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2020 年 第三季度

EXECUTIVE SUMMARY 摘要

Regulatory Updates 法规更新

REGULATORY CONTEXT & OBJECTIVES:

法规背景和目标

- Regulatory news and updates affecting the NB operations.
  影响NB运作的法规资讯和更新。

KEY MESSAGE

关键信息

- EUC published a fact sheet on MDR requirements for Transparency and Public Information, which includes what data will be publicly available from EUDAMED.
  欧盟委员会公布了一份关于MDR透明度和公共信息要求的情况说明，其中包括了欧盟医疗器械数据库将公开提供哪些数据。
- What is the state of play of the implementation of EUDAMED?
  欧盟医疗器械数据库的执行情况如何?
- Commission has confirmed its readiness to deploy the actor registration module of EUDAMED as of 1 December 2020, but will be on voluntarily basis until EUDAMED is fully functional.
- 委员会已确认准备从2020年12月1日起配置欧盟医疗器械数据库的模块，但在欧盟医疗器械数据库完全发挥作用之前，将以自愿的原则进行。
- Covid-19 Impacts on the NB operations.
  新型冠状病毒影响NB运作。
- IMDRF terminologies for categorized Adverse Event
  Reporting (AER): terms, terminology structure and codes are updated
  http://www.imdrf.org/documents/documents.asp.
  Note that it is mandatory both under regulation and directive from 20th of April 2021
  国际医疗器械监管机构论坛关于不良事件分类报告(AER):术语、术语结构和代码更新详见:
  http://www.imdrf.org/documents/documents.asp。请注意，从2021年4月20日起，这在法规和指令下都是强制性的。
- ISO 14155:2020 Clinical investigation of medical device for human subjects has been published and are available at SIS.
  ISO 14155:2020《医疗器械临床实验管理规范》已经出版，可在SIS查阅。
- ISO/TR 20416:2020 Medical device - Post market surveillance for manufacturers has been published and are available at SIS.
  ISO/TR 20416:2020《医疗器械制造商的上市后监督》已经出版，可在SIS查阅。
- (EU) 2020/437 on the harmonised standards for medical devices drafted in support of Council Directive 93/42/EEC.
  支持理事会93/42/EEC号指令而起草的关于医疗器械协调性标准（欧盟）2020/437。
- The first Client Newsletter has been published on our website.
  第一份客户简讯已经在我们的网站上发布。
- MHRA published a guidance on UK Medical regulation in context of Brexit:https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021. IMNB have published a statement on the global and local website, follow this link.
- MHRA发表了英国退欧背景下医疗法规指南：https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021. IMNB已在全球和当地网站上发表声明，请点击此链接。
- Commission Implementing Regulation (EU) 2020/1207 laying down rules for the application of Regulation (EU) 2017/745 as regards to common specifications for the reprocessing of single-use devices. For our assessment please follow the link.
  委员会为法规(EU) 2017/745中关于一次性设备再处理的通用规范应用制定了(EU) 2020/1207，有关我们的评估指导原则，请点击链接。
- Released MDCG's, Standards and Regulations affecting the NB operations.
  医疗器械协调小组发布了指导NB运作的标准和法规。
- Switzerland one step closer to recognize MDR.
  瑞士向MDR认可又迈进了一步。

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MDCG GUIDANCE DOCUMENTS

医疗器械协调小组指导文件

The Table below shows specific MDCG guidance documents that has an impact on your work and responsibilities. If you are interested in getting more detailed information of the specific guidance please click on √. For the complete list of all published MDCG's please follow this Link.

下表显示了对您的工作和职责有影响的具体医疗器械协调小组指导文件。如果您有兴趣了解详细的具体指导信息，请点击√。所有公布的MDCG的完整列表请点击这个链接。

Guideline 指导方针 / Department 部门	MDCG 2018-3 Rev.1 Guidance on UDI for systems and procedure packs MDCG 2018-3 Rev.1 UDI 系统和流程的指南	MDCG 2020-14 Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR) MDCG 2020-14 MDCG 2020-14 公告机构在根据医疗器械法规(MDR)/体外诊断医疗器械法规 (IVDR)在进行监督审核时使用MDSAP审核报告指南。	MDCG 2020-13 Clinical evaluation assessment report template MDCG 2020-13 MDCG 2020-13 临床评估报告模板	MDCG 2020-15 MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States MDCG 2020-15 医疗器械协调小组关于在成员国使用欧盟医疗器械数据库注册模块和单一注册号码(SRN)的意见书
Technical Planning 技术安排	√	√		√
TD 技术文档	√		√	√
Clinical 临床			√	
Audit 审核	√	√		√
Certification 认证		√		√
Management 管理		√		
QA/Regulatory/T&C 质量检查/监管/条款与条件		√		√

REGULATIONS & DECISIONS

法规和决定

The Table below shows regulation/EUC/Team NB relative information that impact your work and responsibilities. If you are interested in getting more detailed information on the regulations or the EUC, Team NB or others please click on √.

下表显示了影响法规/欧盟委员会/公告机构协会的相关信息。如果您有兴趣了解更多关于法规或欧盟委员会、公告机构团队等其他的详细信息，请点击√。

Area 区域 / Department 部门	Regulations 法规	EUC 欧盟委员会	Team NB 公告机构协会	Other 其他	Standards 标准
Technical Planning 技术安排		√	√	√	
TD Assessment 技术文档评估		√	√	√	√
Clinical 临床		√	√	√	√
Audit 审核		√	√	√	√
Certification 认证		√	√	√	
Management 管理		√	√	√	
QA/Regulatory/T&C 质量检查/法规/条款与条件		√	√	√	√

MDCG 2018-3 Rev.1 Guidance on UDI for systems and procedure packs. 系统与程序包的医疗器械唯一标识指南
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Affected Processes: TD Assessment and Audit 受影响的过程:技术文档评估和审核

Impact Assessment: 评估影响

The guidance is not intended to be exhaustive in relation to all UDI obligations associated with systems and procedure packs. The scope of this guidance is therefore limited to the aspects specifically addressed below. For UDI-related aspects that are not specifically mentioned in this guidance, the reader should make reference to the relevant provisions of Medical Device Regulation (EU) 2017/745 (MDR).

本指南并不打算详尽地说明与系统和程序包相关的所有医疗器械唯一标识要求。因此，本指南的范围仅限于以下具体涉及的方面。至于本指引未特别提及的医疗器械唯一标识有关的事宜，读者应参阅医疗器械法规(欧盟)2017/745 (MDR)》的有关条文。

Exemption with regard to "system or procedure pack producer"

对“系统或程序包生产者”的豁免”

Based on a request of a client or hospital, a natural or legal person in the supply chain may make available together different products, including CE marked devices, which are – in that entire combination – neither placed on the market by that natural or legal person, nor intended by that natural or legal person to be used together for a specific medical purpose. Devices made available in the described manner are not considered as systems or procedure packs in accordance with the relevant definitions provided in Article 2 of the MDR. In this case, that natural or legal person is not regarded to be a system or procedure pack producer in accordance with Article 22.1, and is considered to be a distributor as per Article 2(34) of the MDR. It is to be noted that an importer may also make available devices to a client or hospital, in such manner.

根据客户或医院的要求，供应链中的自然人或法人可以提供不同的产品，包括CE标志的器械，这些器械在整个组合中-既不是该自然人或法人投放市场，也不是该自然人或法人打算一起用于特定的医疗目的。 以上述方式提供的器械不被视为系统或程序包，符合医疗器械法规（MDR）第2条规定的相关定义。 在这种情况下，根据第22.1条，自然人或法人不被视为系统或程序包生产者，并根据医疗器械法规（MDR）第2条（34条款）被视为分销商。 应当指出的是，进口商也可以以这种方式向客户或医院提供器械。

Registration of systems and procedure packs

系统和程序包的注册.

The system or procedure pack producer shall apply for registration as a system or procedure pack producer and obtain an SRN. Systems and procedure packs shall undergo a UDI registration, as described in Article 29(2) of the MDR. Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), that is not a custom-made device, the system or procedure pack producer shall assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that system or procedure pack. The UDI data elements applicable for systems and procedure packs are listed in the Annex to this guidance.

系统或过程包生产者应申请注册为系统或过程包生产者，并获得单一注册号码，取得生产许可证。系统和程序包应进行医疗器械唯一标识注册，如MDR第29条第2款所述。在根据第22（1)和(3）条将非定制设备的系统或程序包投放市场之前，系统或程序包生产者应按照发行实体的规则，向系统或程序包分配一个基本的医疗器械唯一标识——数据输入，并将其连同附件六B部分提到的与该系统或程序包有关的其他核心数据元素一起提供给医疗器械唯一标识数据库。 适用于系统和程序包的医疗器械唯一标识数据元素列于本指南附件。

Specific UDI rules for systems and procedure packs 系统和过程包的特定的医疗器械唯一标识规则

The Basic UDI-DI shall identify systems or procedure packs having the same group of components and the same intended purpose, regardless of the original components manufacturers.

无论原始组件制造商如何，基本医疗器械唯一标识——数据输入应确定具有相同组件组和相同预期用途的系统或程序包。

System and procedure packs shall be assigned and bear their own UDI (including both UDI-DI and UDI-PI), in accordance with Annex VI, Part C, points 3.7 and 6.3.1. of the MDR

系统和程序包应按照医疗器械法规（MDR）的附件六，C部分，第3.7点和第6.3.1点进行分配，并具有自己的医疗器械唯一标识(包括UDI- di和UDI- pi)。

Conclusion: 结论

If a natural or legal person in the supply chain make available together different products, including CE marked devices, which are – in that entire combination – neither placed on the market by that natural or legal person, nor intended by that natural or legal person to be used together for a specific medical purpose, based on a request of a client or hospital, the natural or legal person shall be considered as a distributor. In other cases the system or procedure pack producers shall apply and obtain an SRN number and place Basic UDI, UDI-DI and UDI-PI in accordance with MDR 2017/745 and this guidance document.

如果一个自然或法人在供应链提供不同的产品,包括CE标识的器械,这是整个组合——无论是放在自然或法人的市场,也不打算由自然或法人一起用于特定的医学目的,基于请求的客户机或医院,自然或法人应当视为经销商。在其他情况下，系统或程序包生产商应申请并获得单一注册号码编号，并按照MDR 2017/745和本指导文件放置基本的UDI、UDI- di和UDI- pi。

MDCG 2020-15 MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States

MDCG 2020-15 医疗器械协调小组关于在成员国使用欧盟医疗器械数据库公司注册模块和单一注册号码(SRN)的意见书。

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Article 33 of Medical Devices Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (hereafter: 'MDR') sets out that the Commission, after consulting the MDCG, shall set up, maintain and manage the European database on medical devices (EUDAMED). EUDAMED shall be composed of multiple electronic systems (so called 'modules'), including an electronic system on registration of economic operators, also referred to as the actor registration module. In accordance with Article 30(1) MDR, the actor registration module shall allow for the creation of a unique single registration number ('SRN') referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer (including producers of system/procedure packs) and, where applicable, the authorised representative and the importer. As such, the actor registration module forms a prerequisite for the use of the other EUDAMED modules and facilitates a secure way of accessing EUDAMED. The responsibility to assign SRNs to economic operators lies with the Member States. To that end, Article 31(2) stipulates that, after having verified and validated the data entered by an economic operator, the competent authority of a Member State shall obtain an SRN from the actor registration module and approve the issuing of it to the requesting manufacturer, authorised representative or importer.

欧洲议会和理事会2017年4月5日(下称： "MDR")的医疗器械法规（欧盟）2017/745第33条规定，委员会在咨询医疗器械协调小组后，应建立、维护和管理欧洲医疗器械数据库(EUDAMED)。 EUDAMED应由多个电子系统（所谓的 "模块" ）组成，包括一个关于经济经营者登记的电子系统，也称为公司注册登记模块。 根据第30条第（1)款，公司注册模块应允许创建第31条第(2）款所指的唯一单一登记号("SRN")，并整理和处理必要和相称的信息，以确定制造商（包括系统/程序包的生产商），并酌情确定授权代表和进口商。因此，公司注册模块构成了使用其他欧盟医疗器械数据库模块的先决条件，并促进了访问**欧盟医疗器械数据库**的安全方式。 成员国有责任将战略成果文件分配给经济经营者。 为此，第31（2）条规定，在核实和验证了经济经营者输入的数据后，成员国主管当局应从公司注册登记模块获得一个单一注册号码，并批准将其发给请求的制造商、授权代表或进口商。

On 30 October 2019, the Commission published a notice by which it concluded that the full functionality of EUDAMED requires the availability and full operation of all six modules in accordance with the technical specifications and confirmed by an audit as referred to in Article 34. The notice foresees the launch of a fully functional EUDAMED for May 2022. However, at its meeting of 12 March 2020 the MDCG agreed that the Commission makes available to Member States each EUDAMED module on a gradual basis as soon as it is operational.

2019年10月30日，委员会发布了一份通知，在该通知中，委员会得出结论，欧盟医疗器械数据库的全面功能需要所有六个模块按照技术规格提供运行，并经第34条中提到的审核确认。该通知预计将于2022年5月推出一个功能齐全的欧盟医疗器

械数据库。然而，医疗器械协调小组在其2020年3月12日的会议上同意，一旦欧盟医疗器械数据库模块开始运作，委员会将逐步向成员国提供该模块。

In line with the MDCG decision referred to above, the Commission has confirmed its readiness to deploy the actor registration module as of 1 December 2020. The members of the MDCG strongly encourage the use of the actor registration module by all relevant actors on their territories, including the use of the single registration number by actors as stipulated in the MDR (e.g. indicating the SRN on certificates).
The members of the MDCG agree that double registration requirements for actors should be avoided as much as possible. Therefore, actors that obtain an SRN should be considered in compliance with the actor registration requirements (for manufacturers, authorised representatives, importers, system/procedure pack producers) to the extent that national laws accommodate for this. In such cases, those actors should follow the obligations and requirements of the MDR related to both the registration of relevant actors (via the actor registration module) and the use of their SRN as required.
根据上述医疗器械协调小组的决定，委员会已确认准备在2020年12月1日开始启用公司注册模块。本委员会成员强烈鼓励在其领土内的所有有关公司使用注册模块，包括公司使用MDR所规定的单一注册号码(例如在证书上注明身份识别码)。医疗器械协调小组成员同意，应尽量避免对行动者的双重登记要求。因此，获得单一注册号码的公司应被视为符合公司注册要求(对于制造商、授权代表、进口商、系统/程序包生产商)，在国家法律对此作出调整的范围内。在这种情况下，那些参与者应该遵守MDR的义务和要求，这些义务和要求与相关参与者的注册(通过参与者注册模块)和他们的单一注册号码的使用相关。

Conclusion:
The actor Modul will be made available the 1st of December 2020 on a voluntary basis. MPA decides not to enforce the use of the module which means that the is on voluntarily basis until EUDAMED is fully functional.
结论:
注册模块将于2020年12月1日在自愿的基础上提供。MPA决定不强制使用该模块，这意味着在欧盟医疗器械数据库完全发挥作用之前，该模块是自愿使用的。

MDCG 2020-13 Clinical evaluation assessment report template 临床评估评估报告模板
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A clinical evaluation assessment report (CEAR) is a report used by the notified body to clearly document the conclusions of its assessment of the clinical evidence presented by the manufacturer in the clinical evaluation report (CER) and the related clinical evaluation that was conducted – a core requirement of the Medical Device Regulation (EU) 2017/745 (MDR). The clinical evaluation must be a part of the manufacturer's quality management. It should also be aligned with and reflected in other aspects of the technical documentation, such as:
临床评估报告(CEAR)是被公告机构用于明确记录的报告 其对制造商在临床评估报告(CER)中提出的临床证据的评估结论和进行的相关临床评估-医疗器械法规（欧盟）2017/745(MDR)的核心要求)。 临床评估必须是制造商质量管理的一部分。它还应与技术文件的其他方面保持一致并反映在其中，例如:

- The interface of the clinical evaluation with the risk management process and its appraisal and analysis of the preclinical and clinical evaluation and their relevance for the demonstration of conformity with the relevant requirements in Annex I.
  临床评估与风险管理流程的接口，对临床前和临床评估的评估和分析，以及它们与证明符合附件一相关要求的相关性。
- Post-market surveillance including any corrective and preventive actions involving the device.
  产品上市后的监督，包括任何涉及该器械的纠正和预防措施。
- Post-market clinical follow-up plan and where appropriate the post-market clinical follow-up report.
  上市后临床后续跟踪计划，适当时提供上市后临床跟踪报告。
- Instructions for use, which provide adequate information on intended purpose, proper use and warnings about risks to patients and healthcare practitioners.
  使用说明，提供关于预期用途、正确使用的充分信息，以及对患者和医疗从业者的风险警告。

As part of its conformity assessment activities the notified body shall examine, validate and verify that manufacturers' procedures and documentation adequately address the requirements relating to the technical documentation and clearly document its assessment.
作为合格评定活动的一部分，公告机构应审查、验证和验证制造商的程序和文件充分满足与技术文件有关的要求，并清楚地记录其评价。

The notified body shall review the clinical evidence presented by the manufacturer in the clinical evaluation report and the related clinical evaluation that was conducted, which includes:
公告机构应审查制造商在临床评价报告中提供的临床证据以及已进行的相关临床评价，包括:

- Assessing the suitability of using data from claimed equivalent devices, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess to what extent specific claims are supported by specific pre-clinical and clinical data and risk analysis.
  评估使用声称等价设备数据的适用性，考虑到新适应症和创新等因素。公告机构应清楚地记录其关于声称的等价性、以及用于证明符合性的数据的相关性和充分性的结论。对于制造商声称具有创新性或新适应症的任何器械特性，公告机构应评估具体声明在多大程度上得到具体临床前和临床数据以及风险分析的支持。

- Verifying that the clinical evidence and the clinical evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMCF plan proposed, where applicable.
  验证临床证据和临床评价是充分的，并应验证制造商得出的结论是否符合相关的一般安全和性能要求。该验证应包括考虑收益-风险确定、风险管理、使用说明、用户培训和制造商上市后监督计划的充分性，并包括审查所提出的上市临床跟踪计划的必要性和充分性(如适用)。

- Considering the clinical evaluation and the benefit-risk determination, and whether specific milestones need to be defined to allow the notified body to review updates to the clinical evidence that result from post-market surveillance and PMCF data.
  考虑临床评估和效益-风险确定，以及是否需要定义特定的里程碑，以允许公告机构审查由上市后监测和上市后临床跟踪数据产生的临床证据的更新。

The outcome of this assessment must be clearly documented in the CEAR. A harmonized CEAR template provides a standardised method for documenting the notified body's assessment of the manufacturer's clinical evaluation and related documents. CEARs in this format will also support specific additional requirements such as the clinical evaluation consultation procedures and reviews by designating authorities.
评估的结果必须清楚地记录在临床评估报告中。统一的临床评估报告模板提供了一种标准化的方法，用于记录公告机构对制造商临床评估和相关文件的评估。这种格式的临床评估报告还将支持特定的额外要求，如临床评估咨询程序和指定当局的审查。

This template applies to MDR Annexes IX section 4 and Annex X section 3. It also applies to assessments of technical documentations on a sampling basis for class IIa/IIb devices in accordance with Annex IX sections 2.3 and 3.5 and Section 10 of Annex XI(A). Aspects related to the clinical evaluation assessment are also laid down in Section 4.5.5 and other relevant sections of Annex VII. It also applies to medical devices for which clinical data is not deemed appropriate,9 to demonstrate conformity with Annex I, and the demonstration of an adequate justification for this.
此模板适用于MDR附件IX第4节和附件X第3节。它也适用于根据附件九第2.3和3.5节和附件十一(a)第10节对IIa/IIb类装器械抽样评估的技术文件。附件七第4.5.5节和其他相关章节也规定了与临床评价和评估有关的方面。它也适用于临床数据被认为不适当的医疗器械,以证明符合附件一，以及证明对此的充分理由。

Conclusion: 结论

F103-4-5-MED-MDR CEAR form should be updated to look like MDCG 2020-13 Clinical evaluation assessment report template -July 2020 and W103-4-5-MED-MDR should be updated to describe how the above template should be used.
F103-4-5-MED-MDR临床评估报告表单应更新为MDCG 2020-13临床评估评估报告模板- 2020-7，W103-4-5-MED-MDR应更新以描述应如何使用上述模板。
By doing this multiple of the other MDCG guidance documents will also be included in this update.
通过这样做，其他医疗器械协调小组指导文件也将包括在这次更新中。
MDCG 2020-1
MDCG 2020-5
MDCG 2020-6
MDCG 2020-7
MDCG 2020-8

MDCG 2020-14 Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR)
根据医疗器械法规/体外诊断医疗器械法规(IVDR)进行的监督审核，就使用MDSAP审计报告向公告机构提供指导).
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The purpose of this document is to provide guidance to notified bodies on how to take into account MDSAP Medical Device Regulatory Audit Reports issued by MDSAP auditing organizations when performing surveillance audits under Regulation (EU) 2017/745 – Medical Devices Regulation (MDR) and Regulation (EU) 2017/746 – In Vitro Diagnostic medical devices Regulation (IVDR). This is of particular use when a manufacturer has undergone an MDSAP audit and wishes to present this audit report (including the associated attachments) in context of the regular surveillance audits performed in accordance to the MDR or IVDR.
本文件的目的是向被公告机构提供指导，说明如何在根据（欧盟）2017/745-医疗器械法规(MDR)和（欧盟）2017/746-体外诊断医疗器械法规(IVDR)进行监督审核时考虑MDSAP审计组织发布的MDSAP医疗器械技术监督审计报告)。 当制造商进行了MDSAP审核，并希望在根据MDR或IVDR进行的定期监督审核中提交本审计报告（包括相关附件）时，这是特别有用的。

Given that surveillance audits, their periodicity and EU auditors' competencies are mandated by law, yearly surveillance audits need to be maintained. However, it could be possible to take into account the scope and outputs of manufacturers' recent MDSAP audit reports as an input for developing surveillance audit programmes. The taking into account of MDSAP audit reports could define in a more precise manner the activities to be performed during a surveillance audit. For example, the positive quality management system conformity appraisal through MDSAP might lead to a reduction of the focus on aspects already covered by MDSAP audit reports. The notified body may then focus their surveillance audit on specific MDR/IVDR requirements which are either not covered or only partially covered by the MDSAP audit report. Non-exhaustive list of examples (alphabetical order):

鉴于监督审核、其周期和欧盟审核员的能力都是法律规定的，因此需要保持年度监督审核。 然而，可以考虑到制造商最近的MDSAP审核报告的范围和输出，作为制定监督审核方案的输入。 考虑到MDSAP审计报告，可以更准确地界定监督审核期间要开展的活动。 例如，通过MDSAP进行积极的质量管理体系符合性评估可能会减少对MDSAP审计报告已经涵盖的方面的关注。 然后，公告机构可以将其监督审核的重点放在MDR/IVDR的具体要求上，这些要求要么没有涵盖，要么只是MDSAP审计报告的部分涵盖。 不详尽的例子清单（按字母顺序排列）：

- clinical evaluation/performance evaluation process (including post-market clinical/performance follow-up),
  临床评估/绩效评估流程(包括上市后临床/绩效跟踪);
- EU authorised representative contractual provisions,
  欧盟授权代表合同条款,
- EU UDI assignments within the quality management system,
  质量管理体系内的欧盟医疗器械唯一标识任务,
- manufacturer financial coverage in respect of potential liability,

关于潜在责任的制造商财务报告，

- person responsible for regulatory compliance qualification and role,
  监管合规资格和角色的负责人
- records control,
  记录控制,
- system for risk management,
  风险管理系统;
- vigilance and post market surveillance activities, including the associated corrective actions and preventive actions.
  警惕和上市后监督活动，包括相关的纠正措施和预防措施。

Similarly, non-conformities identified in recent MDSAP audit reports can trigger the notified body to pay particular attention to those aspects in the MDR/IVDR planned surveillance audit.
类似地，在最近的MDSAP审计报告中发现的不符合可以促使公告机构在MDR/IVDR计划监督审计中特别注意这些方面。

Conclusion: 结论:
Based on this guideline we are currently looking at the option to consider MDSAP audit report in establishing the audit program for clients under MDR 2017/745. This project is handled by COE and further details will follow.
基于这一指导方针，我们目前正在考虑在MDR 2017/745下为客户建立审核程序时考虑MDSAP审计报告的选项。该项目由COE处理，后面将介绍进一步的细节

- **EU Commission 欧盟委员会**

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Fact sheet on MDR requirements for Transparency and Public Information

The purpose of this fact sheet is to list information which will be available to the public in accordance with transparency obligations in MDR considering that some requirements will be applicable only once the European database on medical devices (Eudamed) is fully functional.

Transparency is a key objective of the Medical Devices Regulation (MDR) aiming at providing a large access to relevant information to the public and strengthening public and patient confidence in the safety of medical devices placed on the EU market.

关于MDR对透明度和公共信息要求的情况说明

本情况说明的目的是列出将根据MDR的透明度义务向公众提供的信息，考虑到一些要求仅在欧盟医疗器械数据库(Eudamed)全面运作后才适用。

透明度是医疗器械法规(MDR)的一个关键目标，旨在为公众提供获取相关信息的渠道，并加强公众和患者对欧盟市场上销售的医疗器械安全性的信心。

1. List of key information which will be accessible to the public in Eudamed
   公众可在欧盟医疗器械数据库查阅的关键信息清单
   - Registration of all manufacturers, their authorised representatives and importers
     所有制造商、其授权代表和进口商的注册
   - Registration of devices, the core elements of the UDI database
     器械注册，医疗器械唯一标识l数据库的核心要素
   - Registration of certificates of conformity
     合格证书的登记
   - List of notified bodies designated under the MDR
     MDR指定的公告机构清单
   - Scientific opinions of the expert panels
     专家小组的科学意见
   - Clinical investigation reports and their summary
     临床调查报告及其摘要
   - The summary of safety and clinical performance
     安全性和临床表现的总结
   - Manufacturer incident reports and field safety notices
     制造商事件报告和现场安全通知
   - Summary of the results of market surveillance activities
     市场监督活动结果摘要
2. List of key information which shall be publicly available outside Eudamed
   应在欧盟医疗器械数据库以外公开获得的关键信息清单
   - National measures taken by competent authorities for the placing on the market of single use devices which are reprocessed
     主管当局为将再加工的单一使用器械投放市场而采取的国家措施
   - Types and levels of fees
     费用的类型和水平
   - National measures governing the assessment, designation and notification of notified bodies
     管理公告机构的评估、指定和通知的国家措施
   - List of standard fees from notified bodies
     来自公告机构的标准费用清单
   - Commission annual summary report of the peer review activities of authorities responsible for notified bodies
     委员会公告机构主管当局同业互查活动的年度摘要报告
   - Declaration of interests of top-level management of notified bodies
     公告机构高层管理人员利益声明

- Declaration of interests of each member of the MDCG, of its sub-groups except for stakeholder organisations, and of the advisors within the expert panels and expert laboratories
  医疗器械协调小组的每个成员、除利益相关组织外的小组、专家小组和专家实验室的顾问的利益声明
- Advice provided by the expert panels
  专家小组提供的咨询意见
- Names and affiliation of the members of the MDCG
  医疗器械协调小组成员的名称和友好关系

The above lists indicates the information which will be made available to the public respectively in Eudamed and outside Eudamed, respectively from the entry into application of the MDR (May 2021) and the release of Eudamed (planned for May 2022).
上述清单列出了自MDR申请(2021年5月)和欧盟医疗器械数据库发布(计划于2022年5月)开始，将分别在欧盟医疗器械数据库和欧盟医疗器械数据库以外向公众提供的信息)。
However, it does not necessarily mean that the information made available in the future will be strictly limited to the one listed. Transparency in the context of the MDR can be considered as a step by step process that may include other areas in the future.
但是，这并不一定意味着将来提供的资料将严格限于所列的资料。可将MDR范围内的透明度视为一个循序渐进的过程，将来可能包括其他领域。
More information, could progressively be made available in Eudamed based on experience gained on the impact of transparency in particular on the various reporting activities and the way this information is beneficial to the public.
根据在透明度的影响，特别是透明度对各种报告活动的影响以及这些信息对公众的好处方面所取得的经验，可以在欧盟医疗器械数据库逐步提供更多的信息。

What is the state of play of the implementation of Eudamed?
欧盟医疗器械数据库实现的现状是什么?

- The development and implementation of Eudamed is a high priority for the Commission
  发展和执行欧盟医疗器械数据是委员会的一项高度优先事项
- The Commission, in agreement with the Medical Device Coordination Group (MDCG), is going to make available the different modules on a gradual basis as soon as they are functional
  根据医疗器械协调小组的协议，委员会将在不同的模块运作后逐步提供这些模块
- The module on Actor registration will be the first module made available. Deployment of the module takes place December 2020.
  企业注册模块是第一个上线的模块，模块的部署将于2020年12月进行
- The module on UDI/device registration (second module) and the module on Certificates and Notified Bodies (third module) will become available by May 2021. Afterwards, the remaining modules will be displayed as soon as they are functional.
  医疗器械唯一标识/器械注册模块(第二个模块)和证书和公告机构模块(第三个模块)将于2021年5月可用。然后，其余模块将在它们发挥作用后立即显示出来。

Commission Implementing Regulation (EU) 2020/1207 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices.
委员会实施法规(欧盟)2020/1207号条例，为欧洲议会和理事会的《条例(欧盟)2017/745》(关于一次性装置再处理的共同规格)的适用制定规则。

This Regulation lays down rules for the application of Article 17(3) of Regulation (EU) 2017/745, where national law has permitted reprocessing of single-use devices and a Member State has decided not to apply all of the rules relating to manufacturers' obligations laid down in that Regulation as regards single-use devices that are reprocessed and used within a health institution.
该法规规定了适用（欧盟)第2017/745号条例第17(3）条的规则，其中国家法律允许对一次性使用器械进行再加工，而一个成员国决定不适用该条例中规定的关于在卫生机构内重新加工和使用的单一用途装置的制造商义务的所有规则。
Note: This does not mean that reprocessing of disposable products according to MDR will be allowed in Sweden.
注:这并不意味着瑞典将允许根据MDR对一次性产品进行再加工。

This must be incorporated into national law. The government assignment to investigate the conditions for reprocessing of disposable products previously announced is still ongoing and will be reported at the end of 2020. In the event that reprocessing is permitted, such activities shall take place in accordance with the specifications in the implementing regulation.
这必须纳入国家法。政府关于调查先前宣布的一次性产品再加工条件的任务仍在进行中，并将在2020年底报告。 在允许再加工的情况下，此类活动应按照实施条例中的规范进行。

- **Team NB 公告机构协会**

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The pandemic situation affects the MDR implementation with regards to pushed preparation and implementation work from both the industry and NB's to prioritize the changed circumstances affected pandemic situation.
As such, a new task force based on Team NB members has been set up to participate in a joint approach to European Commission concerning the COVID-19 challenging situation affecting the Notified bodies operations and certification activities under the MDR. This task force is headed by Ella Helgeman as chair.
疫情状况影响了MDR的实施，影响到各行业和公告机构推动的准备和实施工作，以优先考虑受影响的疫情情况变化的情况。因此，已经成立了一个以公告机构协会成员为为基础的新的工作组，以参与向欧盟委员会提出的关于影响公告机构在MDR下开展业务和认证活动的COVID-19挑战形势的联合做法。该工作组由Ella Helgeman担任主席。

Position paper and several open questions has been raised and sent to the Commission and we are currently seeking for response and negotiations to solve the operational concerns and challenges to the MDR certification activities. The greatest impact for NB's is that there is no guidance available of how to deal with MDR assessments and certification activities under the COVID-19 pandemic. Travel restrictions to countries, and in some cases within countries, makes it impossible to execute initial audits onsite. So far, the Commission has not envisage the possibility of initial audits against MDR. As a consequence, onsite audits may not always be possible due to quarantine and travel restrictions.
已向委员会提出意见书和一些开放式问题，我们目前正在寻求答复和谈判，以解决MDR认证活动面临的运作担忧和挑战。对公告机构的最大影响是，没有关于如何处理COVID-19大流行下MDR的评估和认证活动的指导。前往国家的旅行限制，以及在某些情况下国家内部的旅行限制，使得无法在现场执行首次审核。到目前为止，委员会尚未设想对MDR进行首次审核的可能性。因此，由于检疫和旅行限制，可能并不总是能够进行现场审核。
Team NB has raised the attention to the use derogations as stipulated in the MDR art.59, so far this has not been taken into consideration to find adequate solutions to address concerns due to the COVID-19 situation and how this affects the notified bodies.
公告机构协会已经提高对MDR第59条规定的使用削减的注意，到目前为止，还没有考虑到这一点，以便找到适当的解决办法，解决COVID-19疫情引起的关切，以及这如何影响公告机构。

- **Other 其他**

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Note that it is mandatory both under regulation and directive from 20th of April 2021
请注意，从2021年4月20日起，这在法规和指示下都是强制性的
Release Notes for IMDRF Terminology Edition 4.1
国际医疗器械监管机构论坛（IMDRF）术语4.1版的发布说明。
Edition 4.1 is a minor update to improve usability of the IMDRF Terminology. There are no changes to any terms, codes, and definitions since Edition 4.0 published on 20 April 2020 with the exception of two editorial corrections indicated below.
版本4.1是一个小更新，以提高IMDRF术语的可用性。自2020年4月20日发布的4.0版以来，除了以下两处编辑更正外，其他术语、规范和定义均未发生任何变化。
Overview of changes: 变化概述:

1. Addition of Code Hierarchy information to all Annexes.
   向所有附件中添加代码层次结构信息。
2. Addition of Status / Status Description information to Annexes A, E, and G, to indicate major changes made since Edition 3.0 and to clarify that some level 1 terms should not be used for coding.

在附录A、E和G中添加状态/状态描述信息，以表明自3.0版以来所做的主要更改，并澄清某些1级术语不应用于编码。

3. Addition of a Mapping Table to Annex E. The content of the mapping is unchanged.
   在附件E 中增加了一个映射表，映射的内容没有变化。
4. Correction of definition of Display to reference the correct code for Touchscreen
   修订显示的定义，以参考触摸屏的正确代码
5. Change of term G04040 to Cusp/Leaflet and inactivation of term G04081 due to duplication of "Leaflet."
   将术语G04040改为尖点/说明书，并由于“说明书”的重复而使术语G04081失活；

Brexit 英国脱欧

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They have decided to create their own regulatory system for medical devices, and they will only accept CE marked medical devices until June 30, 2023.
他们决定建立自己的医疗器械监管体系，在2023年6月30日之前，他们只接受有CE标志的医疗器械。
Summary of key requirements for placing a device on the Great Britain market
在英国市场上投放一种器械的键要求摘要
From 1 January 2021, there will be a number of changes to how medical devices are placed on the market in Great Britain. These are:
从2021年1月1日起，医疗器械在英国市场的投放方式将会有一些变化。这些是:

CE marking will continue to be used and recognized until 30 June 2023
Certificates issued by European Economic Area (EEA)-based Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
在2023年6月30日之前，CE标志将继续被使用和认可。
由欧洲经济区(EEA)的公告机构签发的证书将在2023年6月30日之前在英国市场继续有效。

A new route to market and product marking will be available for manufacturers wishing to place a device on the Great Britain market from 1 January 2021
从2021年1月1日起，希望将器械投放英国市场的制造商将有一个新的市场和产品标记途径。

From 1 January 2021, all medical devices and in vitro diagnostic medical devices (IVDs) placed on the UK market will need to be registered with the MHRA. There will be a grace period for registering:
从 2021 年 1 月 1 日起，所有进入英国市场的医疗器械和体外诊断医疗器械(IVDs)都需要在英国药监机构（MHRA）注册。注册会有一个宽限期:

- 4 months for Class IIIs and Class IIb implantables, and all active implantable medical devices
  IIIs类和IIb类植入式及所有现有植入式医疗器械4个月;
- 8 months for other Class IIb and all Class IIa devices
  其他IIb级和所有IIa级器械8个月
- 12 months for Class I devices
  I类器械12个月

The above 12-month grace period will not apply to manufacturers of Class I devices and general IVDs that are currently required to register with the MHRA.
If you are a manufacturer based outside the UK and wish to place a device on the UK market, you will need to establish a UK Responsible Person who will take responsibility for the product in the UK. Further detail on the UK Responsible Person is set out below.
上述12个月的宽限期不适用于目前需要在英国药监机构注册的I类器械和一般体外诊断设备的制造商。
如果你是一个英国以外的制造商，希望把一个器械在英国市场上投放，你将需要建立一个英国代表，这个代表将在英国对这个产品负责。英国代表的详细情况如下。
From 1 January 2021, the MHRA will designate UK Conformity Assessment Bodies (CABs) to conduct assessments against UK requirements for the purpose of the UKCA mark. UK Notified Bodies currently designated under the MDD (BSI, SGS and UL) will become “Approved Bodies” automatically as of 1 January 2021 without having to undergo a new designation process with MHRA.

从2021年1月1日起，英国药监机构将指定英国合格评定机构(CABs)针对英国要求进行UKCA标志的评估。目前在MDD下指定的英国公告机构(BSI、SGS和UL)将从2021年1月1日起自动成为“获批机构”，无需与英国药监机构进行新的指定流程。

Switzerland one step closer to recognize MDR

瑞士更接近认可MDR。

Switzerland and the European Union benefit currently from a Mutual Recognition Agreement (MRA) which facilitates market access especially for medical devices.

Thanks to the European Commission's decision to postpone the date of application of the Medical Device Regulation (MDR) by one year, Switzerland and the EU have won one more year to get the Mutual Recognition Agreement updated, and thus, maintain these benefits for both parties.

A majority has voted for a new MRA. Thanks to this result, one big stone has been removed off the way towards a new MRA. This doesn't mean that there will definitely be an MRA, but at least there is still hope.

瑞士和欧盟目前受益于一项相互承认协定(MRA)，该协定有利于市场准入，特别是医疗器械市场准入。

由于欧盟委员会决定将医疗器械法规(MDR)的实施日期推迟一年，瑞士和欧盟赢得了一年多的时间来更新相互承认协议，从而维护了双方的利益。

- **Standards 标准**

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- In the absence of harmonised standards against the MDR, the latest versions of those standards that were previously harmonised against the MDD are considered state of the art for the MDR
  在没有针对MDR的统一标准的情况下，那些以前针对MDD统一的标准的最新版本被认为是MDR的最新水平
- Where key standards or CS have not been applied or not been applied in full, appropriate justification should be provided in the technical documentation. A summary or gap analysis regarding ability to comply with associated GSPRs (MDR Annex I), and a risk analysis and conclusion of acceptability of any compliance gaps should be provided.
  如果关键标准或CS没有被应用或没有被完全应用，应在技术文件中提供适当的理由。应提供关于遵守相关GSPRs (MDR附件I)的能力的总结或差距分析，以及对任何合规差距可接受性的风险分析和结论。
- MDR technical documentation should continue to demonstrate that the files meet the state of the art, including consideration of revised or replaced standards or CS .
  MDR技术文档应继续证明文件满足最新技术水平，包括考虑修订或替换的标准或CS。
- MDR technical documentation should indicate other Regulations and / or Directives which apply. If a device is governed by multiple regulations or directives, all applicable regulations / directives should be identified (e.g. device intended to be used in accordance with both the MDR and PPE Regulation, device which is also machinery).
  MDR技术文档应注明适用的其他法规和/或指令。如果一个器械受多个法规或指令管辖，则应识别所有适用的法规/指令(例如，拟根据MDR和PPE法规使用的器械，同时也是机械设备)。

ISO 14155:2020 Clinical investigation of medical device for human subjects.

ISO14155:2020 人体医疗器械临床研究。

This third edition cancels and replaces the second edition (ISO 14155:2011), which has been technically revised. The main changes to the previous edition are as follows:

第三版取消并取代了第二版(ISO 14155:2011)，后者已经进行了技术上的修订。对于上一版的主要变化如下:

- inclusion of a summary section of GCP principles (see Clause 4);
  包含药物临床试验管理规范（GCP）原则的摘要部分(见第四条)
- reference to registration of the clinical investigation in a publicly accessible database (see 5.4);
  参考临床研究在公开数据库中的注册(见5.4)
- inclusion of clinical quality management (see 9.1);
  包含临床质量管理(见9.1);
- inclusion of risk-based monitoring (see 6.7);
  包含基于风险的监测(见6.7);
- inclusion of statistical considerations in Annex A;

包含统计考虑因素在附件A;

- inclusion of guidance for ethics committees in Annex G;
  包含道德委员会指导在附录G;
- reinforcement of risk management throughout the process of a clinical investigation (planning to consideration of results) including Annex H;
  在整个临床调查过程(计划考虑结果)加强风险管理在附录H;
- clarification of applicability of the requirements of this document to the different clinical development stages (see Annex I);
  澄清本文件要求对不同临床开发阶段的适用性(见附件一);
- inclusion of guidance on clinical investigation audits (see Annex J).
  包括临床调查审计指南(见附录J)。、

ISO/TR 20416:2020 Medical device - Post market surveillance for manufacturers

ISO/TR 20416:2020医疗器械—制造商的上市后监督

This document provides guidance on the post-market surveillance process and is intended for use by medical device manufacturers. This post-market surveillance process is consistent with relevant international standards, in particular ISO 13485 and ISO 14971. This document describes a proactive and systematic process that manufacturers can use to collect and analyse appropriate data, to provide information for the feedback processes and use this to meet applicable regulatory requirements to gain experience from the post-production activities. The output of this process can be used:

本文件为上市后的监督过程指导，供医疗设备制造商使用。这一上市后的监督过程符合相关的国际标准，特别是ISO 13485和ISO 14971。该文件描述了一个前瞻性和系统性的过程，制造商可以使用该过程来收集和分析适当的数据，为反馈过程提供信息，并利用这些信息来满足适用的法规要求，从生产后活动中获得经验。该过程的输出可以使用:

- as input into product realization;
  作为产品实现的输入;
- as input into risk management;
  作为风险管理的输入;
- for monitoring and maintaining product requirements;
  监视持产品要求;
- for communicating to regulatory authorities;
  与监管当局沟通;
- as input into improvement processes.
  作为改进过程的输入。

This document does not address market surveillance activities to be performed by regulatory authorities. Neither does it specify a manufacturer's actions required by the applicable regulatory requirements resulting from their production or post-production activities, nor reporting to regulatory authorities. This document is not intended to replace or change applicable regulatory requirements for post-market surveillance.

本文件不涉及监管部门执行的市场监督活动。它既没有具体说明制造商因其生产或生产后活动而应适用的监管要求采取的行动，也没有向监管当局报告。本文件无意取代或改变上市后监管的适用监管要求。