况，目前认为是提供一个高水平的健康和安全保护被认为是可接受的副作用。

- Previous literature reviews 先前的文献综述
- Importance of review to risk management process 重要的风险管理过程综述

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17 The term Intervention includes therapies, diagnostic measures, measures for the management of diseases or medical conditions.

18 Includes therapies, diagnostic measures, measures for the management of diseases or medical conditions.

- Previous literature searches conducted by the manufacturer

制造商先前进行的文献搜索

- If including equivalent or benchmark devices, name and model of the devices.

如果包括等效设备和基准设备，设备的名称和型号

- The CER will need to establish equivalence to the device under evaluation or the relevance of benchmark devices to the clinical evaluation.

CER将需要建立评估的等效设备或基准设备的相关性的临床评估。

A5.2. Objective 目标

This section documents the research question(s), which should be consistent with the scope of the clinical evaluation and carefully constructed using a process (e.g. PICO):

搜索问题的文件部分，需要考虑临床评价的范围和小心的构造使用过程（如PICO）

- Population(s)/disease(s) or condition(s)人口/疾病或条件
- Intervention(s) 干预
- Comparator group(s)/control(s) 对照/控制组
- Outcome(s)/endpoint(s)输出/终点

The inputs for the review question(s) (e.g. PICO) are the device description and the intended performance of the device including any claims on clinical performance and clinical safety which the manufacturer wants to use. Also information from the risk management process is needed as an input.

评估问题的输入(如PICO)设备描述和设备的预期性能，包括任何声称制造商想用的临床性能和临床安全。风险管理过程的信息页需要作为输入。

A5.3. Methods方法

The methods section of the protocol documents the plans for literature search, study selection, data collection, and analysis methods. It defines the literature search strategy and the inclusion/exclusion criteria for the documents found.

方案文件的方法部分是文献检索、研究选择、数据收集和分析方法的计划。它定义了文献检索策略和包含/排除标准文档。

The protocol should include:方案包括

- the literature search methodology 文献搜索方法论

The purpose of a literature search protocol is to plan the search before execution. It should be developed and executed by persons with expertise in information retrieval, having due regard to the scope of the clinical evaluation set out by the manufacturer. The involvement of information retrieval experts will help to optimize literature retrieval to identify all relevant published literature.

文献检索方案的目的是在执行之前计划搜索。是专业的开发和执行人员在信息检索方面，由制造商对临床评估设定范围。信息检索专家的参与将有助于优化文献检索来识别所有发表的相关文献。

The importance of a literature search protocol is for critical appraisal of the methods. The search strategy should be based on carefully constructed review questions.

文献搜索方案对方法的严格评价是重要的。 检索策略应基于仔细构造评估问题。

- the sources of data that will be used and a justification for their choice (see Appendix A4, Sources of literature)使用数据源和选择理由（见附录A4）
- the extent of any searches of scientific literature databases (the database search strategy);任何科技文献数据库检索的范围（数据库检索策略）
- attempts to identify all published literature尝试识别所有公开的文献
- which electronic databases are to be searched, with justification 合理检索电子数据库
- the extent of any Internet searching and searching non-published information, including the search strategy and justification

互联网检索和未公开信息检索的范围，包括检索策略和理由

- exact search terms and any limits 符合检索的项目和限制
- limits for start and end dates of each search 每个搜索结束日期的限制
- the selection/criteria (such as inclusion/exclusion criteria) to be applied to published literature and justification for their choice

应用公开文献的选择/标准（入选/排除标准）和选择理由

- strategies for addressing the potential for duplication of data across multiple publications;处理公开发表的数据潜在重复性的策略
- strategies for avoiding retrieving publications of data generated and already held by the manufacturer避免制造商产生或已持有公开数据的检索策略
- the data collection plan that defines data management practices to ensure data integrity during extraction (e.g. quality control/second review of extracted data by additional reviewer)

在提取期间，定义了数据管理实务以确保数据完整性的数据收集计划，(如质量控制/其他评估者对提取数据的二次评估)

- the appraisal plan, which defines the methods for appraising each publication, including the relevance of the data to the intended clinical use and the methodological quality of the data评价计划，定义了每个出版物的评价方法包括预期临床使用的数据相关性和数据的方法论质量

- the analysis plan, which defines the methods for analysing the data including data processing and transformation

分析计划，定义了分析数据的方法，包括数据的处理和转换

Any deviations from the literature search protocol should be noted in the literature search report.任何文献搜索方案的偏差需要在文献搜索报告中注明。

A6. Appraisal of clinical data - examples of studies that lack scientific validity for demonstration of adequate clinical performance and/or clinical safety

临床数据的评估-缺少科学有效的研究实例来充分证实临床性能和临床安全

a. Lack of information on elementary aspects: 缺少基本方面的而信息

This includes reports and publications that omit disclosure of包括遗漏的报告和出版物

- the methods used 使用方法
- the identity of products used 使用产品的识别
- numbers of patients exposed接触病人的数目
- what the clinical outcomes were 临床输出是什么
- all the results the clinical study or investigation planned to investigate

所有临床研究的结果和调查的调查计划

- undesirable side-effects that have been observed 观察到的不良副作用
- confidence intervals/ calculation of statistical significance置信区间/统计数据计算
- if there are intent-to-treat and per protocol populations: definitions and results for the two populations打算治疗和方案人群：两种人群的定义和结果

b. Numbers too small for statistical significance统计数据数目过少

Includes publications and reports with inconclusive preliminary data, inconclusive data from feasibility studies, anecdotal experience, hypothesis papers and unsubstantiated opinions.

包括不确定初始数据的出版物和报告，不确定数据来自可行性研究、趣闻经验、假设论文和未经证实的观点

c. Improper statistical methods不正确的统计方法

This includes包括

- results obtained after multiple subgroup testing, when no corrections have been applied for multiple comparisons. 多组测试得到的结果，没有修正就用于多种比较。

- calculations and tests based on a certain type of distribution of data (e.g. Gaussian distribution with its calculations of mean values, standard deviations, confidence intervals, t-tests, others tests), while the type of distribution is not tested, the type of distribution is not plausible, or the data have not been transformed. Data such as survival curves, e.g. implant survival, patient survival, symptom-free survival, are generally unlikely to follow a Gaussian distribution.

计算和测试基于数据分布的一种类型（就算平均值的高斯分布、标准差、置信间隔、t检验和其他检验），当分布类型不是检测，分布类型不可信、或数据不能转换。数据如生存曲线等，植入生存、患者生存、无症状生存，一般不太可能遵循高斯分布。

d. Lack of adequate controls 缺乏足够控制

In the following situations, bias or confounding are probable in single arm-studies and in other studies that do not include appropriate controls: 下列情况下，在单个研究或其他研究中的偏差或者混淆，不包括合适的控制。

- when results are based on subjective endpoint assessments (e.g. pain assessment).

结果基于主观终结点评价（如疼痛评价）

- when the endpoints or symptoms assessed are subject to natural fluctuations (e.g. regression to the mean when observing patients with chronic diseases and fluctuating symptoms, when natural improvement occurs, when the natural course of the disease in a patient is not clearly predictable).

当终点和症状评估是收自然波动支配（如：慢性病人观察的趋均数回归和波动症状，当自然改善发生、病人的自然进程不能明确预测）

- when effectiveness studies are conducted with subjects that are likely to take or are foreseen to receive effective co-interventions (including over-the-counter medication and other therapies).

当有效性研究的主题可能需要或预见得到有效干扰(包括非处方药物和其他治疗)。

--when there may be other influencing factors (e.g. outcomes that are affected by variability of the patient population, of the disease, of user skills, of infrastructure available for planning/ intervention/ aftercare, use of prophylactic medication, other factors).

可能有其他影响因素（不同患者人群、疾病、使用者技能、可用于计划的基础设施/干预/术后护理、药物预防的使用和其他因素影响的结果）

- when there are significant differences between the results of existing publications, pointing to variable and ill controlled influencing factors.

当现有的出版物的结果有重大差异，表明变量和疾病控制的影响因素。

In the situations described above, it is generally not adequate to draw conclusions based on direct comparisons with external or historic data (such as drawing conclusions by comparing data from a clinical investigation with device registry data or with data from published literature).

在上述情况下，通常是不足以基于外部或历史数据比较直接得出结论 (如从设备登记数据或公开文献的数据的临床研究比较数据得出结论)。

Different study designs may allow direct comparisons and conclusions to be drawn in these situations, such as randomised controlled design, cross-over design, or split-body design.

不同的研究设计允许直接比较和得出结论，如随机对照设计、交叉设计或分离设计。

e. Improper collection of mortality and serious adverse events data

不正确的死亡率收集和严重不良事件数据

Demonstration of adequate benefits and safety is sometimes based on mortality data or occurrence of other serious outcomes that limit a subject's ability to live in his home and be available for follow-up contacts. In this type of study,

足够证实利益和安全有时是基于死亡率数据或出现其他严重后果，限制受试者能力在家和可用于后续接触。研究类型如下：

- consent of the subjects for contacting reference persons/ institutions for retrieval of medical information should be obtained during recruitment; when subjects can no longer be found, outcomes should be investigated with the reference persons/ institutions;

- the consequences of missing data on the results should be analysed (e.g. with a sensitivity analysis); alternatively, when patients can no longer be found and their outcomes cannot be identified, they should be considered to meet the SAE endpoint under investigation (e.g. the mortality endpoint of a study).

结果中缺失数据的后果应该分析 (例如用敏感性分析)，或者，当病人不能再被发现和他们的结果不能识别，在调查中应考虑满足SAE终点（如研究的死亡率终点）。

In mortality studies (and other studies addressing serious outcomes) procedures for investigating serious patient outcomes, numbers of subjects lost to follow-up, reasons why subjects leave the study, and the results of sensitivity analysis should be fully disclosed in reports and publications.

死亡率研究(和处理严重结果的其他研究) 程序调查严重病人结果、受试者失访的数量、受试者离开研究的原因和敏感性分析的结果应在报告和出版物中披露。

f. Misinterpretation by the authors 作者误解

Includes conclusions that are not in line with the results section of the report or publication, such as包括结论不符合报告报告或出版物的结果部分，如

- reports and publications not correctly addressing lack of statistical significance/ confidence intervals that encompass the null hypothesis.

报告和出版物不能直接处理缺乏零假设的统计数据/置信区间

- effects too small for clinical relevance. 临床相关性太小的效果

g. Illegal activities不法活动

Includes clinical investigations not conducted in compliance with local regulations. Clinical investigations are generally expected to be designed, conducted and reported in accordance with EN ISO 14155 or to a comparable standard, and in compliance with local regulations and the Declaration of Helsinki.

包括临床调查没按照当地法规执行。临床调查一般期望按EN ISO 14155 或可比标准设计、执行和报告，满足当地法规和赫尔辛基宣言。

A7. Analysis of the clinical data - compliance to specific Essential Requirements

临床数据分析—符合具体的基本要求

While this appendix describes the needs for the clinical evaluation (MDD ER1, ER3, ER6; AIMDD ER1, ER2, ER5), there may be additional essential requirement(s) that need support of sufficient clinical evidence for the conformity assessment.

临床评价的而要求在附录描述（MDD ER1、ER3、 ER6和 AIMDD ER1、ER2、 ER5），另外的基本要求需要提供一致性评估的充分的文献数据

A7.1. Conformity assessment with requirement on safety 安全要求的合格评估

(MDD ER1 / AIMDD ER1)

The information materials supplied by the manufacturer (including label, IFU, available promotional materials including accompanying documents possibly foreseen by the manufacturer), should be reviewed to ensure they are consistent with the relevant clinical data appraised in stage 2 and that all the hazards, information on risk mitigation and other clinically relevant information have been identified appropriately.

制造商提供的信息材料（标签、说明书、可用的宣传材料包括制造商可能遇见补充资料），应评估以确保他们符合有关第二阶段临床资料评价，所有的危险、降低风险的信息和其它临床相关信息已合适识别。

Input from the risk management and the use of standards:风险管理和标准使用的输出

- Risk management documents should determine if all identified hazards are fully covered by harmonised standards or other relevant standards or if there are gaps needed to be covered by clinical data.

风险管理文档应确定所有识别的危害能被协调标准或相关标准覆盖，或者偏差需要被临床数据覆盖。

- Risk management documents should determine if all identified risks relating to patient treatment, method of operation of the device or risks relating to usability have been minimised or if there are question regarding clinical risks that need to be solved.

风险管理文档应确定所有识别的患者治疗、设备操作方法的风险，或最小化可用性相关的风险或如果有关于临床风险的问题需要解决。

- Harmonised standards are generally expected to be applied in full in order to confer a presumption of conformity.协调标准一般期望应用于完全为了给予一致性的假设。

- If technical developments provide a higher level of safety than current harmonised standards, then the higher level of safety should be prioritised in order to meet the Essential Requirements on reducing the risks as far as possible, that risks must be compatible with a high level of protection of health and safety, and that side effects must be acceptable (MDD ER2 and ER3 and ER6; AIMDD ER1 and ER5).

如果技术发展提供了比目前协调标准更高的安全水平，那么更高的安全水平需要优先考虑以便满足基本要求和尽可能减少风险，风险必须和更高的健康和安全防护水平兼容，副作用必须可接受(MDD ER2、 ER3 、 ER6和AIMDD ER1 、ER5).

Examples: 实例

- Electrical hazards should be covered by compliance to EN 60601-1 and applicable collateral standards regarding medical electrical equipment, so that the device

will not compromise the safety and health of patients or users. Under these circumstances, residual risks regarding electrical hazards are acceptable and additional clinical data are not needed unless negative issues are detected during PMS activities.

电气危害应被EN 60601-1和并行的医疗电气设备标准覆盖，设备在病人和使用者的安全和健康方面不会让步。这种情况下，电气危害的剩余风险是可接受的，另外的临床数据不需要，除非在PMS活动中发现负面问题。

- Harmonised standards on usability (EN 62366 and if applicable EN 60601-1-6) are expected to be applied to ensure that usability aspects are taken into consideration during the device development. However, they do not give guidance on a detailed level of design, while usability aspects are known to cause or contribute to a large portion of incidents. Therefore, clinical data may be needed to prove that the risk of use error, due to the ergonomic features of the device and the environment in which the device is intended to be used, has been reduced as far as possible.

在设备的研发阶段，考虑可用性协调标准（(EN 62366或EN60601-1-6）预期用来确保可用性。然而没有提供在可用性方面会引起或导致大部分事件详细的设计指南。因此，临床数据可能需要提供使用错误的风险，由于设备预期使用的人体工程学特性和环境，尽量减少风险。

A7.2. Conformity assessment with requirement on acceptable benefit/risk profile (MDD ER1 / AIMDD ER1) 可接受风险/收益的符合性评价要求(MDD ER1 / AIMDD ER1)

It is expected,预期

• that the clinical evaluation demonstrates that any risks which may be associated with the intended purpose are minimised and acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety; and

当权衡带给患者的利益与高水平的健康和安全的保护一致，临床评价证实和预期目的相关的风险被最小化和可接受， 和

• that the IFU correctly describe the intended purpose of the device as supported by sufficient clinical evidence; and

说明书直接描述的设备预期目的被足够文献支持，和

• that the IFU contain correct information to reduce the risk of use error, information on residual risks and their management as supported by sufficient clinical evidence (e.g. handling instructions, description of risks, warnings, precautions, contraindications, instructions for managing foreseeable unwanted situations).

说明书包含的正确信息减少错误使用的风险，剩余风险的信息和管理被足够临床证据支持

（如操作说明、风险描述、警示、预防措施、禁忌症、管理可预见意外情况的说明）

a. Evaluation of the description of the intended purpose of the device

设备预期目的的描述的评价

The information materials supplied by the manufacturer (including label, IFU, available promotional materials including accompanying documents possibly foreseen by the manufacturer) should be reviewed. The evaluators should evaluate if the description provided by the manufacturer correctly identifies those medical conditions and target groups for which conformity with the relevant Essential Requirements has been demonstrated through sufficient clinical evidence. When reading the IFU, there should be no uncertainty for users as to when a given medical condition or medical indication or target population is covered by the CE marking or when it falls entirely under the user's own responsibility (off label use).

由制造商提供的信息资料(包括标签、说明书、宣传材料包括制造商可能预见的补充资料)应评估。评价者应该评估制造商提供的描述正确识别符合医疗条件和目标群体的相关基本要求，已经通过足够的临床证据证明。阅读IFU时，用户应该没有不确定性，当给定的医疗条件或医学特征或目标人群，CE标记或当它完全在用户自己的责任(离开标签使用)。

b. Evaluation of the device's benefits to the patient设备对患者利益的评价

Positive impacts of a device on the health of an individual should be meaningful (relevant for the patient) and measurable. The nature, extent, probability and duration of benefits should be considered. Benefits may include:

设备的积极影响个体的健康应是有意义的(有关病人)和可测量的。性质、程度、概率和持续时间应考虑。利益包括:

- positive impact on clinical outcome (such as reduced probability of adverse outcomes, e.g. mortality, morbidity; or improvement of impaired body function),

临床结果的积极影响（减少不良后果的可能性，如死亡率、发病率、改善受损的机体功能）

- the patient's quality of life (significant improvements, including by simplifying care or improving the clinical management of patients, improving body functions, providing relief from symptoms),病人生活质量（显著提高，包括照顾简化或提高病人的临床管理、提高机体功能、症状减轻）

- outcomes related to diagnosis (such as allowing a correct diagnosis to be made, provide earlier diagnosis of diseases or specifics of diseases, or identify patients more likely to respond to a given therapy),诊断相关的结果（得出正确诊断、提供疾病的早期诊断和疾病特性、识别病人对治疗的反应）

- positive impact from diagnostic devices on clinical outcomes, or

临床结果上积极影响诊断设备

- public health impact (such as to the ability of a diagnostic medical device to identify a specific disease and therefore prevent its spread, to identify phases, stages, location, severity or variants of disease, predict future disease onset).

影响公众健康（如诊断医疗设备用于识别疾病特性，因此阻止传播，识别疾病的时期、阶段、位置、严重性和变体，预测未来的疾病攻击）

c. Quantification of benefit(s) to the patients 患者而利益的量化

Defining specified endpoints is indispensable for setting up clinical investigations and properly performing the identification, appraisal, and analysis of the clinical data.

对立临床调查和正确执行临床数据识别、评估和分析，定义具体的终点是必不可少的。

- Benefit(s) are often evaluated along a scale or according to specific endpoints or criteria (types of benefits), or by evaluating whether a pre-identified health threshold was achieved. The change in subjects' condition or clinical management as measured on that scale, or as determined by an improvement or worsening of the endpoint, determines the magnitude of the benefit(s) in subjects. Variation in the magnitude of the benefit across a population may also be considered.

利益往往是沿着规模或根据特定的终点或标准(利益的类型) 来评估，或通过评估预先识别的健康门槛是否达到。受试者条件的变化或临床管理作为范围、或者改善或恶化的终点来测量，决定受试者利益的大小。利益大小的变化可以通过人口来考虑。

- The clinical relevance of these changes should be discussed and justified.

临床相关的变更应讨论或调整。

- Ideally, these parameters should be directly clinically relevant. 参数应直接临床相关

- In certain cases benefits can be assumed when validated surrogate endpoints are met (such as obtaining certain results with laboratory tests or measurements of anatomical or physiological properties). 一定情况下，利益可假设，当确认满足替代终点(如获得某些实验室检测结果、测量解剖或生理属性)

- Based on the current state of medical knowledge, the evaluators shall justify and document the clinical relevance of endpoints used for the clinical evaluation of a device and demonstrate the validity of all surrogate endpoints (if surrogate endpoints have been used).

基于当前的医学知识状态，评价者应证明和文档化终点的临床相关性，用于设备的临床评价和证实所有替代终点的有效性(如果已使用替代终点)。

The probability of the patient experiencing one or more benefit(s) is another important aspect of evaluating benefits and the clinical performance of a device.

病人体验一个或多个利益的概率是评价效益和设备临床性能的另一个重要方面。

- Based on the clinical data provided and on a sound statistical approach, a reasonable prediction of the proportion of "responders" out of the target group or subgroups should be made.

根据提供的临床数据和一个合理的统计方法，目标组或亚组的响应比率能被合理预测。

- The data may show that a benefit may be experienced only by a small proportion of patients in the target population, or, on the other hand, that a benefit may occur frequently in patients throughout the target population. It is also possible that the data will show that different patient subgroups are likely to experience different benefits or different levels of the same benefit.

数据可能显示利益仅被目标人群的小部分患者经历，或者另一方面，利益可能在目标人群的病人经常发生。也有可能数据将显示不同的患者亚组可能会经历不同的利益或相同利益的不同水平

- If the subgroups can be identified, the device may be indicated for those subgroups only.

如果亚组被识别，设备就可能表明仅用于亚组。

- In some cases, however, the subgroups may not be identifiable. Magnitude and probability of clinical benefits will have to be put together when weighing benefits against risks.在一些情况下，亚组可能不被识别。临床利益的大小和可能性必须把风险与收益时放在一起权衡。

- A large benefit experienced by a small proportion of subjects may raise different considerations than does a small benefit experienced by a large proportion of subjects. For example, a large benefit, even if experienced by a small population, may be significant enough to outweigh risks, whereas a small benefit may not, unless experienced by a large population of subjects.

小部分受试者经历一个大的利益，可能提高不同的考虑比大部分受试者经历的小利益。例如：一个大的利益，即使经历了人口不多，可能是足够大的风险比重，而一个小的好处可能不会，除非是大量受试者的经历。

The duration of effect(s) (i.e. how long the benefit can be expected to last for the patient, if applicable to the device)

影响的持续时间（如：利益期望对患者持续多长时间，）

• The duration should be characterised (for example as a statistical distribution) on the basis of sound clinical data and appropriate statistical approaches.

持续时间应特征化（如统计分布），给予合理的临床数据和使用的统计方法。

• PMCF will be decisive to refine and corroborate reasonable predictions over time.

随着时间的推移，PMCF将决定改善和证实合理的预测。

• The mode of action may play an important role: Some treatments are curative, whereas, some may need to be repeated frequently over the patient's lifetime.

行动的模式可能会发挥重要作用：有的治疗是有疗效的，然而有的需要在病人的生命周期里经常重复。

• To the extent that it is known, the duration of a treatment's effect may directly influence how its benefit is defined. Treatments that must be repeated over time may introduce greater risk, or the benefit experienced may diminish each time the treatment is repeated.

在某种程度上是已知的，治疗效果的持续时间可能直接影响定义的利益。治疗的重复随着时间的推移可能会引入更大的风险，或利益经历可减少重复治疗的时间。

• The evaluation of the duration of effect should take into consideration current knowledge/ the state of the art and available alternatives.

持续效果的评价应该考虑当前知识/科学水平和可用的选择。

d. Evaluation of the clinical risks of devices 设备临床风险评价

The risk management documents are expected to identify the risks associated with the device and how such risks have been addressed. The clinical evaluation is expected to address the significance of any risks that remain after design risk mitigation strategies have been employed by the manufacturer.

期望的风险管理文件可以识别设备相关的风险和如何处理风险。临床用来处理任何风险，制造商采取风险缓解措施后任然存在的设计风险。

PMS reports are compiled by the manufacturer and often include details of the device's regulatory status (countries in which the device is marketed and date of commencement of supply), regulatory actions undertaken during the reporting period (e.g. recalls, notifications), a tabulation of incidents (particularly serious adverse events/ incidents, including deaths, stratified into whether the manufacturer considers them to be device-related or not) and estimates of the incidence of incidents.

制造商编写PMS报告和包括具体的设备的视频法规管理（设备销售和供应开始的日期国家），在报告期内的监管行为(如召回、公告)，事件列表(尤其是严重不良事件/事故，包括死

亡，制造商考虑为设备相关或不相关的分层)和估计的事件的发生率。

Post-marketing data about incidents are generally more meaningful when related to usage but caution is needed. The extent of user reporting in the medical devices vigilance system may vary considerably between countries, users, and type of incident. Considerable under-reporting by users is expected. However, the analyses of data within these reports may, for some devices, provide reasonable assurance of both clinical safety and performance.

当使用相关时，上市后事故数据通常更有意义，但谨慎是必要的。不同国家、使用者和事件类型之间医疗器械警戒系统的用户报告范围可能相差很大。大量使用者不希望的漏报，然而这些报告的数据分析对一些设备提供合理临床安全性和性能的保证。

It may be helpful to provide a table summarising device-related incidents, paying particular attention to serious adverse events/ incidents, with comments on whether observed device-related incidents are predictable on the basis of the mode of action of the device.

它可能有助于提供一个相关设备事故的总结表，特别重视严重不良事件/事故，基于设备的作用模式，评述是否观察到相关设备事故是可预测的。

To demonstrate the extent of the probable risk(s)/ harm(s), the following factors - individually and in the aggregate - should be addressed:

证实可能的风险/危害的程度，按照下述独立和总体因素来处理：

• Nature severity, number and rates of harmful events associated with the use of the device: 性质严重性，设备使用相关的危害事件的数量和比率

- Device-related serious adverse events/ incidents: Those events that may have been or were attributed to the use of the device and produce an injury or illness that is life-threatening, results in permanent impairment or damage to the body, or requires medical or surgical intervention to prevent permanent harm to the body.

设备相关的严重不良事故/事件：这些事件可能或者是由于设备的使用和产生伤害或疾病，包括生命威胁、导致永久性损伤或损坏身体、或需要医疗或手术干预以防止永久性伤害身体。

- Device-related non-serious/ non-reportable harmful events: Those events that may have been or were attributed to the use of the device and that do not meet the criteria for classification as a device-related serious adverse events/ incidents.

设备相关的不严重/不报告的伤害事件：这些事件可能或者是归因于设备的使用，但不满足作为设备严重不良事件/事故的分类标准。

- Procedure-related incidents: Harm to the patient that results from use of the device but is not caused by the device itself. For example, anaesthetic-related complications associated with the implantation of a device.

过程相关事件：使用设备的但不是设备本身造成的伤害病人。例如：与植入设备有关的相关麻醉剂的并发症。

- Probability of a harmful event: The proportion of the intended population that would be expected to experience a harmful event; whether an event occurs once or repeatedly may be factored into the measurement of probability.

危害事件的概率：期望经历伤害事件的预期人口，无论事件是一次或多次发生都作为可能性测量因素考虑。

- Duration of harmful events (i.e., how long the adverse consequences last): Some devices can cause temporary, minor harm; some devices can cause repeated but reversible harm; and other devices can cause permanent, debilitating injury. The severity of the harm should be considered along with its duration.

伤害事件持续时间(不良后果持续多长时间)：一些设备可能导致暂时的、轻微的伤害；有些设备可能会导致重复但可逆的损害；其他设备可能会导致永久性的、虚弱的伤害。应该考虑危害的严重性及其持续时间

- Risk from false-positive or false-negative results for diagnostic medical devices :

诊断医疗设备的假阳性或假阴性结果风险：

- if a diagnostic device gives a false-positive result, the patient might, for example, receive an unnecessary treatment and incur all the risks that accompany that treatment, or might be incorrectly diagnosed with a serious disease;

如果一个诊断设备提供了假阳性结果，病人可能，如接受不必要的治疗和伴随治疗承担所有的风险，也可能被错误的诊断出有严重的疾病-

if a diagnostic device gives a false-negative result, the patient might not receive an effective treatment (thereby missing out on the benefits that treatment would confer), or might not be diagnosed with the correct disease or condition;

如果一个诊断设备提供了假阴性的结果，病人可能不接受有效的治疗(因此错过治疗带来的好处)，或不可能被诊断为正确的疾病或状况

- other risks associated with false-positives and false-negatives.

假阳性或假阴性结果风险相关的其他风险

- It is also important to look at the totality of the harmful events associated with the device.

同样重要的是要看相关设备的全部有害事件。

The number of different types of harmful events that can potentially result from using the device and the severity of their aggregate effect has to be considered. When multiple

harmful events occur at once, they have a greater aggregate effect.

不同类型的有害事件的数量可能会由于使用设备和他们的总效应的严重程度。当多个有害事件发生时，有一个更大的总效应。

• Comment specifically on any clinical data that identifies hazards not previously considered in the risk management documentation, outlining any additional mitigation required (e.g. design modification, amendment of information materials supplied by the manufacturer such as inclusion of contraindications in the IFU).

对任何不是在先前风险管理文档考虑的，识别危害临床数据发表具体评论，列出额外的缓解要求 (如设计修改、制造商提供的修改的信息材料修正版，如包含在说明书中的禁忌症)。

e. Evaluation of acceptability of the benefit/risk profile可接受的利益/风险评价

• Evaluate if the clinical data on benefits and risks are acceptable for all medical conditions and target populations covered by the intended purpose when compared with the current state of the art in the corresponding medical field and whether limitations need to be considered for some populations and/or medical conditions.

对覆盖预期目的所有医疗条件和目标人群，基于利益和风险的临床数据是可接受的评估，需要考虑相应的医学领域当前科学水平和需要考虑是否对一些人群和/或医疗条件是限制。

• The current knowledge/ state of the art therefore needs to be identified and defined, possibly also relevant benchmark devices and medical alternatives available to the target population. Typically, documentation of the clinical background shall include the following information:

当前知识/科学水平需要识别和定义，也可能相关的基准设备和医疗方案提供给目标人群。通常情况下,临床背景文档应包括以下信息:

- clinical background 临床背景

- information on the clinical condition(s) to be treated, managed, or diagnosed

治疗、管理和诊断的临床条件信息

- prevalence of the condition(s) 条件下的患病率

- natural course of the condition(s) 条件下的自然进程

- other devices, medical alternatives available to the target population, including evidence of clinical performance and safety 其他设备、可用于目标人群的医疗选择，包括临床性能和安全的证据

- historical treatments 历史治疗

- medical options available to the target population (including conservative,

surgical and medicinal)可用于目标人群的医疗选择（包括保守的、手术和药物的）

- existing devices, benchmark devices 目前的设备、基准设备

• Sufficient detail of the clinical background is needed so that the state of the art can be accurately characterised in terms of clinical performance, and clinical safety profile. The selection of clinical data that characterises the state of the art should be objective and not selective of data on the basis of being favourable for the device under evaluation. Information should be provided on alternative approaches that have been used or considered and their benefits and drawbacks. Deficiencies in current therapies should be identified from a critical and comprehensive review of relevant published literature. The literature review should demonstrate if the device addresses a significant gap in healthcare provision. Where there is no such clinical need, the design solution needs to show an improved or at least equivalent benefit/risk profile compared to existing products or therapies.

足够详细的临床背景是必需的，科学水平可以准确表明临床性能和临床安全性。临床数据的选择表明科学水平应该是客观的，而不是选择性有利于设备评估的数据。提供用于或考虑替代的方法和他们的优缺点的信息。当前治疗的缺陷应被识别，从公开发表的相关文献的关键和综合评估。如果设备在医疗条款处理上有显著差异，文献综述应证明。没有这样的临床需要，设计方案需要表明比现有产品或疗法改进或至少同等的效益/风险。

• If or when treatment comparability versus accepted therapy is not available at the time of placing on the market, this should be clearly described in the device IFU.

如果或当治疗可比性和公认疗法相比，无法用于市场销售，明显应在设备IFU中描述。

• Even if a device cannot compete with an agreed first-line treatment or the best in class, it may add to the portfolio of acceptable treatments, as even a first-line treatment will likely have contraindications or non-responders.

即使设备不能与约定的一线治疗或最好的级别，它可以增加可接受治疗的组合，作为一线治疗可能会有禁忌症或没有响应。

• Devices, that might not be best-in-class, might provide sufficient clinical evidence for an acceptable benefit/risk-profile for specific, defined subgroups or even superior clinical performance under specific conditions (e.g. emergency outdoor conditions).

设备可能不是最佳的，可能提供足够的临床证据来接受特定的利益/风险，定义亚组或甚至在特定条件下(如紧急户外条件)优越的临床性能。

• The position within the treatment portfolio has to be specified properly in the clinical evaluation report and other relevant documentation.

在临床评估报告和其他相关文档中，治疗组合内的位置必须适当指定。

Example: A system for deep brain stimulation has a proven effectiveness for the treatment of depression. However, the implantation of electrodes in the brain is associated with major risks. Less invasive treatment options are available to patients suffering from depression. Taking into account the available treatment portfolio, the manufacturer has limited the medical indication of the device to "therapy resistant depression", which is reflected in the IFU and in other relevant documentation.

如：系统对深部脑刺激治疗抑郁症的证明有效。然而，在大脑中植入电极是主要风险。微创疗方法可用于抑郁症病人。考虑可用的治疗组合，制造商已经限制了设备的医学特征为“抗抑郁治疗，这反映在IFU和其他相关文档中。

A7.3. Conformity assessment with requirement on performance (MDD ER3 / AIMDD ER2) 性能要求的符合性评估

The devices must achieve the performances intended by the manufacturer. The ability of a medical device to achieve its intended purpose as claimed by the manufacturer needs to be demonstrated, including any direct or indirect medical effects on humans as well as the clinical benefit on patients resulting from the technical or functional, including diagnostic characteristics of a device, when used as intended by the manufacturer.

设备必须达到制造商预期的性能。需要证明医疗设备的能力达到制造商宣称的能力。包括任何直接或间接的对人类的医学影响，以及来自于技术或功能病人临床利益，包括设备的诊断特点，按制造商预期的使用时。

Clinical performance includes any claims about clinical properties and safety of the device that the manufacturer intends to use. It is expected:

临床性能包括设备临床特点和安全的声明，如：

- that the devices achieve their intended performances during normal conditions of use, and 设备在正常使用下达到预期性能
- that the intended performances are supported by sufficient clinical evidence.

预期性能被大量临床证据支持

Evaluation of clinical performance can vary widely between device groups, especially between therapeutic and diagnostic devices. The following list gives examples of performance data relevant particularly to diagnostic devices:

临床性能评价在设备间有很大的差异，特别是在治疗和诊断设备。下面的列表给出诊断设备性能数据相关的例子:

- Reproducibility of independent acquisition of images (same patient, same machine, different operator and interpreter).

独立采集图像的再现性(同样的患者、同样的机器、不同的操作员和解释者)。

- Reproducibility of independent reporting of images (same patient, same machine, same images, different interpreter/analyser).

独立报告图像的再现性(同样的患者、同样的机器、不同的解释者和分析者)。

- Diagnostic sensitivity and specificity of the test for major clinical indications; positive and negative predictive values according to varying pre-test probabilities.

主要临床适应症的诊断敏感性和测试特异性，根据不同先期检测的阳性和阴性预测值。

- Comparisons of performance of new iterations of diagnostic software against previous software versions.

比较新的诊断软件对以前的软件版本迭代的性能。

- Normal values by age and gender, covering all groups in which the diagnostic system may be used.

按年龄和性别的正常值，覆盖所有组的诊断系统可能使用。

A7.4. Conformity assessment with requirement on acceptability of undesirable side-effects (MDD ER6 / AIMDD ER5)不良副作用的可接受性要求的一致性评估

Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.当权衡预期性能时，任何不良副作用必须构成可接受的风险

In order to evaluate the acceptability of the side-effects of a device:

为了评价设备副作用的可接受性

- there needs to be clinical data for the evaluation of the nature, severity and frequency of potential undesirable side-effects;

需要临床数据来评估性质、严重性和潜在不良副作用的频率

- the clinical data should contain an adequate number of observations (e.g. from clinical investigations or PMS) to guarantee the scientific validity of the conclusions relating to undesirable side-effects and the performance of the device;

临床数据包含足够的观察次数（来自临床调查或PMS）来保证设备性能和不良副作用结论的科学有效性，

- in order to evaluate if undesirable side-effects are acceptable, consideration has to be given to the state of the art, including properties of benchmark devices and medical

alternatives that are currently available to the patients, and reference to objective performance criteria from applicable standards and guidance documents.

为了评估如果不良副作用是可以接受的，必须考虑科学水平，包括基准设备的属性和可用于的病人医疗选择，和参考客观性能标准的适用标准和指导文件

If there is lack of clinical data or an insufficient number of observations, conformity with the requirement on acceptability of undesirable side-effects is not fulfilled.

如果缺少临床数据或观察数量不足，符合要求的不良的副作用可接受性并不满足。

Example:

A reasonable probability (80%) of observing at least one event of an undesirable side-effect when 15 subjects are studied requires a side-effect with an actual probability of 10%. If only 15 patients have been studied, from a statistical point of view, there could be serious side-effects with an actual probability of 10% that have not had a reasonable chance to be detected. The device would only be acceptable (for any type and severity of undesirable side-effects), if that magnitude is acceptable when weighted against the performance of the device and the current state of the art.

不良副作用事件的合理的观察概率(80%)，当15个受试者研究需要的副作用实际的概率为10%。如果只有15个病人被研究，从统计的角度来看，可能有严重副作用的实际概率为10%，有一个合理的机会没被发现。设备会是可接受的(任何类型和严重程度的不良副作用)如果权重大小是可以接受的，对当前科学水平的设备性能。

The table below shows corresponding numbers for undesirable side-effects with an actual probability of 10%, 5% and 1%.下表表明不良副作用的数量 和10%, 5% and 1%的实际概率

	Cas	Cas	Case 3
Chance of observing at least 1 event (P)1例	80%	80%	80%
Actual probability of event实际事故概率	10%	5%	1%
Number of subjects studied (n)受试者数量	15	32	161

The threshold proposed as acceptable for any new device will depend on the severity and detectability of side effects concerned.

新设备可接受的建议门槛阈取决于有关副作用的严重程度和检测能力。

A8. Devices for unmet medical needs - aspects to consider设备未满足的医疗需求-方面考虑

Like all medical devices, medical devices for unmet medical needs must fully comply with the Essential Requirements in order to be CE-marked. The evaluators should assess whether devices deliver clinical benefits to patients for

如同所有医疗设备，不满足医疗需求的设备必须完全符合CE-marked的基本要求，评价者应评价交付给病人的设备的临床利益。

- medical conditions that are life threatening, or cause permanent impairment of a body function, and医疗条件：威胁生命、导致机体功能永久伤害
- for which current medical alternatives are insufficient or carry significant risks.

当前的医疗选择不足或重大风险。

Corresponding devices are referred to as "breakthrough products" in this Appendix. a. Breakthrough products in exceptional cases, major benefits may justify relatively high levels of uncertainty, and access to the market may be granted on the basis of limited clinical evidence such as

在本附录中相应的设备被称为“突破产品”。 在特殊情况下突破产品，主要的好处可能证明相对不确定的高水平，通过市场只能获得有限的临床证据，如：

- experience available from compassionate use/ humanitarian exemption programs, use of custom-made devices, results of feasibility studies;

经验可能来自同情使用/人道主义豁免项目、使用定制的设备、可行性研究的结果

- limited long-term data. 长期数据有限

In addition to general aspects described in this MEDDEV document, the evaluators should fully disclose the situation and address the following items in the clinical evaluation report:

除了这个MEDDEV文档中描述的一般性质，评估者应充分披露现状和解决临床评估报告下列事项:

- the exact intended purpose, including the medical indication (if applicable to the device), the product was developed for and whether residual risks and uncertainties or unanswered questions are considered acceptable in this indication (often a niche indication);

确切的预期目的，包括医疗特征(如适用)，产品开发、剩余风险和不确定性或悬而未决的问题是否是可接受的(通常是合适指示)

- explanations of why current medical alternatives are considered to be insufficient or to carry significant risks; 解释为什么目前的医疗选择被认为是不足或重大风险
- explanations of the benefits delivered by the device under evaluation;

说明评价设备的利益传递

- whether the IFU clearly describe 说明书明确描述

- the exact intended purpose (including medical indications) and any limitations,

实际的预期目的（包括医学特征）和任何局限

- the limited clinical experience, 临床经验的极限
- uncertainties or unanswered questions about residual risks and benefits to patients[19];

对患者残余风险和利益不确定性或悬而未决的问题

• the need to set up a stringent PMCF plan with information on 需要建立严格的PMCF计划

- the type and quality of data that needs to be generated in the post-market phase in order to further evaluate the clinical performance and clinical safety of the device;

数据类型和质量需要在上市后阶段生成，以便进一步评估设备的临床性能和临床安全

- how to generate data in a timely manner and aspects thereof, including projections on the numbers of patients that will be managed with the device per year;

如何生成实时的数据和方面，包括预测每年设备管理的病人的数量

- in the following cases, the manufacturer should aim at including all patients in PMCF studies: 在下列情况下，PMCF研究中制造商应该集中目的于所有病人
- a device that carries significant risks (i.e. expected to cause serious adverse events), or设备有重大风险
- a device for rare diseases.设备用于稀有疾病

• the need to actively update the clinical evaluation report when new significant information become available, and in accordance with Section 6.2.3 b of the present document.

新的重要信息可用时需要积极更新临床评估报告，按照6.2.3 b部分的文档

In these exceptional cases, notified bodies should perform annual assessments of the updated clinical evaluation reports and the results of PMCF studies.

在这些特殊情况下, NB应该执行更新临床评估报告和PMCF研究结果的年度评估

b. Subsequent products 后面的产品

Devices that enter the market subsequent to a therapeutic/ diagnostic breakthrough can not be judged by the same criteria as listed above for breakthrough devices. When performing a clinical evaluation for these devices, the following considerations should be taken into account:

设备进入市场后续治疗/诊断突破不能按上面列出的突破设备标准评判。当为这些设备执行临床评估时，应考虑以下事项

• when a device enters the market subsequent to a therapeutic/diagnostic

breakthrough, clinical evidence is likely to have evolved rapidly since the first breakthrough device became available

当设备进入市场后续治疗/诊断突破时，临床证据很可能迅速发展，从第一个突破设备变成可获得

- with the evolving body of evidence, entering the market with large uncertainty may no longer be legitimate

随着证据的进化，带着大量不确定性进入市场可能不再是合法的

- if PMCF data are required, PMCF Studies should also be foreseen for devices that enter the market subsequent to a therapeutic/ therapeutic breakthrough

如果PMCF数据被要求，设备进入市场后续治疗/治疗突破后PMCF研究也应该预见

A9. Clinical evaluation report - proposed table of contents, examples of contents

临床评价报告-推荐目录、内容实例

Examples of contents that are shown in the table are for illustration. The contents of the clinical evaluation report will vary according to the nature and history of the device under evaluation.

内容的例在下表说明。临床评估报告的内容将根据不同设备的性质和历史评价。

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19 Example: “No serious long-term adverse effects have been reported to date”. This would be an inadequate description of limited experience and of uncertainties as to residual risks.

20 In exceptional cases where an instruction for use is not required, describe the generally recognised modalities of use

Table of contents	Example of contents
1.Summary 综述	Executive summary, summary for external purposes. 摘要、目的的综述 This section should summarise the determination of the benefit/risk profile in the intended target groups and medical indications, and the demonstration of acceptability of that profile based on the state of the art in the medical fields concerned. 这部分应综述在预期目标组的风险/收益的决定、医疗适应症和描述基于相关医疗领域科学水平的可接受的示范。
2.Scope of the clinical evaluation 临床评价范围	See Section 7 and Appendix A3. 见第7部分和附录A3 Identification of devices covered by this clinical evaluation report, products, models, sizes, software versions, accessories, their proprietary names, code names assigned during device development. Name and address of the manufacturer.识别临床评价报告覆盖设备的产品、型号、软件版本、配件、商品名、研发期间的代号。制造商名称和地址。 Whether this clinical evaluation is submitted to the AIMDD as amended by directive 2007/47/EC, or to the MDD as amended by directive 2007/47/EC.临床评价按AIMDD 2007/47/EC修订指令或MDD2007/47/EC修订指令提交 Concise physical and chemical description, including materials. Whether the device incorporated medicinal substances (already on the market or new), tissues, or blood products. Mechanical and physicochemical characteristics; others (such as sterile vs. non-sterile, radioactivity etc.); picture or drawing of the device.简明的物理和化学描述，包括材料。无论是含药器械（已上市或新的），组织或血液制品。机械和物理参数、其他的（如无菌或非无菌，放射性等）；设备图片或图纸 Technologies used, whether the device is based on a new technology, a new clinical application of an existing technology, or the result of incremental change of an existing technology. Description of innovative aspects of modified, identification of new products, models, sizes, software, accessories, new intended purposes, new claims, new events related to the device with an

	impact on clinical evaluation. Identification of the sections of the clinical evaluation report that are concerned with the new information and have been modified. 使用的技术，无论设备是新技术，先有技术的临床新应用，还是先有技术的增加变化的结果。描述修改的创新方面、识别新产品、型号、尺寸、软件、附件、新的预期用途、新的要求、对临床评价有影响的新事件。临床评价报告识别章节涉及新的信息和已修改的信息。 Other aspects. 其他方面
3.Clinical ackground, current knowledge, state of the art 临床背景、目前知识和科学水平	See Sections 8-10 and Appendices A4-A5. 参见章节8-10，和附录A4-A5。 Identification of medical fields concerned/ relevant medical conditions.相关医学领域/医学环境的识别 Brief summary and justification of the literature search strategy applied for retrieval of information on current knowledge/ the state of the art, including sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent. Appraisal criteria used. 对当前知识/科学水平的信息检索的简要总结和文献检索策略的理由，包括使用来源、搜索问题、搜索项目、应用于搜索输出的选择标准，质量控制措施、结果、数量和发现是相关的检索类型。使用的评估标准。 Applicable standards and guidance documents. 应用标准和指南文件。 Description, natural course and consequences of the medical conditions concerned. Whether there are different clinical forms, stages and severities of the conditions. Frequency in the general population, by age group, gender, ethnicity, familiar predispositions, genetic aspects.描述、自然进程和有关医疗条件结果。不同的临床方式，阶段和条件严重性。总人群频率、年龄、性别、种族、熟悉的倾向、遗传方面等。 Description of available therapeutic/ management/ diagnostic options, historical context and developments, summary of

	advantages and disadvantages of the different options, benefit/ risk profiles and limitations in relation to the different clinical forms, stages, and severities of the medical conditions and in relation to different target populations. Description of the benefits and risks (nature, extent, probability, duration, frequency), acceptability of undesirable side-effects and other risks (including the nature, severity, probability and duration of acceptable harm). 可能的治疗学/管理/治疗选择，历史背景和发展的描述，总结不同选择的优点和缺点、收益/风险和不同治疗方式、阶段和医学条件严重性的限制，不同的目标人群。描述不同的收益和风险（性质、范围、可能性、持续时间和频率），不良副作用的和其他风险的可接受性（班阔性质、严重性、可能性和可接受伤害的持续时间） Hazards due to substances and technologies that could be relevant to the device under evaluation. The mechanisms of harm, clinical aspects of minimisation and management of side effects and other risks. 评估相关的设备引起的物质和技术危害，危害的机制、临床方面的副作用和其他风险的最小化和管理。 Types of users. Diverging opinions of professionals as to the use of the different medical options. Unmet medical needs. 用户类型。专业人士的分歧意见，使用不同的医疗选择。未满足的医疗需求。
4 Device under evaluation评价设备 4.1 Type of evaluation 评价类型	Whether the clinical evaluation is based on 临床评价是否基于 - scientific literature currently available, and/or 目前可获得的科学文献 - clinical investigations made or已进行的临床调查 - whether demonstration of conformity with essential requirements based on clinical data is not deemed appropriate.证实基本要求的符合性是否基于不合适的临床数据 If clinical data is not deemed appropriate, include considerations according to Section 10.3. See Appendix A1. 如果临床数据不是合适的，根据 10.3 章节考虑，参见附录 A1

4.2. Demonstration of equivalence (only when equivalence is claimed) 等效性证实（仅当等效性被声明的时候）	Identification of the equivalent device and its manufacturer. Exact name, models, sizes, software versions, accessories, etc. Name of the manufacturer. Relationship to the device under evaluation (predecessor/ successor, others). Regulatory status. If the device is not CE-marked, justification for the use of the data. 制造商设备和等效设备的识别。要求名称、型号、尺寸、软件版本、附件等。制造商名称。评价设备的关系（前代/继承者，其他）。食品法规管理。如果设备没有CE-标志，给出使用数据的理由。 Comparison of clinical, biological and technical characteristics (see Appendix A1 for details). Justification of equivalence, description of relevant clinical, biological and technical characteristics that affect clinical properties of the device, differences between the intended purpose of the device under evaluation and the equivalent device (indications, contraindications, precautions, target patient groups, target users, mode of application, duration of use/ number of re-applications, others), type of device-body interaction. Choice, justification and validity of parameters and models for non-clinical determination of characteristics. 临床、生物和技术参数的对比（参见附录A1）。影响设备临床性能的等效理由、相关临床、生物和技术参数的描述，评价设备和等效设备的预期使用目的的差异（适应症、禁忌症、预防措施、目标人群、目标使用者、应用模式、使用时间/重复应用次数，其它），设备和人体相互作用的类型。不进行临床的参数和型号的选择、理由和有效性。 Identification of pre-clinical studies carried out and literature used concise summaries of studies and literature (methods, results, conclusions of the authors), evaluation of the methodological quality of the study or document, the scientific validity of the information. 已进行的临床前研究的识别、文献研究的简明总结和文献（方法、结果、作者结论），研究或文件方法质量的评估，信息的科学有效性。 Comparative tabulations for the device under evaluation versus the equivalent device showing parameters relevant to the evaluation of the three characteristics. Comparative drawings or pictures of the device and the equivalent device showing the elements in contact with the body.

	评级按设备和等效设备的对比表格，表明三个评价参数的相关性。对比评价设备和等效设备的图纸或照片，表明与人体接触的原理。 Identification of differences, evaluation if differences are expected or not to influence the clinical performance and clinical safety of the device, reasons for assumptions made. 差异的识别、评价如果差异是预期的或不影响设备临床性能和临床安全，得出假设的原因。 Conclusions concerning equivalence. Whether the comparison carried out covers all products/ models/ sizes/ settings/ accessories and the entire intended purpose of the device under evaluation, or only certain products/ models/ sizes/ settings/ accessories, or selected aspects of the intended purpose, which ones. 与等效有关的结论。执行的对比是否覆盖评价设备所有的产品、型号、设置、附件和全部预期用途，或者仅是某种产品、型号、设置、附件和有选择方面的预期用途。 Conclusions whether equivalence is demonstrated or not; if it is demonstrated, confirmation that the differences are not expected to affect the clinical performance and clinical safety of the device under evaluation; description of any limitations and gaps 等效结论是否被证实，如果被证实，确认差异不期望影响临床性能和临床安全，描述任何限制或偏差。
4.3 Clinical data generated and held by the manufacturer 制造商产生和持有的临床数据	See Section 8.1.Identification of clinical data generated and held by the manufacturer. 参见章节8.1 制造商产生和持有临床数据的识别

4.4. Clinical data from Literature 来自文献的临床数据	See Section 8.2 and Appendices A4-A5. Brief summary and justification of the literature search strategy applied for retrieval of clinical data, including objectives, sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent. 用于检索临床数据的临床检索策略的理由和简要总结，包括目标、使用资源、检索问题、检索关键词、用于检索输出的选择标准，质量控制措施、结果、数量和文献类型。
4.5. Summary and appraisal of clinical data 临床数据综述和评价	See Section 9 and Appendix A6 参见章节9和附录A6 - Feasibility Studies 可行性研究 - Pivotal clinical investigations 关键的临床调查 - PMCF Studies PMCF研究 - Other use data 其它使用数据 Summaries of clinical data generated and held by the manufacturer and of scientific literature found to be pertinent. 制造商产生和持有，以及科学文献的临床数据综述。 Including brief summary of the studies or references (methods, results, conclusion of the authors), evaluation of their methodological quality, scientific validity of contents, relevance to the clinical evaluation, weighting attributed to the data, contents used (performance data, safety data, both) reasons for rejecting a study or document, reasons for rejecting some of its contents. 包括研究和参考（方法、结果、作者结论）的简要综述，方法质量的评价、内容的科学有效性、临床评价的相关性、数据的权重分配、拒绝使用一个研究或文件（性能数据、安全数据、或两者）的原因，拒绝使用其中一些内容的原因。
4.6. Analysis of the clinical data 分析临床数据 4.6.1. Requirement on safety (MDD ER1 / AIMDD ER1) 安全要求(MDD ER1 / AIMDD ER1)	See Section 10 and Appendix A7.1. 参见章节10和附录A7.1 Summary of conformity assessment with requirement on safety (MDD ER1 / AIMDD ER1). 安全要求的合格评定总结 Analysis whether there are special design features that pose special safety concerns (e.g. presence of medicinal, human or animal components) that where identified in the device risk management documentation and that required evaluation from a clinical perspective, and whether these have been adequately addressed.

	分析具体的设计特征造成的具体安全点（如：含药、动物源成分），在设备的风险管理文件中识别和要求从临床观点来评价，并且风险是否被充分处理。 Whether the risks identified in the risk management documentation and literature have been adequately addressed. 风险管理文档和文献里识别出来的风险是否充分处理。 Whether all the hazards and other clinically relevant information (e.g. clinical precautions for reduction of risks, clinical management of risks) have been identified appropriately. 危害或其它临床相关的信息（降低风险的预防措施、风险的临床管理）是否被适当识别。 Whether the safety characteristics and intended purpose of the device requires training of the end-user or other precautions, if users foreseen are adequate, if training requirements and other precautions are described in the IFU. 评价设备的安全特征和预期目的是否需要终端用户的培训或其它预防措施，如果使用者预知是否是充分的，培训要求和预防措施是否在IFU中描述。 Whether there is full consistency between current knowledge/ the state of the art, the available clinical data, the information materials supplied by the manufacturer, and the risk management documentation for the device. 可用的临床数据、制造商提供的材料信息和设备的风险管理文件是否和目前的知识/科学水平完全一致。
4.6.2. Requirement on acceptable benefit/risk profile (MDD ER1 / AIMDD ER1) 可接受的风险/收益要求	See Section 10 and Appendix A7.2.参见章节10和附录A7.2 Summary of conformity assessment with requirement on acceptable benefit/risk profile (MDD ER1 / AIMDD ER1). 可接受的风险/收益要求合格评定综述 Summary of the total experience with the device, including estimated numbers and characteristics of patients exposed to the device in clinical investigations, PMCF, from other user experience, and in the market; duration of follow-up. Nature, extent/severity, probability/frequency, duration of benefits to the patients and of undesirable side-effects and other risks. For each aspect of the intended purpose, whether the benefit/risk profile including its uncertainties or unanswered questions is compatible with a high level of protection of health and safety, corresponding

	justifications. 设备所有经验的综述，包括临床调查中接触设备的患者估计数量和特性，PMCF、已上市的产品和其他使用者的经验、随访时间。性质、程度/严重性、可能性/频率、带给患者的持续利益、不良副作用和其它风险。预期目的的每个方面，风险/收益包括不确定的或未答复的问题是否兼容高水平的健康防护和安全，相应的理由。
4.6.3. Requirement on Performance (MDD ER3 / AIMDD ER2) 性能要求	See Section 10 and Appendix A7.3. 参见章节10和附录A7.3 Summary of conformity assessment with requirement on performance (MDD ER3 / AIMDD ER2). Description of clinical performance. For each intended performance, extent to which evaluation of benefits is possible based on available data, limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions. whether available data allows adequate evaluation of performance, limitations of the data, gaps, uncertainties or unanswered questions. Whether there is sufficient clinical evidence for every intended performance. 性能要求的合格评定综述。临床性能的描述。对每个预期性能、利益评价的程度可能基于可用的数据、数据的限制、偏差描述、未定或未知的问题和假设。可用的数据是否充分评价性能、数据限制、偏差、未知或未定的问题。每个预期性能是否都有科学临床证据。
4.6.4. Requirement on acceptability of side-effects (MDD ER6 / AIMDD ER5) 可接受的副作用要求	See Section 10 and Appendix A7.4.参见章节10和附录A7.4 Summary of conformity assessment with requirement on acceptability of undesirable side-effects (MDD ER6 / AIMDD ER5). Whether the data available is of sufficient amount and quality for the detection of undesirable side-effects and their frequency, limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions. Whether the undesirable side-effects are acceptable and corresponding justifications. 可接受的不良副作用要求的合格评定综述。可用的数据是否充分数量和质量来发现不良副作用、频率、数据限制、偏差描述、未定或未知的问题和假设。不良副作用是否是可接受的和相应理由。
5. Conclusions结论	See Section 11. 参见章节11 Clear statement concerning compliance to Essential requirements. 明确声明符合基本要求。

	Acceptability of the benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives. 根据目前的医疗领域知识/科学水平和可用的医疗选择，风险收益是可接受的。 Adequacy of the information materials supplied by the manufacturer, whether the intended purpose and risk reduction measures are adequate; discrepancies. 制造商提供的信息资料是充足的，预期目的和风险降低措施是否充足和有差异。 Suitability of the device, including its IFU, for the intended users and usability aspects; discrepancies. 设备的适合性，包括IFU，预期使用者和可用方面，差异。 Adequacy of claims foreseen by the manufacturer; discrepancies. If there is consistency between the clinical data, the information materials supplied by the manufacturer, the risk management documentation for the device under evaluation; discrepancies. 制造商声明的充分性，差异性。评价设备临床数据、制造商提供的信息资料、风险管理文档是否一致，或有差异。 Whether there is consistency between these documents and the current knowledge/ the state of the art; discrepancies. Description of residual risks and uncertainties or unanswered questions, whether these are acceptable for CE-marking, how these should be followed during PMS (uncertainties regarding medium- and long term performance, safety under wide-spread use, residual risks such as undesirable side-effects and complications occurring at rates below detection possibilities of currently available clinical data, others). Whether these are already being addressed in ongoing PMS activities, e.g. in currently ongoing PMCF studies. Whether new or additional PMS activities, including PMCF studies, should be foreseen. 文件是否和目前的知识/科学水平一致，或有差异。剩余风险、未知或未定问题的描述是否CE标志可接受的，在PMS期间如何随访（不确定的中-长期性能、大规模使用的安全、不良副作用的剩余风险、当前可

	用临床数据下低比率的并发症发生）。在不间断的PMS活动期间，这些为是否已经被处理，如在目前的PMCF研究中。是否有新的或额外的PMS活动，包括PMCF研究应被预知。
6. Date of the next clinical evaluation下次临床评价的日期	See Section 6.2.3. Suggested date, justification of the date. 建议日期和理由
7.Dates and signatures 日期和署名	See Section 11.参见章节11 Date of the clinical evaluation report.评价报告日期 Statement that the evaluators agree with the contents of the report. Dates, names and signatures of the evaluators.评价者同意报告内容的声明。日期、名称和评价者署名。 Final release by the manufacturer. Date, name and signature. 制造商最终放行，日期、名称和署名。
8. Qualification of the responsible evaluators评价者资格	See Section 6.4. 参见章节6.4
9. References参考	See Section 11. 参见章节11

A10. Proposed checklist for the release of the clinical evaluation report

放行临床评价报告的检查表

The following aspects should be checked for the release of a clinical evaluation report:

放行临床检查报告的检查项目

- Can the report be read and understood by a third party, does it provide sufficient detail for understanding the data that are available, all assumptions made and all conclusions reached?

报告被第三方阅读和理解，提供详细的可理解的数据，能得出所有的设想与结论。

- If clinical data have been generated and are held by the manufacturer, are all data mentioned and adequately summarised in the report?

如果临床数据被制造商产生和持有，报告是否提及所有数据和充分总结。

- If equivalence is claimed,如果声称等效

- is demonstration of equivalence included in the report? 证实报告里的等效性？

- does the report disclose all the differences between the device under evaluation and the equivalent device?报告已披露评价设备和等效设备间的所有差异？

- does it explain why the differences are not expected to affect the clinical performance and clinical safety of the device? 解释了为什么差异不会影响设备的临床表现和临床安全吗？

• If the product is already in the market in Europe or elsewhere, has the latest PMS/ PMCF data been taken into consideration and has it been summarised and referenced in the report? 如果提供已在欧盟或其他地方上市的产品，最新的PMS和PMCF数据被报告考虑、总结和参考吗？

• In respect to current knowledge/ the state of the art, 关于目前的知识和科学水平

- has the report been updated? 报告更新了吗？

-is current knowledge/ the state of the art summarised in the report and is it adequately substantiated by literature? 报告总结目前的知识/科学水平，且被文献充分证实吗？

- does the content of the report fully correspond to current knowledge/ the state of the art? 报告内容和目前的知识/科学水平相当吗？

- does the report explain why the benefit/risk profile and the undesirable side-effects are acceptable in relation to current knowledge/ the state of the art?

在当前知识/科学水平下，报告解释风险/利益和不良副作用是可接受的？

• If the report covers several models/ sizes/ settings and/or different clinical situations, is there sufficient clinical evidence and are the report's conclusions correct for

如果报告覆盖多个型号/尺寸、设置和/或不同临床条件，有充分的临床证据和报告结论包含：

- all the devices? 所有设备？

- all its sizes, models and settings? (including the smallest/ largest size, highest/ lowest dose, etc.) 所有尺寸、型号、设置吗？ 包括最大、最小尺寸，最高/最低剂量。

- every medical indication? (as described in the IFU/ not excluded with contraindications in the IFU) 每个医疗特征（说明书描述的/不包含在说明书里的禁忌症）

- the entire target population? (from pre term infants to old age, for males and females, etc., if not restricted in the IFU) 全部目标人群(婴儿到老年、男性和女性、不受IFU限制)

- every form, stage and severity of the medical condition, as applicable? (including the most severe/ most benign forms, acute/ chronic stage, if not excluded in the IFU) 医疗状况构成、阶段和严重性，可用吗？（包括最严峻/最良性方式、急性/慢性阶段、不受IFU限制）

- all intended users? (including lay persons, if not excluded in the IFU, and any

unusual user group) 所有预期使用者（含外行和一般使用组）

- the whole duration of product use, including the maximal number of repeated exposure? (as allowed by the IFU)产品使用的整个持续时间，包含最大重复暴露时间（说明书允许的）

- if there are any discrepancies as to the above, are they identified in the report's conclusions? 如果有差异，报告结论里是否识别？

• Is conformity to each of the relevant Essential Requirements (AIMDD ER1,2,5 / MDD ER1,3,6) clearly stated and are all discrepancies identified in the report's conclusions?

报告结论符合声明相关的基本要求和识别所有差异吗？

• Do the information materials supplied by the manufacturer correspond with the contents of the report and are all discrepancies identified in the report's conclusions?

制造商提供的信息材料符合报告内容和报告结论识别所有差异吗？

• Do the report's conclusions identify all residual risks and uncertainties or unanswered questions that should be addressed with PMS/ PMCF studies?

报告结论识别所有剩余风险，不确定的或未回答的问题在PMS/ PMCF研究中处理吗？

• Is the report dated? 报告有日期吗？

• Is the qualification of the evaluators included in the report and correct?

报告和纠正中包含评价者资格吗？

• Does the manufacturer hold a CV and declaration of interests of each of the evaluators and are these up-to-date?

制造商是否有评估者的CV（简历））和利益声明，是最新的吗?

A11. Information on declarations of interests 利益声明信息

Declarations of interests of the evaluators should be held by the manufacturer and cover relevant financial interests outside the current work as an evaluator.

制造商应有评价者的利益声明，覆盖当前评估工作之外的经济利益。

Declarations of interests should contain statements that clarify the extent of the declaration.

利益声明应该包含澄清声明的范围

For example: 如

- the time span included (e.g. grants, sources of revenue or benefits paid or promised to be paid over the 36 months prior to the evaluation)

时间跨度包括（(如在评估前36个月的津贴、收入来源或福利支付或承诺支付)）

- whether financial interests of family members are included or not (namely spouse or partner living in the same residence as the evaluator, children and adults for whom the evaluators is legally responsible)

是否包括家庭成员的经济利益(即与评估者生活在一起的配偶、儿童和成人，评估者应为他们承担法律责任)

Typical contents: 典型内容

- employment by the manufacturer 制造商的员工
- participation as an investigator in clinical studies of the device, or in pre-clinical testing of the device参与设备临床研究的研究者，或在临床前测试设备
- ownership/ shareholding possibly affected by the outcome of the evaluation

可能影响评价结果的所有权/股权

- grants sponsored by the manufacturer 被制造商赞助
- benefits such as travelling or hospitality (if beyond what is reasonably necessary for the work as an employee or external evaluator) 利益，比如旅游或宽带(如果超出作为一个员工或外部评估者合理必要的工作)
- interests in connection with the manufacturing of the device or its constituents

与生产设备或组成有关的利益

- interests in connection with intellectual property, such as patents, copyrights and royalties (whether pending, issued or licensed) possibly affected by the outcome of the evaluation

知识产权方面的利益，如可能影响评价结果的专利、版权和版权费(无论待定、公开或许可)

- other interests or sources of revenues possibly affected by the result of the evaluation

可能影响评价结果的其他利益或收入来源

The declaration of interests should be dated and signed by the evaluator and the manufacturer.

利益声明应被评估者和制造商签署和注明日期

A12. Activities of notified bodies 公告机构的活动

A12.1. Notified body assessment of clinical evaluation by conformity assessment route

NB 评估临床评估报告的合格评定路径

The notified body assessment of clinical Evaluation reports and the supporting data presented by manufacturers is required for all medical devices. The timing and frequency of the notified body reviews will vary according to the risk carried by the device, how well established the device is (see Section 6.2.3) and the conformity assessment procedure that is applied.

公告机构评估临床评估报告和制造商的支持数据是所有医疗设备要求的。公告机构评审的时机和频率根据设备风险会有所不同，如何更好确定设备和合格评定程序(参见6.2.3)

This includes for medical devices in accordance with Directive 93/42/EEC:

93/42/EEC指令的包括：

- An audit as part of a quality system approval procedure (Annex II, section 3):

作为质量体系审核程序的部分(Annex II, section 3)

- the notified body assesses the manufacturer's procedure for clinical evaluation, PMS plan and PMCF plan and (if applicable) results of PMCF.

NB机构评估制造商的临床评价程序、PMS和PMCF计划和PMCF结果

- as part of the representative sampling of devices[21]; for review of their technical documentation the notified body assesses the clinical evaluation report presented for class IIa[22] and IIb devices as presented below for a design dossier.

设备典型抽样的部分，公告机构检查评估临床评估报告为IIa类和IIb类设备的技术文档，设计档案介绍如下

- A design dossier (Annex II, section 4) or type examination dossier (Annex III) assessment:评估设计文档(Annex II, section 4)或型式检验文档(Annex III)

- the notified body assesses the data presented in the clinical evaluation report,

NB评估临床评价报告提供的数据

- assesses the validity of the conclusions drawn by the manufacturer, and

评估制造商得出结论的有效性，和

- the conformity of the device to relevant essential requirements.设备基本要求的一致性

For active implantable medical devices in accordance with Directive 90/385/EEC:

90/385/EEC指令器械包括：

• A design dossier (Annex 2, section 4) or type examination dossier (Annex 3) assessment:

评估设计文档(Annex II, section 4)或型式检验文档(Annex III)

- the notified body assesses the data presented in the clinical evaluation report,

NB评估临床评价报告提供的数据

- assesses the validity of the clinical evaluation report and the conclusions drawn by the manufacturer, and

评估制造商得出结论的有效性，和

- the conformity of the device to relevant essential requirements.

设备基本要求的一致性

The notified body should also have documented procedures to address the review of updates to clinical evaluation reports during their scheduled surveillance activities and at the time of changes to or extensions of EC design-examination/EC type-examination certificates. The review should take into account aspects described in Section 6.2.3. This arises from the obligation placed on the manufacturer to actively update the clinical evaluation with data obtained from PMS e.g. PMCF and ongoing literature reviews/surveys.

公告机构也应有文件程序来处理更新临床评价报告，在EC设计审核/ EC 型式检验认证的定期监测活动和更改或扩展时。评审应考虑6.2.3节中的描述。根据PMS积极更新临床评价是制造商的义务，例如PMCF和正在进行的文献评论/调查。

In addition, notified bodies should refer to guidance, checklists and other documents available on the assessment of clinical evaluations by notified bodies from the Notified Body Operations Group (NBOG). These should be considered in addition to this guidance. Any such checklists are intended only as an aide memoire for assessment and should not replace the Clinical Evaluation Assessment Report (CEAR) outlined below.

另外，NB应该参考NBOG在临床评估的指南、检查表和其他文件。都应考虑，不仅是指南。任何检查表的目的仅作为评估的备忘录，不应该取代临床评估的评估报告(CEAR)。

A12.2. Examination of a design dossier (Annex II.4; Annex 2.4) or of a type examination dossier (Annex III; Annex 3)设计文档 (Annex II.4; Annex 2.4)或型式检验文档检查

The notified body examines the clinical evaluation documentation submitted (relevant documentation referenced in previous sections of this MEDDEV), assesses the manufacturer's identification, appraisal and analysis of that data, and validates the conclusions drawn by the manufacturer. In order to do so, the notified body should possess enough knowledge and experience in clinical evaluation as stated in previous sections of this document.

公告机构检查提交临床评估文档(MEDDEV前面部分引用相关文档)，评估制造商的数据识别、评估和分析，并验证了制造商所得出的结论。公告机构应具备足够的临床评估知识和经验，如本文前面部分所述。

A12.2.1. Decision-making by the notified body NB的决策

In reviewing the evaluation of clinical data submitted by the manufacturer, the notified body verifies and concludes whether or not the manufacturer has adequately:

制造商提交的临床数据评估中，NB证实制造商的结论是否充分

- supplied clinical evaluation documentation (as referenced in previous sections);

提供的临床评估文档（参照前面章节）

- followed relevant procedures (as addressed by previous sections);

遵守相关程序（按前面章节处理）

- described and verified the intended characteristics and performances related to clinical aspects;

描述和证实临床方面相关的预期特征和性能

- performed an appropriate risk analysis and estimated the undesirable side-effects which are aligned with the clinical evaluation;

与临床评价保持一致的性能、适当的风险分析和预计的不良副作用

- involved appropriate clinical expertise in the clinical evaluation and in the compilation of the risk analysis to ensure risks and benefits associated with real clinical use are adequately defined;

涉及适当的临床评价和编写风险分析的专业知识，确保实际临床使用的风险和收益是充分定义的

- provided a solid justification as the basis for their estimations of benefits, risks, undesirable side-effects, indications and contraindications of the device in question;

提供可靠理由来讨论设备的利益、风险、不良的副作用、适应症和禁忌症评估

- justified the chosen route(s) of clinical data retrieval (according to previous sections);

调整临床数据评估的选择路线（根据前面章节）

- identified, appraised, analysed and assessed the clinical data (according to previous sections) and demonstrated the relevance and any limitations of the clinical data identified in demonstrating compliance with particular requirements of the Directive or cited in particular aspects of the risk analysis;

识别、评估、分析和评估临床数据(根据前面章节)，并证实临床数据的相关性和任何限制确定证实符合指令的特定要求或引用风险分析的特定方面;

- identified all clinical data, favourable and unfavourable, that is relevant to the device and using an appropriately robust, reproducible and systematic search strategy;

识别临床数据，相关设备有利和不利的，和使用适合的、可重复的和系统检索策略

- provided sufficient clinical evidence relating to the safety, including benefits to the patients, the clinical performance intended by the manufacturer (including any clinical claims for the device the manufacturer intends to use), design characteristics and intended purpose of the device, in order to demonstrate conformity with each of the relevant essential requirements;

提供足够的安全相关 的临床证据，包括病人权益、制造商预期的临床性能（包括制造商预期使用的任何设备临床要求），设计特性和设备的预期目的，以便证实每个基本要求的符合性

- conducted and provided a critical evaluation of relevant scientific literature and data relating to the safety, benefits, performance, design characteristics and intended purpose of the device;管理和提供科学文献的关键评价和有关设备安全、效益、性能、设计特点和目的的数据

- demonstrated the equivalence of the device under evaluation to the device to which the data relates in all necessary areas, i.e. clinical, technical, biological and that the data available adequately addresses conformity to each of the relevant essential requirements (if a critical evaluation of relevant scientific literature is provided as the only source of clinical data);

证明评价设备和等效设备的所有相关区域，如临床、技术、生物和可用的充分处理符合基本要求的数据(如果相关科学文献的关键评估是提供临床数据的唯一来源)

- designed appropriate clinical investigations, when necessary, to address specific questions arising from the critical review of the scientific literature and address each of the relevant essential requirements;

必要时，设计适当的临床调查，处理科学文献评论引起的具体问题和相关的基本要求

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21 In accordance with NBOG BPG 2009-4 符合NBOG BPG 2009-4

22 Alternatively Annex VII coupled with Annex IV, V or VI could apply rather than Annex II.3

- provided specific justification if a specific clinical investigation was not performed for class III or implantable devices;

对III类和植入设备提供不进行临床调查的具体理由

- provided evidence that clinical investigations presented are in compliance with applicable regulatory and ethical requirements e.g. scientific validity, ethics committee approval, competent authority approval;

提供证据证明临床调查符合适用的法律法规和道德的要求，比如，科学的有效性，伦理委员会批准和主管当局批准

- provided detail of the PMS plan in place for the particular device and justified the appropriateness and adequacy of this plan;

在适当的位置提供特定设备的PMS计划的细节，证明该计划的适当性和充分性

- clearly identified which areas in the clinical evaluation and related data need to be further addressed and confirmed in the post-market phase, with specific alignment to the PMCF;

对上市后需要进一步处理和确认的临床评价和相关数据，进行明确定义，并与PMCF一致

- justified the appropriateness of the planned PMCF;

证明计划性PMCF的适当性

- justified and documented if PMCF is not planned as part of the PMS plan for the device;

如果PMCF未被列为设备的PMS计划的一部分，应予以证明和记录

- identified the sources of clinical data which will be gathered from the manufacturer's PMS system and PMCF;

对通过制造商的PMS系统和PMCF收集到的临床资料的来源进行鉴定

- concluded that the contents of the IFU are supported by clinical evidence (description of the intended purpose, handling instructions, type and frequency of risks, warnings, precautions, contraindications, others) and are in line with the risk analysis and clinical evaluation;

总结IFU中有临床证据支持的内容（临床证据指的是对预期目的，使用说明，类型和风险频率，警告，注意事项，禁忌症等内容的描述），以及与风险分析和临床评价一致的内容

- concluded on the basis of documented evidence:

在有文件记录的证据的基础上进行总结:

a. that the risks are acceptable when weighed against the intended benefits and are

compatible with a high level of protection of health and safety,

a. 在权衡预期效益时风险是可以接受的，而且风险与高水平的健康和安全的保护兼容

b. that the intended clinical performances described by the manufacturer are achieved by the device, and

b. 设备的实际临床效果与制造商描述的预期临床效果一致

c. that any undesirable side-effect constitutes an acceptable risk when weighed against the performances intended.

c. 权衡预期效果时，所有的不良副作用构成的风险是可接受的

The assessment carried out by the notified body will in addition typically confirm the following aspects of the manufacturer's clinical evaluation:

公告机构对制造商的临床评价开展评估时，通常会评估以下几个方面：

- appraisal to determine suitability and any limitations of the data presented to address the essential requirements in particular relating to the safety, and performance of the device as outlined in previous sections;

评估满足基本需求，尤其是安全需求的数据的适用范围和限制，评估设备效果，这一点已在前文概述。

- the validity of any justification given;

评估所有有利观点的有效性

- characterisation and evidence-based proof of the clinical performance of the device intended by the manufacturer and the expected benefits for the defined patient group(s);

评估制造商提供的设备的临床效果的特性描述和循证证据，评估特定病人群体的期望利益

- the application of all relevant harmonised standards or appropriate justifications if not;

所有有关的统一标准或适当理由的应用

- identified hazards to be addressed through analysis of clinical data as described in Section 10;

通过分析第10章所描述的临床数据，识别需要解决的危险

- the adequate estimation of the associated risks for each identified hazard by:

充分估计每一个特定危险的风险，通过：

- characterising the severity of the hazard;

描述危险的严重程度

- estimating and characterising the probability of occurrence of harm, impairment of health or loss of benefit of the treatment (documented and discussed based on scientifically valid clinical data);

估计和描述伤害的发生概率，健康损伤或治疗的利益损失（在科学有效的临床资料的基础上进行记录和讨论）

- the adequate description and estimation of the current state of the art in the corresponding medical field;

充分地描述和评估对应的医疗领域中的技术现状

- a justifiable and reasoned basis for estimation of risks and hazards.

评估风险和危害以可证明和有道理为基础

Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product, the notified body is responsible for verifying the usefulness of the medicinal substance as part of the device prior to the submission of an application for scientific opinion from a medicines authority.

某种物质作为设备不可分割的一部分，如果单独使用时，该物质可能是一种药品。在提交申请以寻求药品权威机构的科学观点之前，公告机构负责验证该药用物质作为设备一部分的有用性

For drug-device combination products and products incorporating stable human blood derivatives, where a scientific opinion from a medicinal competent authority or from the European Medicines Agency (EMA) has been sought, the notified body should consider any comments or considerations raised in the medicinal clinical assessment when making its final decision on the device. In the case of devices with a human blood derivative the notified body may not deliver a positive decision to issue a certificate if the EMA's scientific opinion is unfavourable.

对于药物-设备组合产品和结合稳定的人体血液衍生物的产品，已经得到医药主管部门或欧洲药品管理局（EMA）的科学的观点的情况下，对设备做最终决定时，公告机构应当考虑医药临床评价中提出的所有意见或注意事项。在设备含有人体血液衍生物的情况下，如果EMA的科学观点是不利的，公告机构可能不会做出颁发证书的决定

A12.2.2. The report of the notified body

A12.2.2 公告机构的报告

The notified body should write a Clinical Evaluation Assessment Report (CEAR) based on its assessment of the submitted clinical evaluation report and supporting documentation.

公告机构应当对提交的临床评价报告和支撑材料进行评估，并出具临床评价评估报告

（CEAR）

If a design dossier report is applicable to the device, the CEAR may be incorporated into this report or referenced from it. The report should clearly identify the notified body's assessment, verification on each of the critical elements and overall conclusions.

如果该设备有设计档案报告，CEAR可能会合并到这个报告里或者引用这个报告。临床评价评估报告应当明确定义公告机构的评价，验证所有的关键元素和结论

The CEAR at a minimum should address the notified body's assessment of manufacturer's application relating to the following:

CEAR评估公告机构对制造商所提申请的评价时，至少从以下几个方面进行：

- device description and product specification

设备描述和产品规格

- intended purpose of the device

设备的预期目的

- classification proposed for the device

设备分类

- pre-clinical evaluation data presented by the manufacturer

制造商提供的临床前评价数据

- risk analysis and risk management and alignment with the clinical evaluation report

风险分析和风险管理，且与临床评价报告一致

- clinical evaluation process

临床评价过程

- clinical evaluation report authors

临床评价报告的作者

- equivalence assessment – if data from equivalent is used

使用等效数据时进行等效性评价

- clinical investigation plans and reports

临床调查计划和报告

- justification if no clinical investigation has been performed

没有进行临床调查的理由

- instructions for use, labelling and, when necessary, the training plan for users

用户使用说明书，商标，必要的用户培训计划

- justification if no PMCF is planned

不进行PMCF的理由

- PMS

上市后监督

- PMCF

上市后随访

- planned frequency/ criteria for updates to the clinical evaluation

临床评价更新的频率/准则

- summary of review

评论的摘要

- conclusion on clinical benefit/risk profile

临床收益/风险的总结

- conformance of the device to the relevant Essential Requirements

设备符合相关的基本法规

The CEAR should also provide details relating to the submission and notified body review (including staff and experts involved in the review and the aspects assessed by each, signatures of responsible reviewers, etc.)

CEAR也应该提供提交物和公告机构评估的细节（包括参与评估的工作人员和专家，每个人负责评估的方面，负责人签名等）

The notified body should justify and document each step of the decision making process referred in section A12.2.1 above.

公告机构应当证明并记录决策过程的每个步骤，参考A12.2.1章节。

The CEAR at a minimum should include a summary of the information provided by the manufacturer relating to the following:

CEAR至少应当包括制作商所提供信息的摘要，从以下几个方面：

- Record whether the clinical evaluation documentation is complete in accordance with this document and adequate to demonstrate conformance to the Essential Requirements of the relevant Directive.

记录临床评价文件是否完全与本文档一致，是否能够证明其符合相关指令的基本要求

- Record the notified body's verification of each step of the clinical evaluation process, from the planning of the clinical evaluation, choice of route(s), identification, appraisal, analysis and overall assessment of the clinical data, to concluding and reporting

记录公告机构对临床评价过程的每个步骤的确认，包括计划开展临床评价、选择途径、鉴定、评价、分析和临床数据的全面评估、总结和报告

- Record the notified body's assessment of the clinical investigation data and/or literature review assembled, relevant procedures and compliance to relevant standards

记录公告机构对临床调查数据和/或文献综述的评估、相关程序、符合相关标准

- Verify that the device has met the claimed performance/ intended purpose and benefits, and that undesirable side-effects and risks have been properly evaluated

验证设备达到了其所声称的效果/预期目的和收益，对不良副作用和风险的评价是恰当的

- Record the notified body's assessment of the clinical safety, clinical performance and benefit/risk profile

记录公告机构对临床安全性、临床性能和收益/风险的评估

- Record the notified body's assessment of the overall conclusions drawn by the manufacturer from the clinical data presented

记录公告机构对制造商根据临床数据得出的全部结论的评估

- Record the notified body's assessment of the validity of the clinical evaluation and its steps

记录公告机构对临床评价有效性和步骤的评估

- Record the notified body's conclusions on the clinical evaluation, documenting each step in the decision making process as per Section A12.2.1.

记录公告机构对临床评价的评估结论，将决策过程的各个步骤编写成文件中的章节，比如A12.2.1

A12.2.3. Clinical data from an equivalent device and other products

A12.2.3 等效设备和其他产品的临床数据

a. Equivalent devices

a. 等效设备

The notified body should clearly document its assessment of clinical data presented from an equivalent device as part of a clinical evaluation. This should critically review and conclude on the equivalence or not of the device under assessment to the devices presented as equivalent in terms of their technical, biological and clinical characteristics.

The relevance of each dataset from an equivalent device should be clearly evident and assessed by the notified body.

公告机构应当明确记录其对等效设备临床数据的评估，并将该评估作为临床评价的一部分。对设备的技术、生物学、临床方面的等效性应当进行严格的评价和总结。公告机构应当验证和评估等效设备的各个数据集之间的相关性。

The notified body should also assess and document the level of access to the technical and clinical data from an Equivalent device that the manufacturer has. Relevant information may be commercially sensitive/ confidential and not available to the manufacturer. The notified body should challenge the ability of the manufacturer to access information that are relevant to the demonstration of equivalence. Demonstration of equivalence might be difficult or impossible in case of limited access to the technical documentation of the devices.

公告机构应当评估和记录制造商通过等效设备获取技术数据和临床数据的水平。相关信息可能是商业敏感的或机密的，制造商无法提供。公告机构应当挑战制造商获取等效性证明相关信息的能力。设备的技术文档受限时，证明等效性是很难的或者是不可能的。

b. Other products

b. 其他产品

For hazard identification and when assessing the benefit/risk profile of the device, the notified body should consider current knowledge/ the state of the art.

对于危险识别以及评估设备的收益/风险，公告机构应当考虑现有知识/科学水平

The notified body should assess the appropriateness of the use of data from benchmark devices, other devices, and medical alternatives.

公告机构应当通过基准设备、其他设备和医学替代品评价数据使用的合理性

A12.3. Evaluation as part of quality system related procedures[23]

A12.3 评价是质量体系相关程序的一部分[23]

A12.3.1. Review of the manufacturer's procedures

A12.3.1 审查制造商的程序

The notified body shall, as part of the review of the manufacturer's quality system, assess the establishment, maintenance and application of the manufacturer's documented procedures for the evaluation of clinical data. This should cover:

作为制造商质量体系审查的一部分，公告机构应对制造商的临床评价数据的文件程序的建立、维护以及应用进行评估。包括：

a. the proper assignment of responsibilities to suitably qualified persons involved in the clinical evaluation (e.g. clinical evaluator(s), information retrieval expert(s), expert(s) in clinical research);

a. 临床评价过程中，对有资格的人员进行合理的职责划分（比如，临床评价者、信息检索专家、临床研究专家）

b. the integration of clinical evaluation into the quality system as a continuous process, to be specifically inter-related to, and informed by, pre clinical evaluation and risk management;

b. 将临床评价整合到质量体系中是一个持续的过程，临床前评价和风险管理密切相关

c. standard operating procedures to assure proper planning, conduct, evaluation, control and documentation planning of the clinical evaluation, identification of clinical data (previous section), literature searching (previous section), collection of clinical experience (previous section), clinical investigation (previous section and EN ISO 14155), appraisal of clinical data (previous section), analysis of clinical data (previous section), concluding, reporting (previous section) and update of clinical evaluation, procedures, reporting and updating based on data from the PMS system and from PMCF (MEDDEV 2.12/2 rev.2);

c. 标准操作程序，以确保适当的规划，实施，评估，临床评价的管理和文档规划，识别临床数据(前面章节)，文献搜索(前面章节)，收集临床经验(前面章节)，临床调查(前面章节和EN ISO 14155)，评价临床数据(前面章节)，分析临床数据（前面章节)，总结，报告(前面章节)以及基于PMS系统和PMCF(MEDDEV 2.12 / 2 rev.2)的数据更新临床评价、程序和报告

d. document control as part of overall documentation of procedures, reporting, qualifications and technical documentation/design dossier(s);

d. 文档控制作为全部文档（程序、报告、资格证书和技术文件/设计文档）的一部分

e. identification and evaluation of undesirable side-effects and of clinical performance(s).

This involves identification of known or reasonably foreseeable hazards and verification of unfavourable and favourable outcome(s), qualification of their severity/magnitude and of their probability of occurrence. (It is part of the manufacturer's documented risk analysis based on both favourable and unfavourable data identified as relevant in order to give a balanced view).

e. 鉴定和评价不良副作用和临床效果。这包括识别已知的或可预见的危险，验证不利和有利的结果，证明不利结果的严重性/量级和发生概率（这是制造商的风险分析文件的一部分，该分析基于有利和不利数据，之所以纳入不利数据，是为了给出平衡的观点）。

A12.3.2. Review of the technical documentation of representative samples

A12.3.2 审查代表性样品的技术文档

The notified body is required to assess the technical documentation for class IIa and class IIb devices on a representative basis. The clinical evaluation report should be assessed by the notified body for at least one representative sample for each device subcategory for class IIa devices and at least one representative sample for each generic device group for class IIb devices. Further representative samples have to be assessed as part of the annual surveillance assessment cycle.

要求公告机构在一个有代表性样品的基础上，评估IIa类和IIb类设备的技术文档。公告机构对临床评价报告进行评估，IIa类设备的每一个设备亚类至少评估一个有代表性的样品，IIb类设备的每一个通用设备组至少评估一个有代表性的样品。作为年度监测评估周期的一部分，代表性样本必须被评估。

Regarding the choice of representative sample(s) the notified body will consider the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose, and the results of previous relevant assessments. Assessment of representative samples includes assessment of the clinical evaluation report and available clinical data in accordance with the review procedure in this document rather than solely confirming that the manufacturer has a clinical evaluation procedure in place or that the clinical evaluation report is available.

选择代表性样品时，公告机构应考虑技术的新颖性，设计的相似性，技术、制造和消毒方法，预期使用目的，先前相关评估的结果。评估代表性样品包括对临床评价报告和临床数据的评估，应当与本文档中规定的评价过程一致，而不仅仅是确认制造商有临床评价过程或临床评价报告可用。

The criteria for the technical documentation assessment on a representative basis outlined in NBOG BPG 2009-4 should be applied

使用NBOG BPG 2009h-4概述的对有代表性的样品进行技术文档评估的标准

When performing the assessment on samples of a manufacturer's clinical evaluation, the notified body will follow the steps indicated in previous sections of this document.

公告机构将按照前文提到的步骤，对制造商临床评价样品进行评估

A clinical evaluation assessment report should be completed and available for each device sampled and assessed.

临床评价评估报告应当是完整的，并适用于每个设备的采样和评估

A12.4. Notified body specific procedures and expertise

A12.4 公告机构的具体规程和专业知识

A notified body should have formal procedures in place controlled by their quality system relating to the assessment of clinical evaluation reports and associated data provided by medical device manufacturers. These procedures should also cover the review of updates to the clinical evaluation report during their scheduled surveillance activities and at the time of changes to or extensions of EC design-examination/EC type-examination certificates.

公告机构应当有受质量体系约束的正规程序，这些程序是关于临床评价报告评估和医药设备制造商提供的相关数据的。这些程序也应该包括定期监测活动期间以及对EC设计/EC类型证书进行更改或扩展时，对更新临床评价报告的审查

Notified bodies should establish and implement internal policies and procedures for the assessment of clinical evaluation reports and associated data in order to:

对于临床评价报告和相关数据的评估，公告机构应当建立和实施内部的政策和程序，目的是：

a. Ensure that suitable resources, especially clinical competence necessary for such assessment, are available within24 the notified body to conduct and manage assessments of clinical evaluations for the notified body, normally a qualified medical doctor.

a. 确保有合适的资源，特别是这类评估所需的临床工作能力，公告机构引导和管理对临床评价进行评估，通常是一名有资格的医生

Such expertise should be sufficient to conduct a complete review of the clinical data and clinical evaluation presented for a particular device, to identify and estimate the risks and benefits associated with the use of the medical devices and to identify what, if any, specific clinical expertise is required for the full assessment of the device.

这类专家应当能胜任对特定设备的临床数据和临床评价进行完整的审查，识别和评估与医疗设备使用相关的风险和收益，如果有的话，可以明确对设备进行全面评估所需的具体的临床专业知识

The assessment team should be able to assess a risk analysis, the risk management

strategy performed by the manufacturer, and the scientific validity of clinical investigations and publications.

评估小组应当能够评估风险分析，制造商的风险管理策略，临床调查和出版物的科学有效性

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23 According to Article 11 MDD (Annex II.3 MDD, or Annex III MDD coupled with Annex IV, V or VI), and Article 9 AIMDD.

The assessment team should have sufficient expertise in the device technology as the associated medical procedures.

评估小组应当具备该设备所涉及的技术领域充足的专业知识和相关的医疗程序

Such an assessment requires input from a qualified medical practitioner (for example physician, dentist, nurse, etc.), as appropriate for the particular device, who has clinical experience in using the device or similar devices, the pathology of the condition being treated, the usual treatment, other medical alternatives, etc.

对特定设备的评估，应酌情引入一位合格的医生（比如，内科医生，牙科医生，护士等），医生应具备使用该设备或类似设备的临床经验，接受治疗的病理条件，常规治疗，其他医疗方案等

The notified body clinical assessor may work with external clinical experts. The notified body clinical assessor should ensure that any experts are appropriately aware of the relevant legislation, guidance and standards and to identify specific aspects of the clinical data evaluation for their specific review.

公告机构临床评估员可能与外部的临床专家一起工作。公告机构临床评估员应确保所有专家均能准确地理解相关的立法、指导和标准，为特殊审查确定临床数据评价的特殊方面

Notified bodies should have robust procedures around the recruitment, selection, training, conflict of interest and interaction with external clinical experts including clear procedures around how the expert opinion is documented and integrated with the notified body assessment and considered as part of the overall certificate decision.

公告机构应具有强有力的规程，围绕着招募，选择，训练，利益冲突以及与外部临床专家互动，包括明确的程序，围绕如何记录专家意见，如何综合专家意见与公告机构的评估，做出是否颁发证书决策时专家意见是如何被考虑的

When examining the results of clinical investigations, the assessment team shall have knowledge in planning, conduct and interpretation of clinical investigations. All assessors should be appropriately trained and qualified.

检验临床调查的结果时，评估小组应当具备规划、执行、解释临床调查的知识。所有评估者应经过适当的培训并合格

Particular attention should be drawn to training of external experts on the conformity assessment procedure(s), relevant guidance, standards and the context of the assessment they are providing. The notified body should be responsible for reviewing the opinion of these experts, taking account of their level of knowledge of the provisions of the Directives.

应重视对外部专家的训练，包括合格评定程序，相关规定，标准和他们需要提供的评估内

容。公告机构应负责审查这些专家的意见，考虑他们在规定指令中的知识水平

The opinion of an external clinical expert may form part of the assessment conducted by the notified body. The opinion and conclusions of the notified body, in part based on this external opinion, should be clearly documented.

外部临床专家的意见可能成为公告机构评估的一部分。公告机构的观点和结论，在一定程度上基于这个外部意见，应明确记录。

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24 Annex XI.3 of Directive 93/42/EEC. This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Directive and, in particular, those set out in Annex I.

The impartiality and the potential for conflict of interest of an external expert reviewer should be assessed and documented by the notified body.

公告机构应当对外部专家评估员的公正性和潜在的利益冲突予以评估和记录

b. Review the clinical evaluation report and clinical data provided by the manufacturer. The notified body should verify the validity of key statements made in the clinical evaluation report. The notified body should consider

b. 评估临床评价报告和制造商提供的临床数据。公告机构应当在临床评估报告中验证关键表述的有效性。公告机构应当考虑：

- statements based on published literature using the full text version of publications;

基于已发表文献的表述，使用出版物全文

- statements based on clinical data generated from PMS systems in particular PMCF and source verification of such data;

基于PMS系统生成的临床数据的表述，特别是PMCF和数据的验证来源

- statements regarding equivalence to other devices using the original full text version of pre-market study reports assessing parameters of interest.

与其他设备等效的陈述。使用上市前研究报告的原始的全文版本，评估感兴趣的参数。

- statements regarding results of own clinical investigations of the manufacturer using the original full text version of the clinical investigation plan and the clinical investigation report.

使用临床研究计划和临床研究报告最初的全文版本对制造商临床调查结果进行表述

The review of the notified body should consider the scientific validity of the clinical data set presented as part of the clinical evaluation and decide as to whether it provides evidence that the clinical benefit outweighs all associated risks.

公告机构的评审应考虑作为临床评价的组成部分的临床数据集的科学有效性，并决定是否提供了临床效益超过所有相关风险的证据

The data presented by the manufacturer should be scientifically robust and well presented, it should be complete and clear in its reasoning and should be of sufficient quality and validity to demonstrate the conclusions which are being drawn.

由制造商提供的数据应当是科学且充分的，应当有完整且清晰的逻辑，应当是优质和有效的，以证明当前结论

All clinical data relevant to the device in question, both favourable and unfavourable, should be considered, appraised and assessed by the manufacturer and likewise by the notified body. An absence of unfavourable data relating to a medical device should be carefully examined.

应考虑讨论中设备相关的所有临床数据，无论有利的还是不利的。评估由制造商和公告机构进行。应当仔细检查没有不利数据的医疗设备

Clinical evaluation reports which are based on incomplete, unclear or uncertain datasets should not be accepted.

不能接受基于不完整、不清楚或不确定数据集的临床评价报告

Clinical Evaluation reports which are based on incomplete clinical investigations or clinical investigations which were halted or terminated earlier than their intended duration should be carefully examined and a robust justification for halting or termination should be sought. The original endpoints, objectives and statistical basis for the manufacturer's clinical investigation are unlikely to remain valid in circumstances when an investigation is completed prior to its original planned duration and so it is unlikely that scientific conclusions can be drawn.

应该仔细检查基于不完整的临床调查或临床调查被停止或终止时间比预期的时间早的临床评价报告，并给出充分的理由对其暂停或终止。当调查完成时间比预计时间提前时，制造商进行临床调查的原始端点、目标和统计基础不太可能保持有效，所以不太可能得出科学结论

c. Document the opinion with rationale of all experts involved.

c. 记录所有专家观点的依据

d. Document the result of their assessment. This is achieved through a specific clinical evaluation assessment report which may be part of, or may be referenced, in the overall audit report, design / type examination report (as per A12.2.2 of this document) or the report on the assessment of representative samples' documentation.

d. 文档评估的结果。这是通过一个特定的临床评价评估报告得到的，在整个审计报告中，有可能成为设计/类型检查报告(按本文的A12.2.2) 或代表性样本的评估报告文档的一部分，有可能被其引用

e. Preserve confidentiality of the information and data received from the manufacturer, especially within the terms for contracting external experts.

保护制造商的信息和数据的机密，特别是外部专家的合同条款

f. Clearly identify how data from PMS conducted by manufacturers vigilance and market sur /eillance information from competent authorities PMCF data and data from

other relevant sources (e.g. clinical literature) is identified and reviewed by the notified body. This should clearly describe how when and what criteria are used by the notified body to judge when a re-assessment of the benefit risk profile of a paticular device is deemed necessary.

f. 清楚地记录公告机构如何识别和评审1：制造商通过PMS收集的数据；2：主管当局提供的市场敏感信息；3：PMCF数据和其他来源的数据（比如，临床文献）。判断什么时候重新评价某个特殊设备的收益风险预测是否必要时，公告机构应对如何使用、什么时候使用、使用了哪些标准进行清楚的描述。