GUIDE

for

Conducting System Certifications in the Field of Medical Devices acc. to

ISO 13485:2016
根据 ISO 13485:2016 进行医疗器械领域体系认证的指南

(for internal use only 仅供内部使用)

Note: This guidance is available in English language only. Furthermore, other affiliated forms are edited in English only. Be sure, to turn your enabler to "English" when searching for the documents referenced in this guidance.
注意：本指南仅提供英文版本。此外，其他附属表格仅以英文编辑。在搜索本指南中引用的文档时，请确保将启用项设置为"英文"。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

Table of contents 目录

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

1. Introduction 引言

This guideline applies to all accredited conformity assessment procedures related to the management system standard EN ISO 13485:2016 until this guideline is declared to be invalid or replaced by a new version. 本指南适用于与管理体系标准 EN ISO 13485:2016 相关的所有认证符合评估程序，直至本指南被宣布无效或被新版本取代。

The specifications of Quality Austria as well as the requirements stated in IAF Mandatory Document "Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485:2016)" (IAF MD9:2023, Issue 4) will have to be followed for all system certifications in connection with this guideline. In order to maintain customer certification, these requirements shall be met on an ongoing basis. 与本指南相关的所有体系认证都必须遵循 Quality Austria 规范以及 IAF 强制性文件 "ISO/IEC 17021-1 在医疗器械质量管理体系领域的应用（ISO 13485:2016）"（IAF MD9:2023，第 4 期）中规定的要求。为了维持客户认证，应持续满足这些要求。

In special cases, system evaluations and verifications in the field of medical devices will be conducted in cooperation with Medizinprodukte GmbH (DQS MED). Due to the changes in European legislation (introduction of Regulation (EU) 2017/745 and Regulation (EU) 2017/746), this cooperation can no longer be maintained. Existing cooperation clients of DQS MED will continue to be supported according to the requirements of DQS MED until the end of the validity / transition periods of the Directives 98/79/EEC or 98/42/EEC.在特殊情况下，医疗器械领域的系统评估和验证将与 Medizinproducte GmbH（DQS MED）合作进行。由于欧洲立法的变化（引入了（欧盟）2017/745 号条例和（欧盟）17/746 号条例），这种合作无法再维持。在指令 98/79/EEC 或 98/42/EEC 的有效期/过渡期结束之前，DQS-MED 的现有合作客户将继续根据 DQS-MED 要求获得支持。

In special cases, if the ISO 13485 audit is part of the QMD Services conformity assessment procedure with the requirements of Regulation (EU) 2017/745 or Regulation (EU) 2017/746), the Quality Austria ISO 13485 audit will be performed by Quality Austria auditors in cooperation with QMD Services using the QMD Services forms by Quality Austria auditors (see paragraph 5.2).在特殊情况下，如果 ISO 13485 审核是符合第 2017/745 号条例或第 2017/746 号条例要求的 QMD 服务符合评估程序的一部分，则 Quality Austria ISO 13485 审核员将与 QMD 服务部门合作，使用 Quality Austria 审核员的 QMD 服务表格进行审核（见第 5.2 段）。

2. qualityaustria policy for certification qualityaustria 认证政策

Upon organizations' request, Quality Austria conducts audits and other conformity assessment activities required for management system certification for ISO 13485. 应组织要求，Quality Austria 进行 ISO 13485 管理体系认证所需的审核和其他符合评估活动。

Quality Austria supports the use of integrated management systems. Among other things, the use of integrated management systems serves to utilize synergies of quality management systems that may already be applied and other areas like environmental management or OH&S (occupational health and safety). Accordingly Quality Austria offers its services wherever possible, as combined audits. Quality Austria 支持使用综合管理体系。除此之外，综合管理体系的使用有助于利用可能已经应用的质量管理体系与环境管理或职业健康安全等其他领域的协同作用。因此，Quality Austria 尽可能提供联合审核服务。

Quality Austria employs personnel adequately qualified for its activities and ensures maintenance of the high technical competence by means of training and further training. Quality Austria 雇佣了足够合格的人员从事其活动，并通过培训和进一步培训确保保持高技术能力。

Quality Austria promotes the high acceptance of its Certificates among users and its international certification partners. Quality Austria 促进了用户及其国际认证合作伙伴对其证书的高度认可。

In carrying out certification, the impartiality of Quality Austria and its auditors towards the

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

customers must be guaranteed. Among other things, Quality Austria and its auditors must not be involved in the design, production, engineering, and marketing, installation, service or distribution of the medical device concerned. Quality Austria must not be involved in designing, implementation or maintenance of the quality management system to be audited. 在进行认证时，必须保证 Quality Austria 及其审核员对客户的公正性。除其他事项外，Quality Austria 及其审核员不得参与相关医疗器械的设计、生产、工程、营销、安装、服务或分销。Quality Austria 不得参与待审核质量管理体系的设计、实施或维护。

3. Registration and making the offer 登记和报价

3.1 Defining the Time needed for audits acc. to ISO 13485:2016

根据 ISO 13485:2016 定义审核所需的时间

General Note: The audit time and how it is applied is defined in IAF MD9 and reported here in this guidance in this section. It is the responsibility of the auditor to plan the correct audit time in line with this guidance. Any proposed audit time, which is sent through a WIS order and corresponds to the table below must be verified by the auditor, also regarding factors that increase or reduce the audit time. A justification of the adapted audit time shall be sent to the Customer Service Center as evidence. The Customer Service Center (in case of complex orders in cooperation with the product expert) will give the final ok to the proposed audit time (no specific answer is needed if time is ok). A good method for this is to use the IMS calculator (see below) and send the filled excel (or a screenshot of the page) to the CSC. 一般说明：审核时间及其应用方式在 IAF MD9 中定义，并在本节的本指南中报告。审核员有责任根据本指南计划正确的审核时间。任何通过 WIS 订单发送的与下表相对应的拟议审核时间都必须由审核员进行验证，同时还要考虑增加或减少审核时间的因素。调整审核员时间的理由应作为证据发送给客户服务中心。客户服务中心（在与产品专家合作处理复杂订单的情况下）将对拟议的审核时间给予最终批准（如果时间允许，则不需要具体的答案）。一个好的方法是使用 IMS 计算器（见下文）并将填写好的 excel（或页面截图）发送给 CSC。

The audit time (incl. plan and reporting hours) required for certification is calculated in accordance with IAF MD9 (section MD 9.1.4.1 and Annex D). **Please note, the time required may only be rounded up, but not rounded down.** 认证所需的审核时间（包括计划和报告时间）根据 IAF MD9（MD 9.1.4.1 节和附件 D）计算。**请注意，所需时间只能四舍五入，不能四舍五降。**

The on-site audit duration must be at least 80% of the total audit time. For the calculation of the on-site audit time, the **quality**austria IMS Calculator should be used (FO_25_03_17e_IMS Calculator). **现场审核持续时间必须至少为总审核时间的 80%**。为了计算现场审核时间，应使用 **quality**austria IMS 计算器（FO_25_03_17e_IMS 计算器）。

Any factors to be taken into account for increasing or reducing the audit duration will have to be taken from IAF MD 9. 任何增加或减少审核持续时间的因素都必须从 IAF MD 9 中考虑。

Acc. to IAF MD9, the following audit times apply for initial certifications, including preparation, implementation and report 根据 IAF MD9，以下审核时间适用于初始认证，包括准备、实施和报告：

Table D.1 表格 D.1

Determination of Audit Time (Initial Audit Only) 审核时间的确定（仅初始审核）

Effective Number of Personnel 有效人员数量	Audit Duration Stage 1 + Stage 2 (days) 审核持续时间第 1 阶段+第 2 阶段（天）	Effective Number of Personnel 有效人员数量	Audit Duration Stage 1 + Stage 2 (days) 审核持续时间第 1 阶段+第 2 阶段（天）
1-5	3	**626-875**	15
6-10	4	**876-1175**	16
11-15	4.5	**1176-1550**	17

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

16-25	5	**1551-2025**	18
26-45	6	**2026-2675**	19
46-65	7	**2676-3450**	20
66-85	8	**3451-4350**	21
86-125	10	**4351-5450**	22
126-175	11	**5451-6800**	23
176-275	12	**6801-8500**	24
276-425	13	**8501-10700**	25
426-625	14	**>10700**	Follow progression above

For surveillance audits, one-third of this effort is to be assessed; in the case of recertification audits, two-thirds of this effort. 对于监督审核，需要对三分之一的工作进行评估；在重新认证审核的情况下，需要对三分之二的工作进行评估。

Any factors to be taken into account for increasing the audit time from table D.1 are 表 D.1 中增加审核时间需要考虑的任何因素是：

1. when more than one main technical area is required to be audited, the audit time shall be increased to address any additional requirements related to the additional main technical area(s); 当需要审核多个主要技术领域时，应增加审核时间，以满足与额外主要技术领域相关的任何额外要求；
2. complexity of medical devices;医疗器械的复杂性；
3. 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, including own label products. When the manufacturer cannot provide sufficient evidence for conformity with audit criteria, then additional time may be allowed for each supplier to be audited; 制造商使用供应商提供对医疗器械功能和/或用户或成品安全至关重要的工艺或零件，包括自有标签产品。当制造商无法提供足够的证据证明符合审核标准时，可以允许每个供应商有额外的时间接受审核；
4. manufacturers who install product on customer's premises. 在客户场所安装产品的制造商
   Note: Time may be required for customer site visits or installation records review;
   注：客户现场考察或安装记录审查可能需要时间
5. poor regulatory compliance by the manufacturer;制造商监管合规性差；
6. multiple shifts, number of production lines etc. may increase audit time. 多班次、生产线数量等可能会增加审核时间。

Any factors to be taken into account for reducing the audit time but not by more than 20% in total from table D.1 are 根据表 D.1，减少审核时间但总计不超过 20%的因素包括：

1. the organization's scope does not include manufacturing and is activities such as wholesale, retail, transportation, or maintenance of equipment, etc.;该组织的范围不包括制造，而是批发、零售、运输或设备维护等活动。
2. reduction of the manufacturer product range since last audit;自上次审核以来，制造商产品范围缩小
3. reduction of the design/or production process since last audit. 自上次审核以来，设计/或生产过程的减少

Audit durations performed solely for the certification scope of Distribution or transportation services may be reduced by up to 50% in total. 仅针对分销或运输服务的认证范围进行的审核持续时间最多可减少 50%。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

3.2 Specifics for multi-site audits 多现场审核的具体细节

A sampling regulation, as in RE_27_01_074e_Certification of Multi-site Organizations, **is not permitted for sites with design and development or production.** RE_27_01_074e_多现场组织认证中的抽样规定不允许用于设计和开发或生产的现场。

At the request of the organization, so-called "sub-certificates" can be issued.
根据组织的要求，可以颁发所谓的"子证书"。

3.3 Time needed for combined audits 联合审核所需时间

Combined audits denote certification of additional standards or regulations (e.g. ISO 9001) in one audit procedure with ISO 13485 within an integrated management system.联合审核是指在一个综合管理体系内，通过 ISO 13485 对一个审核程序中的其他标准或法规（如 ISO 9001）进行认证。

Combination ISO 13485 with ISO 9001 ISO 13485 与 ISO 9001 的联合:
For combined audits of ISO 9001 + ISO 13485, the following procedure shall be applied: Take the data from the table in section 3.1 and **add 25%**. Additional time may be required if, for example, if there are differences in the scope, the effective number of personnel for the respective system etc. 对于 ISO 9001+ISO 13485 的联合审核，应采用以下程序：从第 3.1 节的表格中获取数据，并添加 25%。例如，如果范围、相应体系的有效人员数量等存在差异，可能需要额外的时间。

For all other management systems, IAF MD11 shall be applied!
对于所有其他管理体系，应采用 IAF MD11！

For calculating the on-site audit time incl. the time for integrated audits, the **quality**austria IMS Calculator may be used (FO_25_03_17e_IMS Calculator).为了计算现场审核时间，包括综合审核时间，可以使用 **quality**austria IMS 计算器（FO_25_03_17e_IMS 计算器）。

3.4 Scopes and the qualification of auditors 审核员的范围和资格

Auditors are requested to verify the attributed scope for the customers Medical Device Quality Management Systems according to IAF MD9 Annex A.要求审核员根据 IAF MD9 附件 A 验证客户医疗器械质量管理体系的归属范围。

The qualification of auditors respective to these scopes is noted in the **quality**austria GPS system. **Quality**austria GPS 系统中注明了这些范围内审核员的资格。

Only those auditors, who are approved for ISO 13485 and the respective technical area, to which the organization can be assigned can be appointed. The audit team shall cover the scope of the organization.只有那些通过 ISO 13485 和相应技术领域认证的审核员才能被任命。审核小组应覆盖组织范围。

3.5 Registration for certification 注册和认证

Registration will be done by using the registration form "FO_25_03_01e_Information_offer_making_IMS" and while considering the Terms and Conditions of Quality Austria according to the general process requirements for this process. 注册将通过使用注册表 "FO_25_03_01e_Information_offer_making_IMS" 完成，同时根据该流程的一般流程要求考虑 Quality Austria 条款和条件。

If the customer provides services in the field of sterile goods supply and/or reprocessing of medical products, additional information must be requested using the form "Preliminary Information on offering organizations of sterile goods supply" FO_25_03_01-01.如果客户在无菌商品供应和/或医疗产品再加工领域提供服务，则必须使用表格"无菌商品供应组织的初步信息"FO_25_03_01-01 获取更多信息。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

3.6 Fees 费用

The **quality**austria General Fee Model will be used. 将使用 **quality**austria 通用收费模式。

4. Requirements placed on the auditors and technical experts 对审核员和技术专家的要求

4.1 Competence Requirements 能力要求

Basis is the qualification process as described in the Regulation RE_05_01_05_01e_Qualification Guidelines for **quality**austria auditors in general, especially section 2 (schematic overview of authorization steps), 4 and 5 apply. 基础是《RE_05_01_05_01e_一般 **quality**austria 审核员资格指南》中所述的资格认证过程，特别是第 2 节（授权步骤示意图）、第 4 节和第 5 节适用。

Due to the sector specific requirements, the qualification requirements differ to other models, as described below (esp. section 3 of RE_05_01_05_01e_Qualification Guidelines for **quality**austria auditors does NOT apply). 由于行业特定的要求，资格要求与其他模型不同，如下所述（特别是 RE_05_01_05_01e_**quality**austria 审核员资格指南第 3 节不适用）。

A. Requirements for Observers 观察员要求:

1. Education according to the technical areas stated in IAF MD9 (Annex C) as evidenced by:
   根据 IAF MD9（附件C）中规定的技术领域进行教育，证明如下:
   - Credentials or educational certificates regarding specialized training(s) preferred in one of the following areas 优先考虑以下领域之一的专业培训证书或教育证书:
     - biology or microbiology 生物学或微生物学
     - chemistry or biochemistry 化学或生物化学
     - computer and software technology 计算机与软件技术
     - electrical, electronic, mechanical or bioengineering 电气、电子、机械或生物工程
     - human physiology 人体生理学
     - Medicine 医学
     - Pharmacy 药房
     - physics or biophysics 物理学或生物物理学

2. sector specific knowledge as evidenced by 部门特定知识，证据如下:
   - **four years of full-time work experience** in the field of medical devices or related sectors (e.g., medical device industry, healthcare, medical device audit or research in medical devices), some specific examples are 在医疗器械或相关领域（如医疗器械行业、医疗保健、医疗器械审核或医疗器械研究）拥有四年全职工作经验，一些具体例子是:
     - activities in sectors related to medical devices (such as industry, health care) in the development, research and/or manufacturing 与医疗器械相关的行业（如工业、医疗保健）在开发、研究和/或制造方面的活动
     - treating patients and/or using medical devices in healthcare institutions. 在医疗机构治疗患者和/或使用医疗设备
     - activities in the field of product inspection and testing and/or using national or international product standards; 产品检验和测试领域和/或使用国家或国际产品标准的活动
     - making clinical studies and/or performance reviews of medical devices and/or IVD (in-vitro diagnostics) products. 对医疗器械和/或 IVD（体外诊断）产品进行临床研究和/或性能评估

   Successful completion of other formal qualification (advanced degrees) can substitute for a maximum of two years of working experience. 成功完成其他正式资格（高级学位）可以替代最多两年的工作经验。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

Exceptionally, shorter duration of experience or experiences in the fields other than medical devices or related sectors may be considered as appropriate. In such cases, the candidate shall provide evidence that the experience is equivalent.在特殊情况下，可以考虑在医疗器械或相关行业以外的领域拥有较短的经验或经历。在这种情况下，候选人应提供证据证明其经验是相等的。

IMPORTANT: A self-declaration of the auditor to demonstrate competence without appropriate verification documents is insufficient.
重要提示：在没有适当验证文件的情况下，审核员自我声明以证明其能力是不够的。

3. Existence of an **certificate „Auditor"** (e.g. **quality**austria certificate **Auditor for Medical Device Quality Management Systems**)[1], Auditor for quality management systems or Auditor on basis of risk management, or an equivalent auditor training, covering the topics 是否存在"审核员"证书（例如医疗器械质量管理体系 **quality**austria 审核员证书）1、质量管理体系审核员或基于风险管理的审核员，或同等的审核员培训，涵盖以下主题:
   - ISO 19011 auditing guidelines ISO 19011 审核指南
   - Essential definitions and terminology 基本定义和术语
   - To analyse standard clauses and interpret correctly requirements for conformity 分析标准条款并正确解释符合性要求
   - The role and responsibilities of an auditor and lead auditor 审核员和审核组长的角色和职责
   - To plan and conduct an interview with top management and evaluate an organisation's quality policy and objectives 计划和进行与高层管理人员的访谈，并评估组织的质量政策和目标
   - To prepare an on-site audit plan that establishes effective audit trails 制定现场审核计划，建立有效的审核跟踪
   - To audit processes for conformance and effectiveness 审核流程的合规性和有效性
   - To gather and evaluate objective evidence 收集和评估客观证据
   - To identify conformance and non-conformance with requirements 识别是否符合要求
   - To report findings accurately against standard requirements 根据标准要求准确报告发现
   - To write and grade non-conformities and evaluate proposals for corrective action 撰写不合格项并对其进行评分，并评估纠正措施的建议
   - To relate audit findings to the policy and objectives of the organisation and present overall evaluation to top management / at a closing meeting.将审核结果与组织的政策和目标联系起来，并在末次会议上向最高管理层提交总体评估

4. Knowledge of current version of ISO 13485 and regulatory framework, e.g. by successfully completing the course **Medical Devices – Basics and Regulatory Requirements MPGRA**, or alternatively a course covering the following 了解当前版本的 ISO 13485 和监管框架，例如通过成功完成医疗器械——基础和监管要求 MPGRA 课程，或者涵盖以下内容的课程:
   a. risk management of medical devices (including ISO 14971)医疗器械的风险管理（包括 ISO 14971）
   b. process validation 过程验证
   c. sterilization and related processes 灭菌和相关过程
   d. electronics manufacture 电子产品制造
   e. plastics manufacturing processes 塑料制造工艺
   f. development and validation of software or hardware for devices and manufacturing processes 设备和制造过程的软件或硬件的开发和验证
   g. in-depth knowledge of specific medical devices and/or technologies.对特定医疗器械和/或技术的深入了解

   Or alternatively, more than 4 years of experience as responsible QM Manager in an ISO 13485 certified organization and verification of knowledge in a structured and documented interview by Quality Austria product expert or sector manager.或者，在 ISO 13485 认证的组织中担任负责的 QM 经理超过 4 年，并在 Quality Austria 产品专家或行业经理的结构化和有记录的访谈中验证知识。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

5. Audit experience in the area of Quality Management Systems by conducting at least 4 complete system or process audits with a total of **20 audit days** (thereof, at least 12 days on-site), 50% of which shall be against ISO 13485 (preferably in an accredited program).在质量管理体系领域的审核经验，通过进行至少 4 次完整的体系或过程审核，共 20 个审核日（其中，现场至少 12 天），其中 50%应符合 ISO 13485 标准（最好是在认证项目中）。
   Experience shall be in the **entire process** of auditing medical device quality management systems, including review of documentation and risk management of applicable medical devices, parts or services (see Table IAF MD9 A.1.7), implementation audit and audit reporting.应具备审核医疗器械质量管理体系的整个过程的经验，包括审查适用医疗器械、零件或服务的文件和风险管理（见表 IAF MD9 A.1.7）、实施审核和审核报告。

---

[1] Exceptional approvals in relation to this requirement are only permissible if all competence requirements acc. to IAF MD9, Annex B are fulfilled and documented.只有满足并记录了 IAF MD9 附件 B 中的所有能力要求，才允许获得与此要求相关的特殊批准。

Note: For competence requirements for auditors for suppliers of "Parts and services", see section 5.7. 注：关于"零件和服务"供应商审核员的能力要求，请参阅第 5.7 节。

B. Requirements Auditor A2 A2 审核员要求

For Observers to be authorized as A2, the following requirements have to be fulfilled 对于被授权为 A2 的观察员，必须满足以下要求:

1. Initial auditor training at Quality Austria 在 Quality Austria 接受初步审核员培训
2. Self-study of this Guideline and successful completion of the Moodle test(s) incl. knowledge check ISO 13485 自学本指南并成功完成 Moodle 测试，包括知识检查 ISO 13485
3. After conducting a complete initial certification audit or recertification audit acc. to ISO 13485 as an observer and positive assessment by a commissioned Auditor A1 (FO_05_01_03_03e_Assessing observers_auditors), he/she can be assigned the status "Auditor A2" in the area of ISO 13485.作为观察员根据 ISO 13485 进行完整的初始认证审核或重新认证审核，并由委托的审核员 A1（FO_05_01_03_03e_评估观察员_审核员）进行积极评估后，他/她可以在 ISO 13485 领域被授予"审核员 A2"的身份。

C. Requirements Auditor A1 A1 审核员要求

For Auditors A2 to be authorized as Auditor A1, the following requirements have to be fulfilled 审核员 A2 要被授权为审核员 A1，必须满足以下要求:

1. Min. 3 audits as co-auditor with status A2 作为 A2 状态的审核组员，至少进行 3 次审核
2. One of these audits shall be a complete initial certification audit or recertification audit acc. to ISO 13485 as auditor A2. A positive assessment by a commissioned Auditor A1 (FO_05_01_03_03e_Assessing observers_auditors) is required, to be assigned the status "Auditor A1" in the area of ISO 13485.其中一项审核应根据 ISO 13485 作为审核员 A2 进行的完整的初始认证审核或重新认证审核。需要由委托的审核员 A1（FO_05_01_03_03e_评估观察员_审核员）进行积极评估，并在 ISO 13485 领域被赋予"审核员 A1"的身份。

Notes 注:

- If auditors to be appointed for ISO 13485 already have the status of „Lead Auditor" in another quality management model (e.g. ISO 9001), they can be appointed directly as A2 (= Co-Auditor). After performing a complete initial certification audit or recertification audit acc. to ISO 13485 as an Auditor A2 and positive assessment by a commissioned Auditor A1 (FO_05_01_03_03e_Assessing observers_auditors), he/she can be assigned the status "Lead Auditor" in the area of ISO 13485 (steps B3 and C1 can be skipped).如果任命为 ISO

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

13485 的审核员在另一种质量管理模型（如 ISO 9001）中已经具有"审核组长"的身份，他们可以直接被任命为 A2（=审核组员）。作为审核员 A2，根据 ISO 13485 执行完整的初始认证审核或重新认证审核，并由委托审核员 A1（FO_05_01_03_03e_评估观察员_审核员）进行积极评估后，他/她可以在 ISO 13485 领域被指定为"审核组长"（可以跳过步骤 B3 和 C1）。

- If auditors to be appointed for ISO 13485 already have carried out audits for another IAF MLA accredited Certification body, they can be appointed directly as A2 (= Co-Auditor). After performing a complete initial certification audit or recertification audit acc. to ISO 13485 as an Auditor A2 and positive assessment by a commissioned Auditor A1 (FO_05_01_03_03e_Assessing observers_auditors), he/she can be assigned the status "Lead Auditor" in the area of ISO 13485 (steps B3 and C1 can be skipped).如果任命为 ISO 13485 的审核员已经为另一个 IAF MLA 认证机构进行了审核，他们可以直接被任命为 A2（=审核组员）。作为审核员 A2，根据 ISO 13485 执行完整的初始认证审核或重新认证审核，并由委托审核员 A1（FO_05_01_03_03e_评估观察员_审核员）进行积极评估后，他/她可以在 ISO 13485 领域被指定为"审核组长"（可以跳过步骤 B3 和 C1）。

4.2 Authorization for a medical devices technical areas 医疗器械技术领域授权

In addition to appointment as an auditor for ISO 13485 standard, it is also necessary to apply for which medical devices technical areas according to IAF MD 9:2023 one wishes to be appointed. See FO_05_01_03_14e_ Qualification form for ISO 13485 auditors 除了被任命为 ISO 13485 标准的审核员外，还需要根据 IAF MD 9:2023 申请希望被任命的医疗器械技术领域。见 FO_05_01_03_14e_ ISO 13485 审核员资格表。

Additionally, for already appointed auditors an extension of appointment for medical devices technical areas can be requested. 此外，对于已经任命的审核员，可以要求延长医疗器械技术领域的任命。The criteria for the extension are at minimum 2 audits as at least co-auditor in the relevant code or 1 years work experience in the related medical devices technical area for which the auditor is applying for. 延期的标准是至少进行 2 次审核，至少作为相关规范中的一名审核组员，或在审核员申请的相关医疗器械技术领域有 1 年的工作经验。

4.3 Impartiality of auditors 审核员的公正性

Quality Austria auditors shall be impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be Quality Austria 审核员应公正，不受可能影响其客观性的聘用和影响，特别是不得：

a) involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services 参与医疗器械或任何相关部件和服务的设计、制造、施工、营销、安装、维修或供应

b) involved in the design, construction, implementation or maintenance of the quality management system being audited 参与被审核质量管理体系的设计、构建、实施或维护

c) an authorized representative of the client organization, nor represent the parties engaged in these activities 客户组织的授权代表，也不代表参与这些活动的各方

The situations hereafter are examples where impartiality is compromised in reference to the criteria defined in a) to c) 以下情况是根据 a）至 c）中定义的标准损害公正性的示例：

a) the auditor having a financial interest in the client organization being audited (e.g., holding stock in the organization) 审核员在被审核的客户组织中拥有财务利益（例如，持有该组织的股票）
b) the auditor being employed currently by a manufacturer producing similar/competitive medical devices 审核员目前受雇于生产类似/竞争性医疗器械的制造商
c) the auditor being a member of staff from a research or medical institute or a consultant having a commercial contract or equivalent interest with the manufacturer or

manufacturers of similar medical devices 审核员是研究或医疗机构的工作人员，或与类似医疗器械制造商签订商业合同或具有同等利益的顾问

4.4 Maintenance of competence 维持能力

The general **quality**austria procedures shall be applied – see RE_05_01_06_01e_Maintenance of competence for auditors. 应采用一般 **quality**austria 程序——见 RE_05_01_06_01e_审核员能力维护。
In addition, each auditor has to provide evidence of professional training of at least 16 hours per year (e.g. Medical Device Technology, regulatory requirements, standards, EU Regulations, and Common Specifications). These trainings can also be attended outside Quality Austria, especially at QMD Services. 此外，每位审核员必须提供每年至少 16 小时的专业培训证明（例如医疗器械技术、监管要求、标准、欧盟法规和通用规范）。这些培训也可以在 Quality Austria 以外的地方参加，特别是在 QMD Services。
Exception: Auditors authorized for scope 7.x only have to provide evidence of professional training of at least 8 hours per year. 例外情况：授权范围 7.x 的审核员只需提供每年至少 8 小时的专业培训证明。

In the field of ISO 13485, internal witness audits must be carried out for each auditor every 5 years. 在 ISO 13485 领域，必须每 5 年对每位审核员进行一次内部见证审核。

5. Conducting audits 执行审核

Unless stated differently, audits in all respects will be conducted analogously to the **quality**austria procedures as defined for ISO 9001. 除非另有说明，否则各方面的审核将类似于 ISO 9001 规定的 **quality**austria 程序进行。

5.1 Specifics 具体内容

For the audit stage 1 and audit stage 2, the corresponding ISO 13485 checklists (stage 1 and stage 2) shall be used 对于阶段 1 和阶段 2 审核，相应的 ISO 13485 检查表（阶段 1 和阶段 2） 应使用:
Stage 1 and combined with ISO 9001: CL_27_01_122e_Stage 1_13485_2016 ISO 9001_2015
阶段 1 与 ISO 9001 联合：CL_27_01_122e_Stage 1_13485_2016 ISO 9001_2015
Stage 2: CL_27_01_112_ISO 13485_2016. FO 27_01_030e audit and assessment plan (time plan), FO 27_01_032e audit/assessment report
阶段 2： CL_27_01_112_ISO 13485_2016. FO 27_01_030e 审核和评估计划 (时间计划), FO 27_01_032e 审核/评估报告

5.2 Specifics of ISO 13485 audit as part of QMD Services conformity assessment procedure 作为 QMD 服务符合评估程序一部分的 ISO 13485 审核的具体内容

For the ISO 13485 audit as part of QMD Services conformity assessment procedure appropriate QMD Services forms which are equivalent to the Quality Austria forms (see table below) can be used. (Note: It is always permissible to create separate documents) 对于作为 QMD 服务合格评定程序一部分的 ISO 13485 审核，可以使用与 Quality Austria 表格（见下表）等效的适当 QMD 服务表格。（注：始终允许创建单独的文档）：

- FO-00384 QMS Audit Plan; FO-00384 质量管理体系审核计划
- FO-00469 MDR Client QMS Audit Checklist; FO-00469 MDR 客户质量管理体系审核检查表
- FO-00473 IVDR Client QMS Audit Checklist; FO-00473 IVDR 客户质量管理体系审核检查表
- FO-00391 Audit Finding List; FO-00391 审核发现清单
- FO-00407 Client Audit Participation List. FO-00407 客户审核参与名单

When using QMD templates, the auditor shall indicate in each form BOTH order numbers in the relevant field for correct refence to both conformity assessment procedures. 使用 QMD 模板时，审核员应在每种表格的相关字段中注明两个订单号，以便正确参考两个合格评定程序。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

E.g. 例如：

Order Nr: QA 138947/394836 QMD 3837/4394

订单号：QA 138947/394836 QMD 3837/4394

Based on the results of the audit, the auditor issues two distinct audit reports:根据审核结果，审核员发布了两份不同的审核报告：

- 1 stage - CL_27_01_122e_Stage 1_13485_2016 ISO 9001_2015/ FO-00471 Client QMS Stage 1 report;
  阶段 1-CL_27_01_122e_Stage 1_13485_2016 ISO 9001_2015/ FO-00471 客户 QMS 阶段 1 报告
- 2 stage - FO 27_01_032e Audit/assessment report / FO-00392 Client QMS Audit Report.
  阶段 2-FO 27_01_032e 审核/评估报告/ FO-00392 客户 QMS 审核报告.

After this audit, the auditors upload in **quality**austria WIS the completed QMD Services forms: FO-00384 QMS Audit Plan, FO-00469 MDR Client QMS Audit checklist or FO-00473 IVDR Client QMS Audit checklist, Quality Austria FO 27_01_032e audit report and FO-00391 Audit finding list.审核后，审核员在 **quality**austria WIS 中上传完成的 QMD 服务表格：FO-00384 QMS 审核计划、FO-00469 MDR 客户 QMS 审核清单或 FO-00473 IVDR 客户 QMS 审核检查表、Quality Austria FO 27_01_032e 审核报告和 FO-00391 审核发现清单。

Also after this audit, the auditors sent to QMD Services the all completed QMD Services forms: FO-00384 QMS Audit Plan, FO-00391 Audit Finding List , FO-00469 MDR Client QMS Audit checklist or FO-00473 IVDR Client QMS Audit checklist, FO-00392 Client QMS Audit Report, FO-00407 Client Audit Participation List. 同样在这次审核之后，审核员向 QMD 服务部门发送了所有已完成的 QMD 服务表格：FO-00384 QMS 审核计划、FO-00391 审核发现清单、FO-00469 MDR 客户 QMS 审计检查表或 FO-00473 IVDR 客户 QMS 审核检查表、FO-00392 客户 QMS 审核报告、FO-00407 客户审计参与清单。

Table of Quality Austria and QMD Services form correspondence
Austria 和 QMD 服务表格对应表

Quality Austria		**QMD Services**	
Template number 模板编号	**Template name 模板名称**	**Template number 模板编号**	**Template name 模板名称**
CL_27_01_122e	Audit report 审核报告 Certification audit ISO 9001:2015 and ISO 13485:2016 - Stage 1 认证审核 ISO9001:2015 和 ISO 13485:2016-阶段 1	FO-00471	Client QMS Stage 1 Report 客户 QMS 阶段 1 报告
FO_27_01_030e	Audit and assessment plan (timeplan) 审核和评估计划（时间计划）	FO-00384	QMS Audit Plan QMS 审核计划
FO_27_01_033e	Action plan 不符合项报告	FO-00391	Audit finding list 审核发现清单
FO_27_01_032e	Audit / assessment report 审核/评估报告	FO-00392	Client QMS Audit Report 客户 QMS 审核报告
CL_27_01_122e	Checklist ISO 13485 ISO 13485 检查表	FO-00469	MDR Client QMS Audit Checklist MDR 客户 QMS 审核检查表
		FO-00473	IVDR Client QMS Audit Checklist IVDR 客户 QMS 审核检查表
		FO-00407	Client Audit Participation List 客户审核参与清单

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

Combined audits for ISO 13485 and QMD Services IVDR/MDR QMS audits are only commissioned to auditors who are authorized in both companies. ISO 13485 和 QMD 服务 IVDR/MDR QMS 审核的联合审核仅委托给两家公司授权的审核员。

5.3 Specialties in ISO 13485 audits ISO 13485 审核的具体内容

Special attention shall be paid to the following focus areas 应特别注意以下重点领域:

- According to Policy ILAC-P10:07/2020, only calibration certificates bearing the accreditation symbol or a textual reference to the accreditation of the calibration laboratory ensuring the scope of accreditation specifically covers the appropriate calibration, may be confirmed as metrologically traceable.根据政策 ILAC-P10:07/2020，只有带有认证符号或校准实验室认证文本参考的校准证书才能被确认为计量可追溯，以确保认证范围具体涵盖适当的校准。

Or 或

- A laboratory whose calibration service is suitable for the intended use but not covered by the ILAC Arrangement or by Regional Arrangements recognized by 校准服务适合预期用途但不在 ILAC 安排或国际实验室认可的区域安排范围内的实验室。
    - ILAC. In this case, the Accreditation Body shall establish a policy to ensure that these services meet the relevant criteria for metrological traceability in ISO/IEC 17025. ILAC。在这种情况下，认证机构应制定政策，确保这些服务符合 ISO/IEC 17025 中计量可追溯性的相关标准。

5.3.1 Additional requests for manufacturers of Class A and Class I devices 对 A 类和 I 类设备制造商的额外要求

ISO 13485 requires the organization to comply with the statutory and regulatory requirements applicable to the safety and performance of the medical devices. The maintenance and evaluation of legal compliance is the responsibility of the client organization.ISO 13485 要求组织遵守适用于医疗器械安全和性能的法律法规要求。维护和评估法律合规性是客户组织的责任。

In case of legal manufacturers of class I and class A devices a documentation review off-site shall be included in the audit. The review shall be schedulded for 2h – 4h and shall include the organisation´s approach/compliance of 对于 I 类和 A 类器械的合法制造商，审核中应包括非现场的文件评审。评审应安排在 2 - 4 小时，并应包括组织对以下方面的方法/合规性:

- General Safety and performance requirements according to MDR/IVDR
- 根据 MDR/IVDR 的一般安全和性能要求
- Product(s) Risk management
- 产品风险管理
- Clinical evaluation/Performance evaluation of devices
- 器械临床评价/性能评价

In case that an organisation manufactures a high amount of products a sample has to be taken. 如果一个组织生产大量的产品，就必须进行取样。

The organisation is asked to upload the documents in advance to a **quality**austria Cloud. The Upload link is provided by the responsible CSC employee.该组织被要求提前将文件上传到 qualityaustria 云。上传链接由负责的 CSC 员工提供。

For the plausibility check of the provided documentation during the on-site audit 1hour additional audit time shall be included in the audit plan.为了在现场审核时对所提供的文件进行合理性检查，审核计划中应增加 1 小时的审核时间。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

The responsibility for the correctness of the classification of the medical devices according to the applicable regulation lies with the manufacturer and the competent authority. Quality Austria auditors shall only verify that the technical documentation contains a justification for the classification of the device.根据适用法规对医疗器械进行正确分类的责任在于生产企业和主管部门。Quality Austria 审核员只应验证技术文件中包含器械分类的理由。

5.4 Major nonconformities 严重不符合项

Examples of major nonconformities which require the acceptance and the verification of the effectiveness of correction and corrective actions are as follows 需要接受并验证纠正和纠正措施有效性的严重不符合示例如下:

a) failure to fully address applicable requirements and implement an entire process for quality management systems (e.g. failure to have a complaint handling or training system)未能充分提出适用的要求并实施质量管理体系的整个过程（例如，未能建立投诉处理或培训体系）
b) failure to implement applicable requirements for quality management systems 未能实施质量管理体系的适用要求
c) failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects 当对上市后数据的调查表明产品缺陷的模式时，未能实施适当的纠正和预防措施
d) products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling 投放市场并根据产品标签使用器械时对患者和/或用户造成不当风险的产品
e) the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements 存在明显不符合顾客规范和/或法规要求的产品
f) repeated nonconformities from previous audits 以前审核的重复不符合项

5.5 Hints and Recommendations 提示和建议

Hints and recommendations shall be formulated in the audit report. Hints shall document that the topic raised may result in a future/potential nonconformity. Recommendations document an opportunity to improve a process without causing any impact to compliance. 审核报告应当提出提示和建议。提示应记录提出的问题可能导致未来/潜在的不符合。建议记录了改进过程的机会，而不会对遵从性造成任何影响。

In formulating hints and recommendations, assure that these are not consultancy. Consultancy would be statements, where specific methods are recommended, where specific solutions to current challenges or guidance on how to solve a problem are formulated.在制定提示和建议时，确保这些不是咨询。咨询将是陈述，其中建议具体方法，其中针对当前挑战的具体解决方案或如何解决问题的指导。
Evaluating hints and recommendations against potential consultancy is a focus in each veto review.评估潜在顾问的提示和建议是每次否决审查的重点。

5.6 Short notice or unannounced audits 临时通知或未通知的审核

Short notice or unannounced audits may be required when 在以下情况下，可能需要进行临时通知或不事先通知的审核:

a) external factors apply such as 外部因素，如:
   - devices in scope of certification indicate a possible significant deficiency in the quality management system 认证范围内的器械表明质量管理体系中可能存在重大缺陷
   - significant safety and performance related information becoming known to Quality Austria 重要的安全和性能相关信息被 Quality Austria 知晓
b) significant changes occur which have been submitted as required by the regulations or become known to Quality Austria, and which could affect the decision on the client's state of compliance with the regulatory requirements 已按法规要求提交或 Quality Austria 的重大变更，并可能影响对客户符合法规要求状态的决定
c) when required by legal requirements under public law or by the relevant Regulatory Authority 当公法或相关监管机构的法律要求时

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

5.7 Triggers for unannounced or short notice audits 临时通知或未通知审核的触发因素:

a) QMS – impact and changes 质量管理体系——影响和变化:

i) new ownership 新的所有权

ii) extension to manufacturing and/or design control 扩展到生产和/或设计控制

iii) new facility, site change 新设施、场地变更

a. modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralizing the design and/or development functions for several manufacturing sites) 涉及生产活动的现场操作的变更（例如，将生产操作搬迁到新现场或集中几个生产现场的设计和/或开发功能）

iv) new processes, process changes 新过程、过程变更

a. significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on-site facility or a change in the method of sterilization) 特殊过程的重大变化（如生产从供应商灭菌改为现场设施灭菌或灭菌方法的改变）

v) QM management, personnel 质量管理、人员

a. modifications to the defined authority of the management representative that impact 对已定义的管理者代表权限的修改，其影响:

i. quality management system effectiveness or regulatory compliance 质量管理体系的有效性或法规符合性

ii. the capability and authority to assure that only safe and effective medical devices are released 确保只放行安全有效的医疗器械的能力和权限

b) product related changes 产品相关变化:

i) new products, categories 新产品、新品类

ii) addition of a new device category to the manufacturing scope within the quality management system (e.g. addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment) 在质量管理体系的生产范围中增加一个新的设备类别（例如，在现有仅限于血液透析设备的范围中增加无菌一次性透析设备，或在现有仅限于超声设备的范围中增加磁共振成像设备）

c) QMS & Product related changes)质量管理体系和产品相关的变更:

i) changes in standards, regulations 标准、法规的变化

ii) post market surveillance, vigilance 上市后的监督、警惕

An unannounced or short-notice audit may also be necessary if the Quality Austria has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements. 如果 Quality Austria 对纠正措施的实施或对标准和法规要求的遵守有合理的关注，也可能需要进行未经通知或临时通知的审核。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

5.8 Audit team for suppliers of "Parts and Services" "零件和服务"供应商审核小组

The auditors for suppliers of "Parts and services" shall be authorized for the scopes 7.x.
"零件和服务"供应商的审核员应获得范围 7.x 的授权。

If the answer is "Yes" to any of the questions below, the audit team shall always include competence for the relevant Technical Areas in Tables A.1.1 – A.1.6 and the "Auditor" requirements in Table B.1. If the answer to all questions is "No", then the audit team shall satisfy only the "Parts and Services" auditor requirements in Table B.2
如果对以下任何问题的回答是"是"，审核组应始终包括表 A.1.1 - A.1.6 中相关技术领域的能力和表 B.1 中"审核员"的要求。如果所有问题的答案均为"否"，则审核组应仅满足表 B.2 中"部件和服务"审核员的要求。

Table B.1 表 B.1

Question 问题	Yes 是	No 否
Is the product a nearly finished medical device? (i.e., it is intended to be used for a medical purpose and only needs packaging and/or labeling) 产品是接近完成的医疗器械吗？（即，用于医疗目的，只需要包装和/或标签）		
Is the product intended to be a component/part of a medical device? 该产品是否打算成为医疗器械的组件/部分？		
Is the organization contracted to carry out any activities that are regulated by a medical device regulation (e.g., relabeling, remanufacturing of other medical devices? 组织是否签约进行任何受医疗器械法规监管的活动（例如，重新贴标签，其他医疗器械的再制造）？		
Is the product supplied sterile? 供应的产品是否无菌？		
Does the product contain software developed by the client organization or a supplier? 产品是否包含客户组织或供应商开发的软件？		
Is "Design and Development" in the scope of the ISO 13485 certification (e.g., when public law permits exclusion of design and development which is the case very often for low-risk medical devices)? "设计和开发"是否在 ISO 13485 认证的范围内（例如，当公法允许排除设计和开发时，低风险医疗器械经常出现这种情况）？		
Is the product (Raw Materials, Parts, Components, Subassemblies, Maintenance Services, or Other Services) intended to support associated medical devices? 产品（原材料、零件、组件、子组件、维护服务或其他服务）是否旨在支持相关医疗器械？		

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

Table B.2 – Table of knowledge and skills 表 B.2——知识和技能表

Certification functions 认证功能 / **knowledge and skills** 知识和技能	Personnel conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit duration 进行申请审查的人员，以确定所需的审核团队能力，选择审核团队成员，并确定审核持续时间	Personnel reviewing audit reports and making certification decisions 审查审核报告并作出认证决定的人员	Auditor 审核员	**Parts and Services Auditor REF Table A.1.7 零件和服务审核员参考表 A.1.7**	Personnel managing program 人员管理程序
Knowledge of generic quality management system practices 通用质量管理体系实践知识	x	x	x	x	x
Knowledge of legal framework of regulations and role of the CAB 了解法规的法律框架和 CAB 的作用	x	x	x	x	x
Knowledge of medical device risk management, e.g. ISO 14971 医疗器械风险管理知识，例如 ISO 14971	x	x	x	x	x
Knowledge of intended use of medical devices 了解医疗器械的预期用途			x *		
Knowledge of risks associated with the medical device 了解与医疗器械相关的风险			x *		
Knowledge of relevant product standards in the assessment of medical devices 了解医疗器械评估中的相关产品标准			x *		
Knowledge of CAB's ISO 13485 processes 了解 CAB 的 ISO 13485 流程	x	x	x	x	x
Knowledge of Medical Device business/technology 医疗器械业务/技术知识	x	x	x *	x	x

* The knowledge in the areas marked with *could be provided by a technical expert.
标有*的领域的知识可以由技术专家提供。

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

6. Certificate, printing the Certificate and granting Certificates 证书、打印证书和颁发证书

As for Certificates and for printing Certificates, the procedures as defined for ISO 9001 will generally apply. 对于证书和打印证书，通常适用 ISO 9001 规定的程序。

6.1 qualityaustria System Certificates (ISO 13485:2016 / EN ISO 13485:2016) qualityaustria 体系证书（ISO 13485:2016 / EN ISO 13485:2016）

The **quality**austria system certificates according to ISO 13485:2016 or EN ISO 13485:2016 are generally valid for 3 years. The scope of the certificate is formulated by the respective auditor together with the customer before or during the audit. 根据 ISO 13485:2016 或 EN ISO 13485:2006 的质量工业体系证书通常有效期为 3 年。证书的范围由各审核员在审核前或审核期间与客户共同制定。

The standard stated on the certificate is also coordinated with the customer. There are 2 options available: The European standardization EN ISO 13485:2016 is usually offered. For organizations that serve the international market (=outside Europe), optional certificates according to ISO 13485:2016 will be issued. 证书上规定的标准也与客户协调。有两种选择：通常提供欧洲标准 EN ISO 13485:2016。对于服务于国际市场（=欧洲以外）的组织，将颁发符合 ISO 13485:2016 的可选证书。

The scope must be clearly defined; it must be ensured, that it does not seem as a „product certification". 必须明确界定范围；必须确保它看起来不像是“产品认证”。

7. Maintenance and recertification 维持和重新认证

7.1 Maintenance 维持

As for maintenance of the Certificate (recertification), the requirements relating to ISO 9001 will principally apply. 至于证书的维护（重新认证），主要适用与 ISO 9001 有关的要求。

Existing cooperation clients with DQS med DQS-med 现有合作客户:
Existing cooperation clients of DQS MED will continue to be supported according to the requirements of DQS MED until the end of the transition period of Directive 98/79/EEC and Directive 92/43/EEC.在指令 98/79/EEC 和指令 92/43/EEC 的过渡期结束之前，DQS MED 的现有合作客户将继续根据 DQS MEDI 的要求得到支持。

8. Accreditation 认可

Quality Austria is accredited by Accreditation Austria.

Quality Austria 由奥地利认证委员会认证。

9. Enclosures 附件

- FO_05_01_03_14e_ Qualification form for ISO 13485 auditors ISO 13485 审核员资格表
- FO_25_03_01e_Information_offer_making_IMS IMS 信息表
- FO_25_03_01-01_Zusatzinformation_13485_Sterilgutversorgung
- FO_25_03_17_IMS Calculator IMS 计算器
- RE_27_01_074e_Certification of multi-site organizations 多现场组织认证

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com

- CL_27_01_112e_ISO 13485_2016
- CL_27_01_122e_Stage 1_13485_2016 ISO 9001_2015
- FO 27_01_030e audit and assessment plan (time plan) 审核评估计划（时间计划）
- FO 27_01_032e audit/assessment report 审核/评估报告
- **quality**austria - Sample Certificate ISO 13485 **quality**austria - ISO 13485 样本证书
- IAF MD9 issue 4: 2023

QMD Services forms QMD 服务表格:

- FO-00471 Client QMS Stage 1 report 客户 QMS 一阶段报告
- FO-00384 QMS Audit Plan; QMS 审核计划
- FO-00391 Audit finding list; 审核发现清单
- FO-00392 Client QMS Audit Report; 客户 QMS 审核报告
- FO-00469 MDR Client QMS Audit checklist; MDR 客户 QMS 审核检查表
- FO-00473 IVDR Client QMS Audit checklist ; IVDR 客户 QMS 审核检查表
- FO-00407 Client Audit Participation List. 客户审核参与清单

Customer Service Center: A-4020 Linz, Am Winterhafen 1
Phone: +43 732 34 23 22, www.qualityaustria.com
E-Mail: office@qualityaustria.com