QMD Services Quality | Medical | Devices	Title: Client QMS Audit 医疗器械法规认证实施规则		
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Author(s): Blaimauer Ingrid	Reviewer(s): Varney Mark; Grohme Diana; GRP - QM Team for QM Review - Any		Approver(s): Blaimauer Ingrid

Table of Content 目录

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1. General

This process describes the quality management system audits of manufacturers of medical devices regardless of specific company structures. It includes the planning phase of regular and special audits and defines the preparation, implementation and follow-up of the quality management system audits and on-site activities according to Regulation (EU) 2017/745 or RE (EU) 2017/746.

The planning activities like developing/updating the audit programs (e.g., manufacturer, critical supplier, etc.), selecting an audit team, creating an audit plan, preparing for conducting an audit, and client maintenance are described in "SOP-00123 Project Management".

According to the requirements of Regulation (EU) 2017/745 or RE (EU) 2017/746 QMD Services will assess:

- that the quality management system of the manufacturer meets the requirements of Regulation (EU) 2017/745 or RE (EU) 2017/746;
- that the manufacturer complies with the documentation and information obligations set out in the relevant annexes and that the necessary procedures for the implementation of quality management systems are taken into account;
- that the manufacturer does not use the quality management systems or product assessments in a misleading manner.

The result from the system audit is used for the certificate according to "PRC-00132 Certification Decision".

The following person are involved in the on-site audit:

- The **lead auditor** represents the notified body and is responsible for the audit process and the coordination of the audit team. The lead auditor is responsible to assure that the audit objectives are met and that the audit process is effective and efficient.
- The **auditor** works as a fully responsible member in the audit team under the coordination of the lead-auditor.
- **Experts and Product Reviewers** contribute with their special expertise and are responsible to collect the necessary information to achieve the objective of their specific assignment. They inform the lead auditor before the on-site audit about the results of the assessment of the technical documentation.
- **The project leader acts as communicator/contact person for the auditor.**

Based on results from the product assessment the lead auditor and the project leader may agree that the experts shall be part of the on-site audit team.

In the case that the product reviewer takes part in the on-site audit the product reviewer will coordinate their on-site activities with the lead auditor within the common audit plan. Whenever possible from the assigned audit times, they will participate in introductory and closing meetings. The expert is responsible only for his expertise part. Findings are integrated in the common action list.

Audits may not be subcontracted to auditing or certification organisations.
Operations (Planning) ensures, that the Audit Team has the competence / authorization for auditing the applicable activities.

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1. 总则

本程序适用于对医疗器械制造商的质量管理体系进行审核，不受其具体组织结构的限制。内容涵盖常规审核与特殊审核的策划阶段，并规定了依据《欧盟法规（EU）2017/745》或《欧盟法规（EU）2017/746》（以下简称"MDR/IVDR"）进行质量管理体系审核及现场活动的准备、实施与后续处理要求。

相关的策划活动，包括制定/更新审核方案（例如制造商、关键供应商等）、审核组的选定、审核计划的制定、审核准备及客户维护等，详见《SOP-00123 项目管理程序》。

根据 MDR/IVDR 要求，QMD Services 将评估以下内容：

- 制造商的质量管理体系是否符合 MDR/IVDR 的规定；
- 制造商是否履行了相关附录中规定的文件和信息义务，并已建立必要的程序以实施其质量管理体系；
- 制造商是否存在对质量管理体系或产品合格评定的误导性使用。

体系审核的结果将作为《PRC-00132 认证决策程序》中证书发放的依据。

以下人员参与现场审核：

- **审核组长**：代表公告机构，负责整个审核过程及审核组的协调工作，确保审核目标的实现及审核过程的有效性与效率。
- **审核员**：在审核组长的协调下，作为审核组的正式成员，独立承担审核任务。
- **技术专家与产品评审员**：提供其专业领域的支持，负责收集实现其指定任务所需的信息。在现场审核前，他们应将技术文件评审结果告知审核组长。
- **项目负责人**：作为审核期间的协调人和主要联系人，与审核员沟通对接。

根据产品评审结果，审核组长和项目负责人可共同决定是否由专家参与现场审核。

若产品评审员参与现场审核，其现场工作内容应在统一的审核计划框架内与审核组长进行协调。在审核时间安排允许的情况下，应尽可能参加首次会议和末次会议。专家仅对其专业范围内的工作负责，其发现将整合入统一的整改措施列表中。

审核工作不得外包给其他审核或认证机构。

运营部门（审核策划）应确保审核组具备执行相关审核活动所需的**资质与授权**。

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2. Flowchart 流程图

Process Flow 审核流程	Responsibilities 职责分工	Remarks 备注 <= 输入，>= 输出 <= Input, >= Output
Figure-1		
"SOP-00123 Project Management"	PL	< Information to be provided acc. "SOP-00123 Project Management" < Checklists
Stage 1 audit (desktop document review or on-site audit)	LA	> FO-00471 Client QMS Stage 1 report <> Database of QMD Services
Conformity achieved? — No → Informing customer	LA	<> Database of QMD Services < "FO-00410 IV Assessment Program"/ "FO-00412 IVDR Assessment Program", FO-00471 Client QMS Stage 1 report, "FO-00390 MDR TDAR" / "FO-00344 IVDR TDAR" > "FO-00384 QMS Audit Plan"
"SOP-00103 MDR TD Conformity Assessment" / "SOP-00124 IVDR TD conformity assessment" — Yes		
Preparation of announced / unannounced QMS audit on-site	PL, MAT	<> relevant Checklists > "FO-00469 MDR Client QMS Audit checklist"/ "FO-00473 IVDR Client QMS Audit checklist", "FO-00407 Client audit participation list"
Announced / unannounced QMS audit on-site	LA, SA	> "FO-00391 Audit finding list"
Conformity achieved? — No → Informing customer about non-conformities	LA	> "FO-00392 Client QMS Audit Report" > "FO-00391 Audit finding list"
Audit report, Upload to WIS ← Action list — Yes		> Database WIS of QMD Services
"PRC-00132 Certification Decision"	LA	

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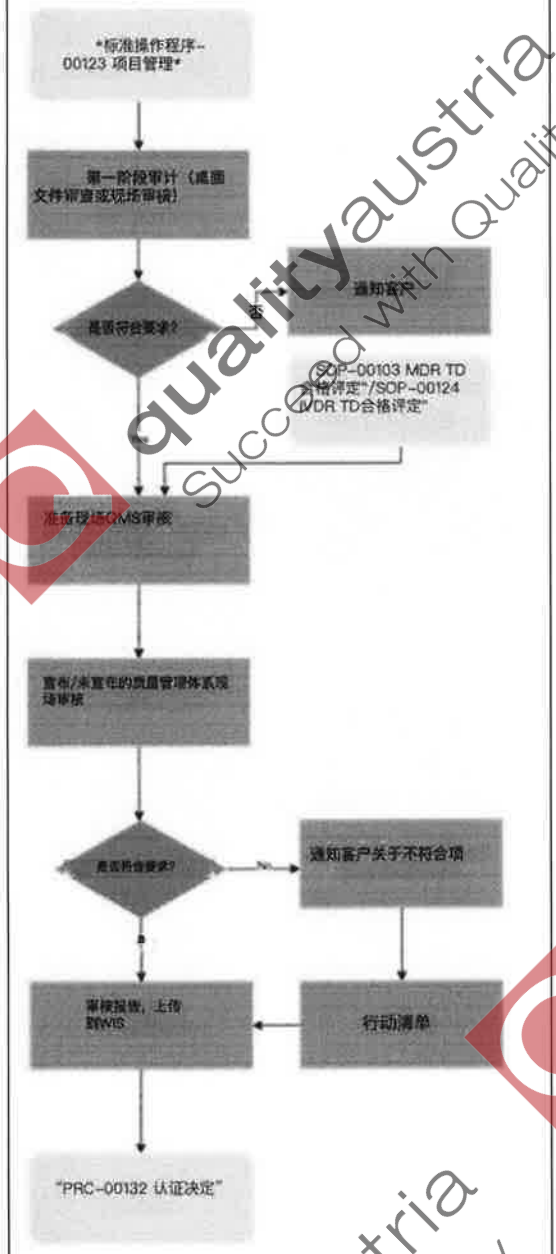

PL（项目负责人）	< 需提供的信息，参考《SOP-00123 项目管理程序》
LA（审核组长）	> FO-00471 客户 QMS 第一阶段审核报告 <> QMD Services 数据库 <> QMD Services 数据库
LA（审核组长）	< FO-00410《MDR 评审计划》/ FO-00412《IVDR 评审计划》 FO-00471 客户 QMS 第一阶段审核报告 FO-00390《MDR 技术文件评审记录 (TDAR)》/ FO-00344《IVDR TDAR》 > FO-00384《QMS 审核计划》
PL, MAT（审核组成员）	<> 相关审核清单 > FO-00469《MDR 客户 QMS 审核清单》/ FO-00473《IVDR 客户 QMS 审核清单》 > FO-00407《客户审核参与人员名单》
LA, SA（现场审核员），PR（产品评审员）	> FO-00391《审核发现清单》
LA（审核组长）	> FO-00392《客户 QMS 审核报告》 > FO-00391《审核发现清单》 > QMD Services 的 WIS 数据库
LA（审核组长）	

PL...Project leader, LA...Lead Auditor, MAT...Members of Audit Team, SA...Site Auditor, PR...Product Reviewer

"PL 表示项目负责人（Project Leader），LA 表示审核组长（Lead Auditor），MAT 表示审核组成员（Members of Audit Team），SA 表示现场审核员（Site Auditor），PR 表示产品评审员（Product Reviewer）。

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3. General Information

The main objective of a quality management system audit is to assess the overall effectiveness of the auditee's quality management system, including compliance with applicable regulatory requirements.

Initial certification of the quality management system under MDR/IVDR requires a two-stage audit process. To maintain certification, the auditee's quality management system must be monitored through surveillance audits in the subsequent years following the certification decision, along with a recertification audit in the fifth year, timely prior to the expiration of the certification.

Quality management system audit and relevant technical documentation assessment shall complement each other, preferably evaluating the same medical device sample(s) or at least same device category. Audit planning includes technical documentation assessment results. The auditor is provided with the results that require consideration by the project manager.

The quality management system audit is carried out according to the applicable client´s assessment program. This document shall be used to acquire the information from the client.

Changes might occur based on the result of the system analysis (if applicable) and of the assessment of the technical documentation.

During initial certification, the on-site audit (stage 2) can only take place after the first review (round) of the TD assessment is completed regardless if a second round is required.

As preparation of the assessment of the quality management system QMD Services will carry out the following tasks prior to the on-site audit:

- assess the technical documentation submitted in accordance with the relevant conformity assessment Annex, and draw up an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of the manufacturer's quality management system and to determine whether it meets the requirements of MDR/IVDR,
- identify links and allocation of responsibilities among the various manufacturing sites, and identify relevant suppliers and/or subcontractors of the manufacturer, and consider the need to specifically audit any of those suppliers or subcontractors or both,
- define an audit program the objectives, criteria and scope of the audit ("FO-00410 MDR Assessment Program"/ "FO-00412 IVDR Assessment Program"), and draw up an audit plan ("FO-00384 QMS Audit Plan"), that adequately addresses and takes account of the specific requirements for the devices, technologies and processes involved,
- draw up and keep up to date, for class IIa and class IIb devices / class B and class C, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate, and
- select and assign appropriately qualified and authorised personnel for conducting the individual audits. For the Technical Documentation conformity assessment project,

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the respective roles, responsibilities and authorities of the team members are documented in the order planning of the respective project.
- if the applicant does not yet have a quality management system according to ISO 13485 of an IAF recognized accredited certification body, or notified body, in place a system analysis (stage 1 audit) will be performed prior to the on-site audit.

3. 一般信息

质量管理体系审核的主要目的是评估受审核方质量管理体系的整体有效性，包括其是否符合适用的法规要求。

根据 MDR/IVDR 规定，质量管理体系的初始认证需经过两阶段审核程序。为维持认证，在认证决定之后的年度内必须进行监督审核，并在第 5 年认证有效期届满前及时进行再认证审核。

质量管理体系审核应与相关技术文件评审相辅相成，优先针对相同的医疗器械样品或至少相同的器械类别进行评估。审核策划过程中需考虑技术文件评审结果，项目负责人将向审核员提供需关注的评审信息。

质量管理体系审核应根据适用的客户评审计划执行。本文件用于收集客户的相关信息。

系统分析结果（如适用）或技术文件评审结果可能引起审核计划的调整。

在初始认证过程中，第二阶段现场审核只能在技术文件第一轮评审完成后进行，无论是否需要第二轮评审。

作为质量管理体系评审的准备工作，QMD Services 将在现场审核前开展以下任务：

- 评估申请人提交的技术文件（依据相关符合性评审附录），并制定审核方案，明确展示覆盖制造商整个质量管理体系所需活动的数量与顺序，评估其是否符合 MDR/IVDR 要求；
- 识别各生产场所之间的职责分配及关联性，识别与制造商相关的关键供应商和/或分包商，并评估是否有必要对这些供应商或分包商进行专项审核；
- 制定审核方案的目标、准则与范围（参考 FO-00410《MDR 评审计划》/ FO-00412《IVDR 评审计划》），并制定审核计划（参考 FO-00384《QMS 审核计划》），确保充分考虑器械、技术和工艺的特定要求；
- 对于 IIa 类、IIb 类医疗器械（或 B 类、C 类器械），制定并更新技术文件抽样评审计划（依据附录 II 和 III），确保在认证有效期内所有覆盖器械均被抽样评审；
- 指派具备相应资质与授权的审核人员承担各项审核工作。针对技术文件符合性评审项目，各审核组成员的职责、权限与角色已在项目订单策划中进行记录；
- 若申请人尚未获得 IAF 认可的认证机构或公告机构签发的 ISO 13485 质量管理体系证书，则应在现场审核前进行系统分析（即第一阶段审核）。

4. Auditing Quality Management system

The QM system audit includes:

1) Information and evidence of compliance with all requirements of Regulation (EU) 2017/745 or RE (EU) 2017/746 for the management system and other applicable normative documents; especially ensuring that the quality management system for the products covered meets the relevant provisions of Regulation (EU) 2017/745 or RE (EU) 2017/746 at every stage, from design through final quality control to ongoing surveillance;
2) Monitoring of performance, measurement, reporting and verification by key performance targets (consistent with Regulation (EU) 2017/745 or RE (EU) 2017/746 regarding expectations of the management system or other normative documents) especially for the aspects required by Article 10 and Chapter I, Section 2 of Annex IX of MDR or IVDR,
3) Review and audit the manufacturer's management system and its performance in terms of compliance with the general safety and performance requirements;

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4) Audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,
5) Conduct assessments of the technical documentation ("SOP-00103 MDR TD Conformity Assessment" / "SOP-00124 IVDR TD conformity assessment") based on its sampling plan,
6) QMD Services ensures that audit findings are appropriately and consistently classified in accordance with the requirements of the Regulation (EU) 2017/745 or or RE (EU) 2017/746 and with relevant standards, or with best practice documents developed or adopted by the MDCG. These are recorded and managed by using "FO-00391 Audit finding list".

The detailed requirements of RE (EU) 2017/745 or RE (EU) 2017/746 which need to be checked on-site are included in "FO-00469 MDR Client QMS Audit checklist" / "FO-00473 IVDR Client QMS Audit checklist".

The audit team must analyze all information and audit evidence collected during the audit to evaluate audit findings and agree on audit conclusions. The result of the audit is summarized in an audit report "FO-00392 Client QMS Audit Report".

All applicable processes are to be reviewed.

The quality management (QM) system audit takes place at the customer's locations. In certain and justified cases, the audits can also be carried out in hybrid form. That means that at least one auditor is present on the premises of the manufacturer and other members of the audit team participating from elsewhere using information and communication technologies (ICT).

4. 质量管理体系审核

质量管理体系审核包括以下内容：

1. 审核制造商质量管理体系及相关合规性证据，确认其符合《欧盟法规（EU）2017/745》或《欧盟法规（EU）2017/746》以及其他适用规范性文件的全部要求，尤其需确保所覆盖产品的质量管理体系在从设计、最终质量控制到持续监督的每一个阶段，均符合上述法规的相关规定；
2. 绩效监测、测量、报告与验证机制的审查，依据法规对于管理体系的预期（如 MDR 或 IVDR 第 10 条及附录 IX 第一章第 2 节）设定的关键绩效指标（KPI）进行评估；
3. 审核制造商的管理体系及其在符合法规中基本安全与性能要求方面的表现；
4. 在成品器械合规性显著受供应商活动影响，或制造商无法充分证明对供应商的有效控制时，对关键供应商现场的过程控制进行审核；
5. 根据抽样计划开展技术文件符合性评估（参见《SOP-00103 MDR 技术文件符合性评估》 / 《SOP-00124 IVDR 技术文件符合性评估》）；

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6. QMD Services 确保审核发现依据《欧盟法规（EU）2017/745》或《欧盟法规（EU）2017/746》、相关标准，或 MDCG 发布/采纳的最佳实践文件进行恰当且一致的分级。审核发现记录并通过《FO-00391 审核发现清单》进行管理。

需要在现场确认的法规要求详见《FO-00469 MDR 客户 QMS 审核清单》/ 《FO-00473 IVDR 客户 QMS 审核清单》。

审核组需分析在审核过程中收集的所有信息与证据，以评估审核发现并形成审核结论。审核结果总结记录于《FO-00392 客户 QMS 审核报告》中。

所有适用的过程均需进行评审。

质量管理体系审核通常在客户现场进行。若存在合理理由，亦可采用混合形式进行审核：即至少一名审核员需在制造商现场，其他审核员可通过信息通信技术（ICT）远程参与。

4.1. Information and Communication Technology for Auditing (ICT)

ICT may be utilized for auditing and assessment purposes, including but not limited to:

- Virtual meetings: Conducting meetings via audio, video, and data sharing.
- Document Auditing: Remote access to documents and records, either synchronously (real-time) or asynchronously (when applicable).
- Evidence Recording: Using video or audio recordings to capture information and evidence.
- Virtual Access:
  - Conducting virtual site audits.
  - Accessing potentially hazardous locations (due to political issues, crime, or natural disasters).

The use of ICT must be mutually agreed upon by the auditee and the auditing organization before implementation, adhering to information security and data protection regulations and documented in the audit plan.

For virtual audits, the auditee's infrastructure should be utilized. For example, during a manufacturer's on-site audit, participants from virtual sites may join via platforms. Audit reports shall include details on how ICT was used.

4.2. Initial certification

Initial certification of the quality management system under MDR/IVDR requires a two-stage audit process

During a stage 1 audit, the auditee's readiness for certification is evaluated.

In the case of new customer a system analysis shall always be part of the conformity assessment process whether they are ISO 13485 certified or not. If the organization is already certified according to ISO 13485 the main focus during the stage 1 audit shall be given to the MDR or IVDR requirements. "FO-00379 Self-declaration - providing ISO 13485 certificate" should be provided by the client.

A system analysis is carried out as a desktop document review. However, the lead auditor can decide whether an on-site audit or a remote audit or a combination is required for the evaluation of the readiness for the certification audit stage 2.

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The audit team shall cover at least one applicable MDT/IVT code listed in the assessment program from an authorization perspective, however the full scope shall still be addressed.

4.1 信息与通信技术（ICT）在审核中的应用

ICT 可用于审核与评估活动，包括但不限于：

- 虚拟会议：通过音频、视频及数据共享方式开展会议；
- 文件审核：以同步（实时）或异步方式远程访问文档与记录；
- 证据记录：通过视频或音频记录的方式收集信息与证据；
- 虚拟访问：
  - 实施虚拟现场审核；
  - 进入因政治、安全或自然灾害等因素导致不宜实地访问的高风险场所。

ICT 的使用须在审核实施前经受审核方与审核机构双方协商同意，并符合信息安全与数据保护规定，同时在审核计划中明确记录。

在虚拟审核中，应尽可能利用受审核方提供的 IT 设施。例如，在制造商现场审核中，远程参与的审核员可通过平台接入会议。审核报告中须明确 ICT 的使用方式及内容。

4.2 初次认证

依据 MDR/IVDR 进行质量管理体系的初次认证，需采用两阶段审核流程。

在第一阶段审核中，将评估受审核方的认证准备情况。

若为新客户，则无论其是否持有 ISO 13485 证书，均必须纳入合规性评审流程中的系统分析。若其已获得 ISO 13485 认证，则第一阶段审核的重点应放在 MDR 或 IVDR 的适用要求上。客户需提交《FO-00379 ISO 13485 自我声明表》。

系统分析一般为文件审查。然而，审核组长可根据情况决定是否需现场审核、远程审核或混合方式评估其是否具备进行第二阶段认证审核的准备条件。

从授权角度出发，审核组至少应覆盖评审计划中列明的一个适用的 MDT/IVT 代码，但审核内容应覆盖整个申请范围。

4.2.1. Stage 1 audit

A stage 1 Audit contains the following aspects:

- Review of the quality management system
- Determine the preparedness for the stage 2 audit
- Factors influencing audit time / audit plan for stage 2
- The status of the auditee / company and his understanding regarding system, key performance or significant requirements, aspects, processes, objectives, and operation
- Obtain necessary information regarding the scope of the management system, including:

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- The client's site(s)
- Processes and equipment used
- Levels of controls established (particularly in case of multi-Site clients)
- Applicable statutory and regulatory requirements

- The level of implementation (through the assessment of management review and internal audit activities)
- Declaration of liability from the top management in place
- Status of documentation confirming with the requirements of Section 2.2 of Annex IX of Regulation (EU) 2017/745 or Regulation (EU) 2017/746
- Appropriate process for managing risk and a process for clinical evaluation in place
- **The level of control of all critical suppliers and determination if a critical supplier audit is required to be a part of the initial certification**
- If the manufacturer has an extensive critical supplier list, then time may be required to be added to the initial certification audit to ensure proper controls are in place
- Planning and resources needed for the stage 2 audit

The system analysis is documented with a report using "FO-00471 Client QMS Stage 1 report". The auditor uploads the audit report into WIS and Operations submits the report immediately after the audit to the client.

In the event of a negative result of the system analysis, the assessment is terminated with a negative result.

A stage 1 audit can be repeated once within 60 days after the client has been informed about the negative result. In case that the second stage 1 audit results again in a negative decision then the conformity assessment process will be aborted.

The PL initiates the final review and decision making process with the recommendation to abort the conformity assessment process.

In the event of a positive result of the system analysis further steps for the system audit (stage 2) can be planned. The auditor agrees the audit date directly with the client and informs the project leader accordingly. The project leader informs the planning team to assign the orders for the stage 2 audit. The project leader must always ensure that the results of the system analysis are taken into account in the QMS on-site audit.

Note: If the system audit (stage 2) is not carried out within 6 months after the system analysis, a new system analysis (stage 1) is required.

4.2.2. Stage 2 audit

The same lead auditor should perform stage 1 and stage 2 audits.

Stage 2 Audit aims to evaluate the implementation, including the effectiveness of the client's quality management system. Stage 2 shall take place at the site(s) of the client. In certain and justified cases, the audits can also be carried out in hybrid form. That means that at least one auditor is present on the premises of the manufacturer and other members of the audit team participating from elsewhere using information and communication technologies (ICT).

For MDR/IVDR, the audit team shall cover **ALL** MDT/IVT codes.

The stage 2 audit shall include the Auditing of at least the following:

- Information and evidence about conformity to all requirements of the applicable quality management system standard or other normative documents

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- Performance monitoring, measuring, reporting, and reviewing against key performance objectives and targets (consistent with the expectations in the applicable quality management system standard or other normative documents)
- The client's quality management system ability and its performance regarding the meeting of applicable statutory, regulatory, and contractual requirements
- Operational control of the client's processes
- Internal auditing and management review
- Management responsibility for the client's policies
- The audit team shall analyze all information and audit evidence gathered during stage 1 and stage 2 to review the Audit findings and agree on the audit conclusions.

QMD Services ensures that audit findings are appropriately and consistently classified in accordance with the requirements of the Regulation (EU) 2017/745 or Regulation (EU) 2017/746 and with relevant standards, or with best practice documents developed or adopted by the MDCG. These are recorded and managed by using "FO-00391 Audit finding list".

The detailed requirements of RE (EU) 2017/745 or RE (EU) 2017/746 which need to be checked on-site are included in "FO-00469 MDR Client QMS Audit checklist"/ "FO-00473 IVDR Client QMS Audit checklist"

A formal closing meeting, where attendance is recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited.

The purpose of the closing meeting, conducted by the lead auditor, is to present the audit conclusions, including the preliminary recommendation regarding certification. The items which should be addressed during the closing meeting are included in "FO-00469 MDR Client QMS Audit checklist" / "FO-00473 IVDR Client QMS Audit checklist".

Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

The customer needs to accept the non-conformities by signing "FO-00391 Audit finding list" before the on-site audit is closed.

The audit team must analyze all information and audit evidence collected during the audit to evaluate audit findings and agree on audit conclusions. The result of the audit is summarized in an audit report "FO-00392 Client QMS Audit Report".

All applicable processes are to be reviewed

In the event of any detected discrepancies, certificate issuance can only take place after the non-conformities have been closed-out.

4.2.1 第一阶段审核（Stage 1 Audit）

第一阶段审核应包含以下内容：

- 审查质量管理体系文件；
- 确定是否具备开展第二阶段审核的准备条件；
- 确定影响第二阶段审核时间和审核计划的因素；

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- 评估受审核方/公司的状态以及其对体系、关键绩效要求、重要要求、相关过程、目标和运行情况的理解程度；
- 收集有关质量管理体系覆盖范围的必要信息，包括：
  - 客户的现场（Site）情况；
  - 使用的流程和设备；
  - 建立的控制等级（尤其适用于多场所客户）；
  - 适用的法律法规要求；
  - 实施程度（通过对管理评审和内部审核活动的评估）；
  - 管理层签署的责任声明；
  - 文件状态是否符合 MDR/IVDR 附录 IX 第 2.2 节的要求；
  - 风险管理和临床评估程序的建立情况；
  - 对所有关键供应商的控制水平，并判断是否需要将关键供应商审核纳入初始认证的一部分；
  - 若制造商存在大量关键供应商，可能需要延长初始认证审核时间以确保控制措施充分；
  - 第二阶段审核所需的策划与资源准备情况。

系统分析的审核结果记录在《FO-00471 客户 QMS 第一阶段审核报告》中。审核员需将报告上传至 WIS 系统，运营部门应在审核结束后立即将报告提交给客户。

若系统分析结果为负面结论，则评审过程终止。

客户在收到负面结果后，可在 60 日内重复进行一次第一阶段审核。若第二次第一阶段审核仍为负面结果，则合规性评审流程将被终止。

项目负责人应启动最终审议和决策流程，并提出终止合规性评审流程的建议。

若系统分析结果为正面，则可继续开展第二阶段审核的策划工作。审核员应直接与客户商定审核日期，并通知项目负责人。项目负责人通知计划部门分配第二阶段审核任务，并确保系统分析的结果已在第二阶段审核计划中被纳入考虑范围。

注：若第二阶段审核未在系统分析完成后的 6 个月内执行，则需重新进行第一阶段审核。

4.2.2 第二阶段审核（Stage 2 Audit）

第一阶段与第二阶段审核应由同一位审核组长主导完成。

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第二阶段审核旨在评估客户质量管理体系的实施情况及其有效性。该审核应在客户现场进行；在特定合理情形下，也可采用混合形式审核，即至少有一名审核员在制造商现场，其他审核员通过信息与通信技术（ICT）远程参与。

根据 MDR/IVDR 要求，审核组需涵盖所有适用的 MDT/IVT 代码。

第二阶段审核应包括但不限于以下内容：

- 对客户质量管理体系是否符合适用标准及其他规范性文件的要求进行信息和证据的收集与审查；
- 对照关键绩效目标和指标，对绩效的监测、测量、报告和评审机制进行审核（需符合适用管理体系标准及规范性文件的预期）；
- 审查客户的质量管理体系能力及其在满足法律、法规和合同要求方面的执行情况；
- 对客户流程的运行控制进行审核；
- 审查内部审核和管理评审的实施情况；
- 审查管理层对公司政策的职责履行情况。

审核组需整合第一阶段与第二阶段期间收集的所有信息与审核证据，以分析审核发现并形成审核结论。

QMD Services 将确保审核发现根据《欧盟法规（EU）2017/745》或《欧盟法规（EU）2017/746》、相关标准或 MDCG 制定/采纳的最佳实践文件进行适当且一致的分级，并通过《FO-00391 审核发现清单》进行记录与管理。

需现场审核的法规要求详见《FO-00469 MDR 客户 QMS 审核清单》/《FO-00473 IVDR 客户 QMS 审核清单》。

必须召开正式末次会议，记录出席人员，由客户管理层及相关职能或被审核流程的负责人参加。

该会议由审核组长主持，主要目的是汇报审核结论并提出初步的认证建议。会议应覆盖《FO-00469 MDR 客户 QMS 审核清单》/《FO-00473 IVDR 客户 QMS 审核清单》中列出的所有内容。

所有不符合项应以客户明确理解的方式进行说明，并与客户协商整改期限。客户必须在现场审核结束前通过签署《FO-00391 审核发现清单》接受不符合项。

审核组需分析审核过程中收集的所有信息与证据，形成审核结论，并通过《FO-00392 客户 QMS 审核报告》进行总结。

所有适用流程均需被评审。

若发现存在任何差异或不符合项，仅在所有不符合项关闭后方可颁发证书。

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4.3. Surveillance audit

Surveillance audits are carried out to ensure that the manufacturer in question applies the approved quality management system and the post- market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, QMD Services, where necessary, carry out or ask for tests in order to check that the quality management system is working properly.

At least one of the codes within each applicable code category (e.g., MDT, IVT) must be covered at each surveillance audit.

Surveillance audits are carried once per year after the date of the issuance of the certificate. The first surveillance audit after the initial audit needs to take place within 12 months after issuance of the certificate. In case that project planning ("SOP-00123 Project Management") will verify that significant quality system changes have been reported by the manufacturer ("FO-00411 IVDR Change Notification" or "FO-00567 MDR Change notification"), the auditor may receive the instruction to perform a Stage 1 audit before the system audit.

During surveillance audits the results from the technical document conformity assessment have to be taken into account. These results and follow-up findings are documented in "FO-00402 Follow Up Request" and are available for the audit team members via WIS.

Some special aspects are to be considered for a surveillance audit. These aspects are included in "FO-00469 MDR Client QMS Audit checklist" / "FO-00473 IVDR Client QMS Audit checklist".

In the case of class III devices, the QMS surveillance assessment will include a test of the approved parts and/or materials that are essential for the integrity of the device, including where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

QMD Services will provide the manufacturer with a surveillance audit report "FO-00392 Client QMS Audit Report" and, if a test has been carried out, with a test report.

For any major nonconformity, QMD Services shall define time limits for correction and corrective actions. These actions shall be implemented and verified within 14 – 30 calendar days.

4.4. Calculation of audit time

Audit times are calculated by the means of "FO-00449 Audit Calculator". As a basic amount of audit hours the calculation according to IAF MD9 based on the employee numbers is used adding 25% for the IVDR/MDR.

Conditions where additional time may be required include differences in scope, high amount of medical devices in the portfolio, size of manufacturinf site, etc. High risk devices normally require more audit time.

The duration of an audit day is normally 8 hours and may or may not include a lunch break depending upon local legislation.

The effective number of personnel consists of all personnel (permanent, temporary, and part-time) involved within the scope of certification including those working on each shift.

A reduction of audit time of management systems shall not exceed 30% of the times established in IAF MD9.

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Further factors which may influence the duration of the audit are:

- initial audit (i.e. the site's first ever audit) – it is likely that the auditor will require additional time, for example, during opening and closing meetings
- communication difficulties, e.g. language
- several conformity assessments routes for different devices
- significant number of certificates
- audit scope including class III, class D devices
- number of MDA or MDN (MDR) or IVR (IVDR) codes included in the audit scope
- Manufacturers using suppliers to supply processes or parts that are critical to the function of the medical device and/or the
- safety of the user or finished products the number of non-conformities recorded in the previous audit
- Complicated logistics involving more than one building or location
- Manufacturing in clean rooms and / or in-house sterilization activities (MDT 2008, MDS 1005, IVT2008, IVS1005)

If additional requirements are added to the scope of the audit like ISO 13485, additional audit time of 25% of the IAF MD9 time may be added.

4.3 监督审核（Surveillance Audit）

监督审核的目的是确保制造商持续实施经批准的质量管理体系以及其上市后监督计划。此类审核应包括制造商现场的审核，以及在适当情况下对制造商的供应商和/或分包商的审核。必要时，QMD Services 可在现场审核期间开展或委托开展相关测试，以验证质量管理体系是否正常运行。

每次监督审核中，必须覆盖每一类适用代码（如 MDT、IVT）中的至少一个代码。

监督审核应在证书签发后的每一年进行一次。初次认证后的第一次监督审核必须在证书签发后 12 个月内完成。

若项目策划流程（《SOP-00123 项目管理》）确认制造商已报告了重大质量体系变更（如通过《FO-00411 IVDR 变更通报》或《FO-00567 MDR 变更通报》），审核员可能会被指示在体系审核前重新执行第一阶段审核。

监督审核时，应纳入技术文件符合性评审的结果。这些结果及其后续处理通过《FO-00402 跟进请求表》记录，并可通过 WIS 系统供审核团队成员访问。

监督审核应关注一些特殊方面，这些内容在《FO-00469 MDR 客户 QMS 审核清单》 /《FO-00473 IVDR 客户 QMS 审核清单》中有所体现。

若涉及 III 类器械，质量管理体系的监督审核应包括对所批准的零部件和/或材料的检测（这些材料对器械完整性至关重要），必要时还应核查所生产或采购的零部件数量是否与成品器械数量一致。

QMD Services 应向制造商提供《FO-00392 客户 QMS 审核报告》。如有进行测试，还应提供测试报告。

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对于严重不符合项，QMD Services 应规定整改与纠正措施的时间限期，并要求在 14–30 个自然日内完成实施与验证。

4.4 审核时间的计算（Calculation of Audit Time）

审核时间根据《FO-00449 审核时间计算器》计算。基础审核工时的计算基于 IAF MD9 中的员工数量规则，并在此基础上增加 25%以覆盖 IVDR/MDR 的附加要求。

在以下情况下可能需要额外审核时间：

- 认证范围复杂或存在差异；
- 医疗器械种类繁多；
- 生产场所规模较大；
- 高风险器械通常需要更长的审核时间。

标准审核日时长为 8 小时，视当地法律规定，可能包含或不包含午休时间。

"有效人员数"应包括所有在认证范围内参与活动的人员（包括全职、兼职和临时员工），并涵盖所有轮班工作者。

管理体系的审核时间减时不得超过 IAF MD9 规定时间的 30%。

其他可能影响审核时长的因素包括：

- 初次审核（即该场所首次审核）可能需增加审核时间（如首次/末次会议）
- 语言障碍或沟通困难；
- 不同器械采取多种合规评审路径；
- 持有大量认证证书；
- 审核范围中包含 III 类（MDR）或 D 类（IVDR）器械；
- 审核中涉及多个 MDA/MDN（MDR）或 IVR（IVDR）代码；
- 使用对医疗器械功能和使用安全至关重要的供应商所提供的过程或零部件；
- 上次审核中存在大量不符合项；
- 多地点或建筑物流复杂；
- 使用洁净室生产、或执行内部灭菌工艺（如 MDT 2008、MDS 1005、IVT2008、IVS1005）；

如审核范围增加了如 ISO 13485 等附加标准，应增加相当于 IAF MD9 规定时间 25%的额外审核时长。

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4.5. Re-certification

The re-certification according to Regulation (EU) 2017/745 or RE (EU) 2017/746 will be carried out within 5-years after the initial certification or last re-certification or timely before the expiry of the certificate.

When planning the re-certification by the lead auditor, the performance of the company's management system must be taken into account. This includes, but is not limited to, the review of the company's management documentation and a review of audit reports from the previous certification cycle.

Re-certification of approved quality management systems or EU technical documentation certificates is considered in the assessment program ("FO-00410 MDR Assessment Program") and has to be carried out at least every five years.

A re-certification shall be planned and conducted to evaluate the continued fulfilment of all of the requirements of IVDR or MDR. This shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date. The on-site audit shall take place timely before expiry of the certificate.

The manufacturer is required to submit a summary of changes and scientific findings for the device by the means of "FO-00399 Re-certification Client Readiness check", including:

- all changes to the originally approved device, including changes not yet notified,
- experience gained from post-market surveillance,
- experience from risk management,
- experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,
- experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,
- changes to the requirements, to components of the device or to the scientific or regulatory environment,
- changes to applied or new harmonised standards, Common Specifications or equivalent documents, and
- changes in medical, scientific and technical knowledge, such as:
  - new treatments,
  - changes in test methods,
  - new scientific findings on materials and components, including findings on their biocompatibility,
  - experience from studies on comparable devices,
  - data from registers and registries,
  - experience from clinical investigations with comparable devices.

The received information is assessed by the internal clinician whereas particular attention shall be paid to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' clinical evaluation reports. The documentation for this assessment is done on "FO-00399 Re-certification Client Readiness check".

The process of re-certification is equivalent to the initial certification therefore "PRC-00081 Client Applications", SOP-00123 Project Management, SOP-00088 Conformity Assessment Orders as well as "SOP-00087 MDR Conformity Assessment Overview" and "SOP-00119 IVDR Conformity Assessment Overview" are applicable.

For any major nonconformity, QMD Services shall define time limits for correction and corrective actions. These actions shall be implemented and verified prior to the expiration of

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certification. When re-certification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the re-certification decision.

In the event of any non-conformities detected, the certificate can only be issued after the non-conformities have been closed.

If QMD Services has not completed the re-certification audit or is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then the validity of the certification shall not be extended. The client shall be informed and the consequences shall be explained.

Following expiration of certification, QMD Services can restore certification within 6 months provided that the outstanding re-certification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the re-certification decision and the expiry date shall be based on prior certification cycle.

4.6. Follow-up audits

A follow-up audit may be necessary after any audit in order to verify the implementation of corrective measures to non-conformities. The deadlines for reporting the original audit remain unaffected. The follow-up audit can be carried out on-site or as an off-site document check.

The order for the follow-up audit will generaly be assigned after the audit report from the previous audit is uploaded and accepted in WIS.

The lead auditor ensures that the customer provides the evidence on time and clarifies with the project leader the further procedure if the documents are not made available on time.

The non-conformity cannot be closed until the action plan has been completed and is accepted by the lead auditor and uploaded in the WIS system.

4.5 再认证审核（Re-certification）

根据《欧盟法规（EU）2017/745》或《欧盟法规（EU）2017/746》，再认证审核应在初始认证或上一次再认证后的 5 年内，或在现有证书到期前及时进行。

在审核组长规划再认证时，必须综合考虑企业质量管理体系的运行绩效。这包括但不限于：审查企业的管理体系文件，以及前一认证周期的审核报告。

经批准的质量管理体系或欧盟技术文件证书的再认证，已纳入评审计划（见《FO-00410 MDR 评审计划》），并须至少每 5 年执行一次。

再认证审核的策划与实施应确保评估制造商持续满足 MDR/IVDR 的所有要求，并需在证书到期前适时进行现场审核以确保证书可及时续发。

制造商须通过《FO-00399 再认证客户准备检查表》提交以下内容的摘要材料：

- 所有已批准产品的变更，包括尚未通报的变更；
- 上市后监督的经验；

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- 风险管理的经验；
- 对附录 I 中基本安全与性能要求的符合性证据更新；
- 临床评估的复审经验，包括任何临床试验和 PMCF 活动的结果；
- 法规、器械组件或科学/监管环境的变化；
- 已采用或新增的协调标准、通用规范（Common Specifications）或等效文件的变化；
- 医疗、科学及技术知识的更新，例如：
  - 新疗法；
  - 检测方法的改变；
  - 有关材料和组件（包括生物相容性）的新科学发现；
  - 与同类器械的研究经验；
  - 登记数据库或注册系统中的数据；
  - 有关同类器械的临床研究数据。

上述资料将由内部临床审核人员进行评估，重点关注上市后监督（PMS）与 PMCF 活动新获得的临床数据，必要时更新制造商的临床评估报告。所有评估过程记录在《FO-00399 再认证客户准备检查表》中。

再认证流程等同于初始认证，因此适用以下程序与文件：

- 《PRC-00081 客户申请流程》
- 《SOP-00123 项目管理》
- 《SOP-00088 合规性评审订单》
- 《SOP-00087 MDR 合规性评审总览》
- 《SOP-00119 IVDR 合规性评审总览》

如发现严重不符合项，QMD Services 应设定整改与纠正措施的时间限期，且必须在认证到期前完成验证。若在证书到期前完成再认证流程，则新证书的到期日可延续原证书的有效期，但新证书的签发日期应不早于再认证决策日。

如审核中发现不符合项，必须在完成整改并关闭后方可颁发新证书。

若 QMD Services 未能在证书到期前完成再认证审核，或未能验证严重不符合项的整改措施是否落实，则不得延长证书有效期，应告知客户并说明其后果。

若证书已到期，QMD Services 仍可在 6 个月内恢复认证前提是所有未完成的再认证活动得以完成；否则，至少需重新执行第二阶段审核。新证书的起始日期为再认证决策日，到期日按原认证周期计算。

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4.6 跟进审核（Follow-up Audit）

如在任何审核中发现不符合项，可能需安排跟进审核以验证纠正措施的实施情况。该跟进审核不影响原审核报告的截止提交时间要求。跟进审核可作为现场审核或远程文件审核进行。

跟进审核的订单通常在前次审核报告上传并被 WIS 系统接受后分配。

审核组长负责确保客户按时提供整改证据。如客户未按时提交，审核组长应与项目负责人沟通下一步处理方式。

在整改方案被接受并由审核组长审核通过且上传至 WIS 之前，该不符合项不得被关闭。

5. Unannounced audits and for-cause audits

Unannounced audits shall be performed according to Regulation (EU) 2017/745 or RE (EU) 2017/746 Annex IX 3.4. Unannounced audits shall be performed by QMD Services at least once every five years on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors. The unannounced audits may be combined with the periodic surveillance audits (see section 4.3 above) or be performed in additional to the surveillance audit. Unannounced audits may be carried out in a hybrid manner.

5.1. General aspect related to a contract

Unannounced audits on the premises of the manufacturer or its critical subcontractors or crucial suppliers are regulated in the contractual arrangements between the notified bodies and the manufacturers. There, in acc. with the recommendation the following points, among others, are regulated: continuous information on the periods when devices will not be manufactured, the measures to be taken to ensure the security of the auditors, provide for financial compensation for the unannounced audits, etc. (further information see "LEG-00455 Terms and Conditions: Addendum" and "SOP-00078 Pricing Structure").

5.2. Determination of frequency

According to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 Annex IV 3.4 the minimum frequency for unannounced audits without a specific cause is at least once every five years at the manufacturer´s site (and, if applicable, the manufacturer´s critical supplier and/or its subcontractors). QMD Services considers the risk class and type of products when determining intervals.

The following information may affect the frequency of unannounced audits:

1) Actual rates of incident and/or complaints exceeds the expected limits of the clinical evaluation report and risk management report
2) Information from contributing experts/product reviewers/auditors regarding: indications of the existence of a violation of the terms and conditions of QMD Services indications for breach of reporting obligations
3) Many - nonconformities from the regular audit, technical documentation review and change notifications or objections to audits at a manufacturer's site may also lead to

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unannounced audits without cause in one or more (other) sites of the manufacturer with further random sampling.

4) Hints from the market/market observation/change of state of the art

However, these audits are always for cause-related unannounced audits that are not subject to the requirement of at least once within five years.

5. 不预先通知的审核与因特殊原因进行的审核

不预先通知的审核应依据《欧盟法规（EU）2017/745》或《欧盟法规（EU）2017/746》附录 IX 第 3.4 条的规定执行。QMD Services 应至少每五年对制造商的现场及（如适用）其供应商和/或分包商进行一次不预先通知的审核。不预先通知的审核可与定期监督审核（参见 4.3 节）结合进行，或单独执行。该类审核亦可采用混合审核方式实施。

5.1 与合同相关的一般事项

在制造商或其关键分包商/关键供应商场所进行的不预先通知审核，必须在公告机构与制造商签署的合同条款中予以明确。依据相关建议，合同中应规定如下要点（包括但不限于）：

- 持续通报制造商产品不在生产期间的信息；
- 确保审核员人身安全所需的措施；
- 关于不预先通知审核的财务补偿安排。

（详见《LEG-00455 条款与条件：补充协议》及《SOP-00078 价格结构》）

5.2 频次的确定

根据《欧盟法规（EU）2017/745》和《欧盟法规（EU）2017/746》附录 IX 第 3.4 条，不具特定原因的不预先通知审核的最小频率为每五年至少一次，需在制造商现场（以及如适用的关键供应商/分包商）执行。

QMD Services 在确定具体审核间隔时，将参考产品的风险等级与类型。

以下信息可能会影响不预先通知审核的频率：

1. 事件率和/或客户投诉数量超过临床评估报告及风险管理报告中预期限值；
2. 来自专家、产品评审员或审核员的信息，例如：
    - 存在违反 QMD Services 条款与条件的迹象；
    - 存在违反报告义务的迹象；

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3. 常规审核、技术文件评审或变更通报中发现多项不符合项，或制造商现场审核中存在质疑，可能导致在一个或多个制造商地点（含其他地点）开展无特定原因的不预先通知审核，并进一步执行抽样；

4. 来自市场的信息、市场观察结果、或技术发展状态的变化等提示信息。

需要注意的是：上述情况引发的审核均为因特殊原因而进行的不预先通知审核，因此不计入最低五年一次的审核频次要求。

5.3. Defining audit team

The selection of auditors is carried out against the criteria set out in "PRC-00005 Allocation of Resources".

These audits are to be scheduled with at least 2 auditors for at least one day (Recommendation 2013/473/EU, Annex III). It is required that at least one of the auditors is a permanent employee of the Notified Body and at least one person is qualified as a product reviewer and has sufficient experience in the technology concerned. The audit team must have the complete qualification for the selected products for which a review is planned as part of an unannounced audit.

QMD includes the planning of such unannounced on-site audits in its assessment program "FO-00410 MDR Assessment Program" / "FO-00412 IVDR Assessment Program" but will not disclose it to the manufacturer.

For-cause audits or audits for special reasons may be necessary, for example, for:

- Expanding the scope
- Short notice announced audits to review complaints, significant changes and after suspension of certificates

In the event of incidents with products on the market, these reviews can be announced and unannounced

In the unannounced audits, the audit targets and criteria are determined on a case-by-case basis by QMD Services but include checking an appropriate sample of manufactured products or an appropriate sample from the manufacturing process to check whether the products comply with the specifications of the technical documentation.

5.4. Scope of Audit

Within the context of such unannounced audits, QMD Services check a recently produced adequate sample, preferably a device taken from the ongoing manufacturing process, for its conformity with the technical documentation and with legal requirements. The check of the conformity of the device includes the verification of the traceability of all critical components and materials and the manufacturer's traceability system. The check encompasses a file review and, if necessary, to establish conformity, a test of the device. QMD Services retains the right, in addition to the steps foreseen in Sections 1, 2, and 3 of the Recommendation 2013/473/EU, AnnexIII, to verify whether the manufacturing activity is ongoing at the time of the unannounced audit.

Regarding sampling regulations, QMD Services follows the recommendations set out in point 4, Annex III.

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In addition to the steps foreseen in Sections 1, 2, and 3, QMD Services will verify whether the manufacturing activity is in line with the manufacturer's documentation relevant for the manufacturing and in conformity with legal requirements (two critical processes such as design control, the establishment of material specifications, purchasing and control of incoming material or components, assembling, sterilization, batch-release, packaging, or product quality control).

5.5. Selection of the products to be reviewed

The following criteria are defined for the selection of -medical or in-vitro diagnostic devices to be reviewed:

1) Criticality: Critical medical or in-vitro diagnostic devices are:
   - medical devices falling under Regulation (EU) 2017/745 MDR: implantable Class IIb and Class IIb active devices.
   - in-vitro diagnostic devices falling under Regulation (EU) 2017/746 IVDR: Class C and Class D, self-testing devices, near-patient devices, companion diagnostics
   - life-sustaining medical devices
   - innovative medical or in-vitro diagnostic devices
   - Medical or in-vitro diagnostic devices for which information regarding serious incidents is available
   - Medical or in-vitro diagnostic devices with critical production steps
2) Risk class: the following general rule applies: The medical product of the highest risk class in the company's portfolio is selected unless
   - there is another product of a lower risk class that meets one or more criteria in point 1).
   - the product of the highest risk class is in a review (as a sample or change notification).
   - there is an indication (by the auditor, product and/or final review, etc.) for testing a particular product (see also "Determining Frequency" above).
   - the product of the highest risk class has already been audited (in the last 6 months) and there is another lower risk product that has not yet been reviewed as a sample or change report.
   - the product of highest risk class has already been reviewed (in the last 6 months) and there are other products, product groups, or subcategories of a lower risk class, for which nonconformities from previous audits are documented.

It is the responsibility of the project leader to select the product to be reviewed.

5.3 审核组的定义（Defining Audit Team）

审核员的选定应符合《PRC-00005 资源分配程序》中规定的标准。

不预先通知审核应由至少两名审核员进行，持续至少一天（依据《2013/473/EU 建议》第 III 附录）。其中至少一名审核员须为公告机构的正式员工，并且至少有一人具备产品评审员资格，且在相关技术领域具有充分经验。

审核组必须具备对计划评审产品的全范围资质能力，以满足不预先通知审核的要求。

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QMD Services 将不预先通知的现场审核纳入其评审计划中（见《FO-00410 MDR 评审计划》/《FO-00412 IVDR 评审计划》），但不会将该审核计划提前告知制造商。

因特殊原因的审核（for-cause audit）或其他特殊审核（special audits）可能在以下情况下执行，例如：

- 认证范围扩大；
- 快速通知后的审核（例如用于处理投诉、重大变更、证书暂停后的恢复审核）。

若市场上发生器械相关事件，此类评审可为通知或不通知审核。

对于不预先通知审核，审核目标和准则由 QMD Services 视个案确定，通常包括从正在生产过程或成品中抽取适当样品以验证其是否符合技术文件要求。

5.4 审核范围（Scope of Audit）

在不预先通知审核中，QMD Services 应抽取近期生产的器械样品（优先选取来自正在生产过程中的器械），以验证其是否符合技术文件及法规要求。

器械的符合性核查应包括：

- 对所有关键部件和材料的可追溯性验证；
- 对制造商追溯体系的评估；
- 文件审核（如有必要，包含器械测试以确立合规性）。

除履行《2013/473/EU 建议》第 III 附录第 1、2、3 项的要求外，QMD Services 保留验证生产活动是否在审核时正在进行的权利。

在抽样规范方面，QMD Services 遵循该建议附录 III 第 4 项的规定。

此外，QMD Services 还将核查制造活动是否与制造商相关文档一致，并符合法规要求。该核查应涵盖两个关键过程，如：

- 设计控制；
- 材料规格的建立；
- 材料或部件的采购与进料检验；
- 组装、灭菌、批次放行；
- 包装与产品质量控制。

5.5 被审核产品的选择（Selection of the Products to Be Reviewed）

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以下标准用于选择需审核的医疗器械或体外诊断器械：

- **1) 关键性（Criticality）**

具有以下特征的产品被视为关键器械：

- 根据《MDR（EU）2017/745》：可植入的 **IIb 类器械**与有源 **IIb 类器械**；
- 根据《IVDR（EU）2017/746》：**C 类与 D 类体外诊断器械**、自测产品、近患者检测设备、伴随诊断产品；
- 维持生命所必需的医疗器械；
- 具有创新性的医疗器械或体外诊断器械；
- 已获得严重事件报告的器械；
- 含有关键生产步骤的医疗器械或体外诊断器械。

- **2) 风险等级（Risk Class）**

基本规则：选择制造商产品组合中**风险等级最高的产品**，除非符合以下任一情况：

- 存在风险等级较低但满足第 1 项中任一标准的产品；
- 风险等级最高的产品已处于其他审核评估中（如作为样品或变更评审对象）；
- 审核员、产品评审员等提供了需针对某特定产品开展审核的指示（参考 5.2 节"频次的确定"）；
- 过去 6 个月内已对风险等级最高的产品执行过审核，且存在其他未评审的低风险产品；
- 过去 6 个月内风险等级最高的产品已被评审，且存在其他产品/产品组/子类别属于低风险等级，但在先前审核中记录存在不符合项。

由**项目负责人（Project Leader）负责最终决定审核产品的选择**。

6. Preparing the on-site audit

In order to prepare the on-site audit (Stage 2, surveillance, unannounced or recertification audits), the lead auditor receives via WIS the relevant information about the organization to be reviewed.

The lead auditor must agree with the client the dates of the audit.

He is also resonsible for coordinating travel, timely start, proper conduct of the assessment and the necessary resources.

The lead auditor must issue the audit plan "FO-00384 QMS Audit Plan" and shall communicate the audit plan at least 2 weeks in advance, to the client. The audit plan shall include all members of the audit team including if applicable observers and/or witness auditors.

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6.1. Administrative organisation/preparation

The lead auditor is responsible for:

- Preparation of the audit plan, including
  - Consultation with the organization to be surveyed on whether the agreed date can be met.
  - Reviewing the provided information to develop an audit-plan covering all necessary aspects (including all findings and information from the assessment of the technical documentation)
  - Identification and communicating the need for interpreters
  - Required personal protective equipment (PPE) e.g helmet, safety shoes, safety goggles, cleanroom clothes
  - If a site has cleanrooms, the lead auditor is to confirm any special requirements that the audit team should be aware of
- Agreement with the audit team on audit time and assignments
- Directions to the organization and hotel to the audit team
- In case of hybrid audits, coordinate with the manufacturer the communication technology to be used

Each audit team member organizes for themselves and uploads respective receipts in WIS directly:

- Hotel reservation and bill
- Transport fees;
- Note for flight booking: flights are to be booked directly through the QMD Services booking agency

The auditors receive all necessary documents to be reviewed prior to the on-site audit via the WIS system directly after the assessment confirmation (see "PRC-00005 Allocation of Resources").

A coordination between the audit team will take place in a timely manner before the on-site audit. The agenda includes:

- Focal points of the audit
- Assessing and sharing any relevant results of other conformity assessment activities (e.g. review of technical documentation, review of clinical assessment)
- Changes in details of planning if necessary
- Planning the shared trip if needed
- Arrival to the audit (separate, common)

6. 现场审核准备（Preparing the On-Site Audit）

为准备现场审核（包括第二阶段审核、监督审核、不预先通知审核或再认证审核），审核组长将通过 WIS 系统 获取有关待审核组织的相关信息。
审核组长必须与客户确认审核日期，并负责协调差旅安排、审核准时开始、审核活动的规范执行及所需资源的落实。
审核组长需制定审核计划《FO-00384 QMS 审核计划》，并至少提前两周向客户发送。审核计划中应列明审核组的所有成员，如适用，还应包括观察员和/或见证审核员。

6.1 行政组织/准备工作（Administrative Organisation / Preparation）

审核组长的职责包括：

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- 编制审核计划，其中包括：
  - 与受审核组织确认所约定的审核日期是否可行；
  - 审查所提供的信息，制定覆盖所有必要审核内容的审核计划（包括技术文件评审中提出的所有发现和信息）；
  - 确认是否需要口译服务，并提前沟通安排；
  - 确定是否需要穿戴个人防护装备（PPE），如安全帽、防护鞋、防护眼镜、洁净室服等；
  - 若审核场所含有洁净室，应与客户确认是否有任何审核组应遵守的特殊要求；
  - 与审核组成员协商审核时间及分工任务；
  - 提供审核场所及酒店的路线指引给审核组成员；
  - 若为混合审核形式，应与制造商协调所使用的通信技术工具。

审核组成员个人准备与报销上传
每位审核组成员需自行完成以下安排，并将相应单据直接上传至 WIS 系统：

- 酒店预订与发票
- 交通费用（如出租车、地铁等）
- 航班预订须知：航班需通过 QMD Services 指定预订机构进行预订

审核前的审核组协调会议
在现场审核前，应适时组织审核组内部协调会议，议题包括：

- 审核的重点与关注领域；
- 分享并评估其他合规评审活动的相关结果（如技术文件评审、临床评估等）；
- 如有需要，对审核计划进行调整；
- 协调是否需共同行程安排（如拼车）；
- 审核当天的到达安排（分别抵达或统一抵达）。

7. Conduction of the on-site audit

7.1. Opening Meeting

The lead auditor starts the audit with a formal opening meeting. Participants of the opening meeting shall be the client's management, the PRRC (Person Responsible for Regulatory Compliance) and, where appropriate, those responsible for the functions or processes to be audited. The purpose of the opening meeting, conducted by the audit team leader, is to provide a short explanation of the purpose of the audit and how the audit activities will be undertaken. The items which should be addressed during the opening meeting are included in "FO-00469 MDR Client QMS Audit checklist" / "FO-00473 IVDR Client QMS Audit checklist".

7.2. Carrying out the quality management system audit

The audit of the management system is carried out on the basis of the requirements of the MDR or IVDR ("FO-00469 MDR Client QMS Audit checklist" / "FO-00473 IVDR Client QMS Audit checklist") and a report template ("FO-00392 Client QMS Audit Report").

During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be obtained by appropriate sampling and verified to become audit evidence.

Methods to obtain information shall include, but are not limited to:

a) interviews

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b) observation of processes and activities
c) review of documentation and records

Identified non-conformities and corrective actions taken must be discussed with the top management and its representatives during the closing meeting (see sec 6.6).

The audit includes both, the assessment of the effective implementation of the requirements of the Regulation (EU) 2017/745 or RE (EU) 2017/746 and the effectiveness of the QM system in daily live practice.

As part of the required evidence, at least the results of a complete cycle of internal system audits and the management review are considered.

Depending on the degree of control of the manufacturer over its subcontractors and/or suppliers, the relevant manufacturing processes will be assessed in the manufacturing facilities of these subcontractors and/or suppliers. The justification criteria for a supplier audit are described in "SOP-00123 Project Management".

If an audit at subcontractors and/or critical suppliers is omitted, this decision must be adequately justified by the auditor or the relevant specialist experts and must already be considered in the assessment program "FO-00410 MDR Assessment Program"/ "FO-00412 IVDR Assessment Program", as covered in the "CL supplier audit" tab of the workbook.

7.3. Communication during the audit

During the audit, the audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.

7. 现场审核的实施（Conduction of the On-Site Audit）

7.1 开场会议（Opening Meeting）

审核由审核组长主持正式开场会议拉开序幕。

会议参与人员应包括：

- 客户管理层；
- 法规符合性负责人（PRRC）；
- 如适用，还应包括与即将接受审核的职能或流程相关的负责人。

开场会议的目的在于由审核组长向与会人员简要说明本次审核的目的及执行方式。

应在开场会议中涉及的事项详见：

- 《FO-00469 MDR 客户 QMS 审核清单》
- 《FO-00473 IVDR 客户 QMS 审核清单》

7.2 执行质量管理体系审核（Carrying out the Quality Management System Audit）

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管理体系的审核基于以下标准文件执行：

- 《FO-00469 MDR 客户 QMS 审核清单》
- 《FO-00473 IVDR 客户 QMS 审核清单》
- 审核报告模板《FO-00392 客户 QMS 审核报告》

在审核过程中，应通过适当的抽样获取并验证与以下内容相关的信息作为审核证据：

- 审核目标；
- 审核范围；
- 审核准则；
- 各职能、活动及流程之间的接口信息。

获取信息的方法包括但不限于：

a) 访谈；
b) 对流程及活动的现场观察；
c) 文件和记录的审查。

在末次会议（见第 7.6 节）中，所有已识别的不符合项及相关纠正措施必须与管理层及其代表进行讨论。

此次审核应涵盖两方面内容：

- 是否有效落实了《欧盟法规（EU）2017/745》或《EU）2017/746》所要求的条款；
- 质量管理体系在日常实际运行中的有效性。

作为必要的审核证据，至少需审核以下两个要素的结果：

- 完整的内部审核周期；
- 管理评审活动。

若制造商对其分包商和/或供应商的控制度有限，相关的生产过程应在这些分包商或供应商的场所中接受审核。

对是否执行关键供应商/分包商审核的判断标准详见《SOP-00123 项目管理程序》。

若不执行对关键供应商或分包商的现场审核，必须由审核员或相关技术专家提供充分的书面理由，且该决定应已纳入审核计划（见《FO-00410 MDR 评审计划》/《FO-00412 IVDR 评审计划》），并在"CL supplier audit"工作表中列明。

7.3 审核期间沟通（Communication During the Audit）

审核过程中，审核组应定期评估审核进展并在审核组成员之间进行信息交流。

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审核组长需视情况重新分配任务，并定期向客户通报审核进展及任何审核中发现的问题或疑虑。

7.4. Non-conformities

Audit findings summarizing conformity and detailing nonconformities are identified, classified, and recorded to facilitate an informed certification decision or to maintain certification.

Any non-fulfilment of requirements is listed as non-conformity in "FO-00391 Audit finding list", classified by the auditors and recognized by the company representative. The company receives a copy of the audit finding list. This also applies to non-conformities that are closed during the audit.

A finding of nonconformity is defined against a specific requirement / Audit Criteria / Additional Audit Criteria and contains:

- a clear statement of the Nonconformity,
- the criterion against which the Nonconformity is raised,
- identifying in detail the objective evidence on which the Nonconformity is based
- if applicable, the identification of the associated device

Minor non-conformities are nonconformities that does not affect the capability of the management system to achieve the intended results or it is related to a non-fulfillment of an enabling requirement that does not directly impact the medical device safety and performance. In the action plan, the auditor assesses the plan of the organization to eliminate the minor non-conformity. The implementation is assessed in the next audit (surveillance or re-certification) or in a follow-up audit.

Major non-conformities are nonconformities, that affects the capability of the management system to achieve the intended results or deviations to laws and legal requirements in the context to medical devices (influence on general safety and function of the device) and furthermore, a non-fulfillment of a requirement that directly influences the medical device safety and performance.

Immediate correction, root cause analysis and corrective action to prevent reoccurrence are needed. Objective evidence must be made available by the defined due date and approved by the audit team. This can be done by an on-site follow-up review.

Nonconformities could be classified as major in the following circumstances:

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Any non-conformity from a previous audit, which has not been eliminated, is to be classified as a major non-conformity, exceptions to this must be substantiated in the audit report.

If one of the experts in the on-site audit determines during the audit that a non-conformity is so serious that it places **imminent danger** and immediate action by QMD Services is required, he/she immediately informs the lead auditor and the project leader for coordinating further actions.

The definitions of non-conformities are further defined in "REG-00510 Term Descriptions And Abbreviations"

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7.5. Preparing audit conclusions

Under the responsibility of the audit team leader and prior to the closing meeting, the audit team shall:

1) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities;
2) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;
3) agree any necessary follow-up actions;
4) confirm the appropriateness of the audit programm or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

Any non-fulfilment of requirements is listed as non-conformity in "FO-00391 Audit finding list".

Each auditor should present their own findings.

All findings (non-conformities) are documented in the "FO-00391 Audit finding list".

The customer needs to confirm the non-conformities during the closing meeting.

7.6. Closing meeting

A formal closing meeting, where attendance is recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited.

The purpose of the closing meeting, conducted by the lead auditor, is to present the audit conclusions, including the preliminary recommendation regarding certification. The items which should be addressed during the closing meeting are included in "FO-00469 MDR Client QMS Audit checklist"/ "FO-00473 IVDR Client QMS Audit checklist".

Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

Nonconformities will be discussed with the client to ensure that the evidence is accurate and clearly understood. The Audit Team should refrain from suggesting the causes of nonconformities or proposing solutions.

The Lead Auditor will work to resolve any differences of opinion between the Audit Team and the client regarding audit evidence or findings, and any unresolved points will be documented.

The customer needs to accept the non-conformities by signing "FO-00391 Audit finding list" before the on-site audit is closed.

7.7. Audit report

An audit report "FO-00392 Client QMS Audit Report" must be prepared by the audit team for the on-site audit. The audit report must clearly indicate whether the requirements of the MDR/IVDR are fulfilled or if there are any restrictions which must be considered for the certificate decision. The lead auditor is responsible for uploading the final report to WIS, no later than two weeks after the on-site audit. Each on-site audit needs to be accomplished

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with an audit report. In case of re-audits a new audit report for the re-audit has to be provided.

The report must not contain any concealed non-conformities from system elements and must not give any instructions for action (hidden consultancy).

The next process step is to check all evidence of the review for completeness (see "PRC-00132 Certification Decision").

In the event of any detected discrepancies, certificate issuance can only take place after the non-conformities have been closed out.

7.4 不符合项（Non-conformities）

审核发现应总结合规性情况并详细列出不符合项，以支持认证决策或维持认证。

所有不符合项必须记录于《FO-00391 审核发现清单》中，由审核员进行分级并由公司代表确认签字。公司将收到该清单的副本，即使不符合项在审核期间已关闭，仍应予以记录。

每条不符合项必须针对明确的审核准则或附加审核准则，内容应包括：

- 对不符合项的清晰陈述；
- 不符合项所对应的具体要求或标准条款；
- 支持不符合项结论的详细客观证据；
- 如适用，涉及的器械识别信息。

一般不符合项（Minor Nonconformity）是指未影响质量管理体系实现其预期结果能力，或属于与器械安全性和性能无直接关联的次要支持性要求未满足的情况。审核员需评估客户提出的整改计划，执行情况将在下一次监督审核、再认证审核或跟进审核中确认。

严重不符合项（Major Nonconformity）是指以下情况之一：

- 对管理体系实现预期结果的能力产生实质性影响；
- 涉及与法规要求偏离，可能影响医疗器械的安全性和功能；
- 任何直接影响医疗器械安全性或性能的要求未被满足。

对于严重不符合项，客户必须立即采取纠正措施、根本原因分析和防止再次发生的纠正预防措施，并在规定期限内提供客观证据，经审核组验证通过。必要时可通过现场跟进审核进行验证。

下列情况应被视为严重不符合项：

- 审核发现有效过程控制存在显著疑问，或产品/服务可能不符合要求；
- 多个一般不符合项集中于同一要求或领域，构成系统性失效；

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- 前次审核发现的不符合项未被纠正，除非在审核报告中有充分理由说明。

如现场审核中专家认为某项不符合严重至足以构成迫切危险并需 QMD Services 立即采取措施的，应立即通知审核组长及项目负责人，以协调后续行动。

有关不符合项定义的更多细节，见《REG-00510 术语与缩略语定义》。

7.5 审核结论准备（Preparing Audit Conclusions）

在末次会议前，审核组应在审核组长的主持下完成以下工作：

1. 根据审核目标与审核准则，对审核发现及其他信息进行复核，并对不符合项进行分级；
2. 综合审核中存在的不确定性因素，达成一致审核结论；
3. 确认是否需要后续审核活动；
4. 确认当前审核计划的适用性，或是否需对未来审核进行调整（如认证范围、审核时间、频次、审核组能力等）。

所有不符合项需记录于《FO-00391 审核发现清单》中。

每位审核员应陈述其所识别的审核发现，所有不符合项必须统一记录并提交客户确认。

7.6 末次会议（Closing Meeting）

应召开正式末次会议并记录与会人员，由客户管理层及被审核职能或流程负责人出席（如适用）。

会议由审核组长主持，目的是汇报审核结论，包括初步认证建议。应在会议中覆盖的事项详见：

- 《FO-00469 MDR 客户 QMS 审核清单》
- 《FO-00473 IVDR 客户 QMS 审核清单》

所有不符合项应以客户清楚理解的方式进行说明，并与客户协商整改时间表。

审核组应避免建议不符合项的原因或直接提出解决方案。

如客户与审核组对审核发现或证据存在分歧，审核组长负责协调，任何未解决的问题必须记录在案。

客户必须在审核结束前签署《FO-00391 审核发现清单》确认不符合项。

7.7 审核报告（Audit Report）

审核组应就现场审核编制审核报告《FO-00392 客户 QMS 审核报告》。

报告必须清晰表明 MDR/IVDR 要求是否被满足，或是否存在需考虑的限制影响认证决策。

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审核组长负责在现场审核后两周内将最终报告上传至 WIS 系统。每次现场审核都必须配有完整的审核报告。若为补充审核，应重新提交该次补充审核的独立报告。

审核报告不得隐瞒任何体系不符合项，亦不得包含任何形式的隐性咨询性建议。

下一步流程为审核证据完整性检查，详见《PRC-00132 认证决策程序》。

如审核中发现不符合项，必须在其关闭后方可进行证书发放。

8. Procedure in case of no access is granted

1) In case the manufacturer or a critical supplier prevents the auditors to carry out the unannounced on-site audit despite the manufacturer's agreement to the terms and conditions of QMD Services, the auditors need to emphasize the consequences on-site and subsequently issue a negative audit report.
2) It is essential to accurately document the incident, including the date, time, location and people involved. Additionally, it is crucial to record all communication attempts and the organisation's reactions.
3) It is necessary to insist on compliance and to remind the organisation of the contractual obligations and the consequences of a refusal of access.
4) If access is still refused, the auditor shall write a formal letter to the client, copying the project leader, stating that access has been refused and the possible consequences.
5) The auditor shall point out that a refusal of access can negatively affect the audit and possibly lead to an incomplete or negative audit report.
6) If access is still refused and the auditor has to leave the site without starting the audit, the certificate will be suspended at a minimum until the next unannounced audit is closed.
7) The certificate suspension is entered into Eudamed by the project leader.

8.1. Abortion of audit

There are several reasons why an audit at a client's premises may have to be cancelled. The following reasons may apply as examples:

- Lack of co-operation:

If the customer does not provide the required information, refuses access to key areas or does not co-operate with the auditor, this can make the audit impossible.

- Discovery of serious violations:

In the event of a serious violation of legal regulations, internal policies or ethical standards being identified during the course of the audit, the auditor may be required to cancel the audit and report the discovery immediately.

- Danger to independence or integrity:

If the auditor's independence is compromised by conflicts of interest, undue influence or other circumstances, the audit could be cancelled to preserve the integrity of the process.

- Hazard to safety or health:

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In the event of an unforeseen circumstance during the audit that could compromise the safety or health of the auditor or other individuals involved, the audit may need to be terminated for safety reasons.

- Lack of resources or time:

In the event that the requisite resources, time or data are unavailable to complete the audit, cancellation may be necessary until such resources are in place.

- Change in audit scope or conditions:

If the client significantly changes the scope of the audit

- Legal or regulatory requirements:

In some cases, legal or regulatory requirements may necessitate the interruption or cessation of an audit in certain circumstances.

- Detection of fraud:

In the event of fraud, the auditor may halt the audit and report the matter to the relevant authorities.

- Lack of documentation:

The absence of essential documentation may prevent the audit from being conducted in an appropriate manner.

In case the auditor decides to abort the audit, the decision shall be documented carefully and provided to the Project leader as well as to the Head of operations as soon as possible. In case of any doubts or difficulties the auditor shall align with head of operations.

8.2. Follow-up

Depending on the degree of non-conformities and within the time set by the lead auditor, but no later than 14 days, the company must enter the planned corrective actions in the action plan including implementation schedule and submit this to the lead auditor. The communicated timelines depend on the severity of the non-conformities.

In the event of a determined major non-conformity, the correction and its review for implementation by the lead auditor, and if necessary, the relevant expert or product reviewer, must take place within a maximum of 90 days of the on-site last audit day. The audit team is free to set shorter deadlines, depending on the severity of the non-conformity (see also sec 6.4). If necessary, this may require an additional follow-up audit on-site.

The final review of the effectiveness and the implementation of minor non-conformities of specified corrective measures will take place during the next regular assessment.

If the QMS audit team should wish to request any information to be assessed that is captured in the Technical Documentation that will be subjected to conformity assessment document "FO-00402 Follow Up Request". This form is made available to all team members via WIS.

8.3. Transitional provisions –MDR Article 120(3), IVDR Article 110(3)

In addition to quality management system requirements, the audit program for products placed on the market under EC-Directive and which under surveillance according to RE(EU)

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2024/1860 or RE(EU) 2023/607 provided there are no significant changes in the design and intended purpose, the following requirements of the MDR/IVDR shall be included:

- Post-market surveillance
- Market surveillance
- Vigilance
- Registration of economic operators and devices
- Applicable aspects from the European Medical Device Directives (if applicable)
- Review of actions taken for notification of adverse events, advisory notices, and FSCA (if applicable: e.g., recalls related to all applicable regulatory requirements)
- Procedure for significant changes during transition times

MDR Article 120(3) and IVDR Article 110 (3) audits are conducted in accordance with the procedures described in "SOP-00346 Procedure - Surveillance under Article 120" and "SOP-00562 IVDR Surveillance under Article 110".

8. 客户拒绝进入现场的情形处理程序

（Procedure in Case of No Access is Granted）

1. 若制造商或其关键供应商阻止审核员执行不预先通知的现场审核，尽管其已在合同中接受 QMD Services 的相关条款与条件，审核员应当在现场向客户强调其后果，并随后出具负面审核报告。
2. 审核员必须准确记录该事件，包括日期、时间、地点及相关人员，并记录所有沟通尝试及客户的反应。
3. 审核员需强调客户履行合同义务的必要性，并提醒其拒绝进入现场的后果。
4. 如仍被拒绝进入，审核员应向客户发送正式函件，抄送项目负责人，说明访问被拒，并指出可能带来的后果。
5. 审核员应明确指出，拒绝进入可能影响审核结果，且可能导致审核结论不完整或为负面报告。
6. 若审核员最终无法开展审核并需离开现场，该证书将至少被暂停直至下一次不预先通知审核完成。
7. 证书暂停信息由项目负责人录入至 Eudamed 系统。

8.1 审核中止（Abortion of Audit）

审核可能因多种原因在客户现场被中止，包括但不限于：

- 缺乏合作：客户未提供所需信息、拒绝进入关键区域或拒绝配合，致使审核无法进行；
- 发现严重违规行为：若审核过程中发现违反法律、内部政策或道德标准的重大问题，审核员可中止审核并立即上报；
- 影响独立性或完整性：若存在利益冲突、不当干预等情况危及审核员独立性，审核应中止以保障审核公正；
- 安全或健康风险：如审核现场存在不可预见的安全/健康隐患，审核可因安全原因被终止；
- 资源或时间不足：如缺乏必要的资源、时间或数据以完成审核，审核可能被推迟或中止；
- 审核范围或条件发生重大变化；
- 法律或监管要求导致审核中断或终止；

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- 发现欺诈行为：如在审核中发现欺诈行为，应立即中止并向相关部门报告；
- 缺乏必要文档：若审核所需核心文档缺失，审核无法有效开展。

若审核员决定中止审核，应尽快将该决定完整记录，并报告给项目负责人及运营主管。如遇判断困难，审核员应及时与运营主管协调。

8.2 跟进

依据不符合项的严重程度，在审核组长设定的期限内（最迟不超过 14 日），客户必须将拟定的纠正措施与实施计划填写至整改计划中，并提交审核组长审批。整改时间要求将依据不符合项的严重程度确定。

若存在严重不符合项，审核组长需对其整改措施及实施效果进行验证，必要时可由相关专家或产品评审员参与。验证时间应在现场审核结束之日起最多不超过 90 天内完成。审核组也可根据具体情形设定更短时限。如有必要，需进行额外现场跟进审核。

对于一般不符合项的最终整改效果验证，将在下次常规评审中完成。

若 QMS 审核组需要针对技术文件中的内容进行补充评审，应填写《FO-00402 跟进请求表》。此表格通过 WIS 系统供所有审核组成员访问。

8.3 过渡性条款 – MDR 第 120(3)条 / IVDR 第 110(3)条

（Transitional Provisions – MDR Article 120(3), IVDR Article 110(3)）

对于依据旧指令（EC-Directive）已投放市场、目前在 RE(EU) 2024/1860 或 RE(EU) 2023/607 过渡规定下接受监督的产品，在未发生设计和预期用途重大变更的前提下，其审核除质量管理体系外，还需覆盖以下 MDR/IVDR 要求：

- 上市后监督（PMS）
- 市场监管（Market Surveillance）
- 警戒系统（Vigilance）
- 经济运营者和器械的注册要求
- 适用的原有欧盟医疗器械指令内容（如适用）
- 针对不良事件、建议性通知和 FSCA（如召回）的处理审查（适用时）；
- 过渡期内的重大变更管理程序

此类审核根据以下程序进行：

- 《SOP-00346 基于 MDR 第 120 条的监督审核程序》
- 《SOP-00562 基于 IVDR 第 110 条的监督审核程序》

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