

UKAS & RvA Accredited ISO 13485 Certification Scheme Manual

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Revision History

Rev No	Revision Date	Author	Approved by	Page No	Sec. No	Brief Description of Change
0	Feb 2018	Y Buisson	Medical Device Document Control	New	New	<p>New document – based on PP370 and MDP200/MDP7300 plus updates:</p> <p>Removal of lone references to old procedures numbers (MDP200) and incorrect reference (MDF7012).</p> <p>Section 7.4 Client best fit codes added with IAF-MD9:2017 additions related to service provision.</p> <p>Section 7.2 Assessor competence now refers to CE and other scheme manuals</p> <p>Section 8 Removal of MDC prefix as both UKAS and RvA certificates will have the same MD prefix</p> <p>Section 12.1 Certification process: removal of reference to MDF4803 in line with a move to the use of email templates based on this form for APAC submissions with links to PG content</p> <p>Section 12.2 scope writing – Reference to IAF-MD9 Technical Areas and addition of IAF-MD9 parts and services scoping requirements</p> <p>Section 10.9 Transfer assessments – offsite reporting for onsite assessments</p> <p>References to C13485:2016 included</p> <p>Delete references to old / withdrawn (per Nov 2017) MDP / MDF procedures</p>
1	April 2018	Y Buisson	Medical Device Document Control	21 24	11 12.3	<p>Reference to corrective action plan procedures and templates</p> <p>Insertion of “should be used.”</p>
2	Sept 2018	Y Buisson	Medical Device Document Control	6 7 9 11	Rel Doc 1 5.1 7.2	<p>Add references to the Document (incl RVA's SAP and MDP3300)</p> <p>Add sentence to Introduction BSI-UK and BSI-NL both hold an Accreditation Certificate as a Conformity Assessment Body (CAB) providing audit and certification of management systems per ISO 17021-1.</p> <p>Add responsibility of QMS team to ensure the CAB's QMS Assessment Process meets the accreditation requirements.</p> <p>Contractual requirements for external resource QMS assessors added in accordance with MDP3400 and “under direct local observation” inserted in relation to trainee QMS assessments</p>

Rev No	Revision Date	Author	Approved by	Page No	Sec. No	Brief Description of Change
				13	7.2.5	Addition of CE requirements for Re-qualification
				22	12.1	Amendments in accordance with new form name changes and MDP8820 ISO 13485 Technical & Regulatory Compliance (TRC) Procedure.
3	Jan 2019	Y Buisson	Medical Device Document Control	5	9	Correction of reference to SAP-C021, adding references BR004, MDfs related CIF, MDP4200)
				15	9.1	Clear reference to GP016 added (formerly only referenced via EMCP119)
				16	10	Addition of reporting requirements, effective April 2019
				23	12.3	New section describing the issue of certificates referencing the harmonised "EN" version of ISO13485
				all	all	Throughout: Change of terms from assessor and assessment to AUDIT and AUDITOR
4	March 2019	Y Buisson	Medical Device Document Control	all	all	Throughout: Change of P13485:2003 + C13485:2016 to P13485 – ISO13485 in accordance with transition plan. Amendment of 17021-1 to 17021 where 17021-3 also applies. Addition of 17021-3 to list of references.
				14	7.4	Clarification of competence code requirements for medical devices incorporating specific substances/technologies, including requirement where P37/05HAT and P37/05B are already applied.
				22	12.1	Clarification and changes to APAC PSPanel1Reg TRC submission process. Minor clarification of certification scope review with relation to the scope of ISO13485:2016 generally (i.e. including services).
5	July 2019	Y Buisson	Medical Device Document Control	13	7.2.5	Maintaining competence for key activities staff
				18	10.6	Phase out of recertification by OPT1
				20	10.9	Removal of UKAS to RVA transfer assessments
				21-22	11-12	New section on remote auditing using ICT linking to GP145
				23	13.2	Removal of G011/A7 requirement for NCR close-out visits
				25-30	App A	Scoping guidance and phase out of "control of" manufacture A new appendix listing IAF MD9 technical areas

Rev No	Revision Date	Author	Approved by	Page No	Sec. No	Brief Description of Change
6	January 2020	K. Rolf	Medical Device Document Control	9	2	Replace the Regulatory Lead-The Netherlands of BSI-NL to Global RVA Scheme manager.
				16	8	Removal of maintaining original certificate dates for transfers between UKAS and RvA accreditations.
				17	9.1	Sampling plan requirements for PR China added
				22	10.9	Addition of auditor's T code requirements for transfer audits
				22	10.11	BSI UK to NL NB Transition
				28	App A	Addition of dental devices to technical area table in accordance with IAF MD8.
				All	All	Replace Global QMS with GQA (Global Quality and Accreditation) Team, assessor/assessment by auditor/audit, Technical and Regulatory Compliance (TRC) by Certificate Decision Making (DM 13485).
				All	All	Remove reference to previous ISO 13485 versions, ISO 13485:2016 Transition and EMCP119.
				All	All	MDF8823: ISO13485 Audit Duration Calculation Form and removal of renewed duration information.
				All	All	Reference to IAF MD2 and RvA-VR003-UK (logo)
				33	App B	Policy for addressing clause 4.2.3 in ISO 13485:2016

Related Documents

Document Number	Title
ISO/IEC 17021-1	Conformity Assessment – Requirements for bodies providing audit and certification of management systems. Part 1: Requirements
ISO/IEC 17021-3	Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 3: Competence requirements for auditing and certification of quality management systems
ISO 13485	Medical Devices – Quality Management Systems – Requirements for regulatory purposes.
IAF-MD2	Transfer of Accredited Certification of Management Systems
IAF-MD5	Determination of Audit Time of Quality and Environmental Management Systems.
IAF-MD8	Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485)
IAF-MD9	Application of ISO/IEC 17021-1 in the field of Medical Device Quality Management Systems (ISO 13485).
CPM1060	UKAS Brand Identity Guidelines
GD211	Health Canada - Study Guide: Guidance on the content of quality management system audit reports
RVA-BR004	RVA's Policy rule Non-conformities and Corrective actions
RvA-VR003-UK	Regulation for the use of Accreditation marks and logo's
SAP-C000	RVA's Specific Accreditation protocol for Accreditation of Certification of Management Systems (general based on ISO/IEC 17021-1)
SAP-C021	RVA Specific Accreditation Protocol for Certification according to EN ISO 13485
Procedures	
GP005	Principles of certificate issue
GP009	Impartiality Process
GP011	Code System (Best Fit) Index
GP016	Assessment Durations Multi-Site Clients
GP027	Conducting a BSI Assessment
GP031	Global Transfer Process
GP033	Guidance for audit in China
GP035	Staff Competency & the Competency Code System
GP044	Integrated Audits & Extension to Scope Durations
GP047	Certificate Decision Policy
GP145	Information and Communication technology - use in audits
MDP1200	Independence and Impartiality
MDP2000	Medical Devices Quality Management System Structure
MDP3300	Qualification, training and authorisation of personnel
MDP3400	Subcontractors and External Specialists
MDP3500	Monitoring of competences training and exchange of experience
MDP4200	Medical Device Preapplication Activities and Proposals (MDR/IVDR, QMS and MDSAP)
MDP4520	Quality Management System Auditing in Support of CE Certification
MDP7300	Medical Device Preapplication Activities and Proposals (MDD/AIMDD/IVDD, QMS and MDSAP)
MDP8810	ISO 13485 MDSAP Audit Manual
MDP8820	ISO 13485 Certificate Decision Making (DM 13485) Process
FORMS	
GF013	Form for qualification applications
GF058	Risks and opportunities use of ICT on audit
MDF3315	ISO 13485 Competency Matrix
MDF4200	MDR Company Information Form (CIF)
MDF4201	IVDR Company Information Form (CIF)
MDF4202	13485 Company Information Form
MDF4521	Opening and closing meeting
MDF4523	Medical Devices Assessment E-report Template
MDF4801	Certification Report

MDF4802	Certification suspension-cancellation-refusal authorisation
MDF7300	Medical Devices Company Information Form (CIF)
MDF7301	Company Information Form In Vitro Diagnostic
MDF8820	ISO13485 Certificate Decision Making (DM 13485) Checklist
MDF8823	ISO13485 Audit Duration Calculation Form

1 Scope

This manual applies to all UKAS and RvA accredited ISO 13485 certification audits of Quality Management Systems conducted under the authority of BSI worldwide, for all manufacturers of medical devices, sub-contractors, related service providers and sterilisation units. BSI-UK and BSI-NL both hold an Accreditation Certificate as a Conformity Assessment Body (CAB) providing assessment and certification of management systems per ISO 17021. BSI-UK is accredited as a Conformity Assessment Body for ISO 13485 by UKAS. UKAS is the United Kingdom Accreditation Service. BSI-NL is accredited for ISO 13485 by the RvA. RvA means = Raad voor Accreditatie (Dutch Accreditation Council).

Note – this ISO 13485 certification Scheme Manual / procedure does not cover CE marking activities for products which require the involvement of a Notified Body, nor does it cover the regulatory application of ISO 13485, such as for MDSAP.

This manual is designed to enable and ensure a consistent delivery of UKAS/RvA accredited ISO 13485 certification throughout BSI, wherever in the world this service may be provided.

This manual defines the activities to be followed in order to ensure that the accreditation held for this scheme is obtained and maintained and hence it establishes the policies and rules which must be adhered to as the minimum standard applicable for the delivery of UKAS/RvA accredited ISO 13485 certification.

The scope of the BSI accreditation covers all medical devices business areas that are currently covered by the ISO 13485 Schedule of Accreditation as issued by UKAS and RvA. There are no areas of exclusion.

This manual also applies to the delivery of all current versions of ISO 13485 and where the terminology 'ISO 13485' is used, all valid versions of this standard are applied.

2 Legally Enforceable Agreement with Client

Standard BSI conditions of contract will normally apply. Any deviation from these standard terms will first need to be approved by Group Legal. Contract review documentation will identify which accreditation body has been selected. Main and critical locations will have conditions of contract available in their local language. (Currently English, Dutch and Japanese).

The global procedure GP024 outlines the rules to be followed for use of BSI Symbols and Accreditation logos in relation to this product. Client guidelines on using BSI logos is detailed in GP045, which is available to clients on the BSI website. RvA-VR003-UK provides details on regulation for the use RvA accreditation marks and logos.

The accredited certification process is expected to ensure that the organization has a quality management system, suitable for the nature of its activities, products and services, that conforms to the requirements of ISO 13485, and in particular can demonstrate for the defined scope that the organization has met customer requirements and regulatory requirements applicable to medical devices and related services. ISO 13485 certification cannot be provided where the product is not regulated as a medical device in at least one country in the world. Where the organisation provides associated services e.g. transportation, the applicability relates to the devices within the scope of the organisation's activity, e.g. the devices being transported. Any queries regarding applicability should be resolved with the Global UKAS/RvA ISO 13485 Scheme Manager.

3 Legal and Regulatory Requirements of the Scheme

All applicable local, national and ratified International laws and regulations in relation to "ISO 13485" activities are applied. Such laws and regulations are based upon the location of clients and the location of where products and services are being supplied. Any requirements over and above standard BSI global procedures are specified in this manual. There may be the need to update this manual in order to be able to prepare for new accreditation applications. Under these circumstances, certificates shall NOT be issued until the new accreditation is confirmed formally by the respective accreditation body.

4 Scheme Description

ISO 13485 is a management system standard that can be used where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this International Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization. While this is a stand-alone standard, it is based on ISO 9001:2008, which has been superseded by ISO 9001:2015. The adoption of the **High-Level Structure** (HLS) by ISO 9001:2015, but not by ISO 13485:2016 (remained Clause-Structured) means that the assessment of these schemes is less unified and additional time requirements may apply per MDP7300.

This International Standard includes some particular requirements for organizations involved in the life-cycle of medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management system meets all the requirements of ISO 9001.

The scheme is an accredited third-party certification scheme that is offered globally, and which will result in the certification of clients against ISO 13485.

The UKAS ISO 13485 scheme is managed by the Medical Devices group in the UK therefore the contract review, certification decisions and certificate issues must be carried out by this office. The exceptions to this are: approved critical locations under the UKAS accreditation. This is a location that has been authorised to undertake critical activities, such as certificate decisions, for example BSI Japan.

The RvA ISO 13485 scheme is managed by the Medical Devices group of the BSI's Conformity Assessment Body in the Netherlands therefore the contract review, certification decisions and certificate issues must be carried out by this office. The exceptions to this are: approved critical locations under the RvA accreditation. This is a location that has been authorised to undertake critical activities, such as certificate decisions and contract review, for example BSI UK. All terms and definitions as used within ISO 13485 apply.

5 Oversight of Critical Locations

Critical locations (as defined in Section 4) will follow the guidelines set out in this manual and the appropriate global procedures. Where there are specific regional requirements in addition to the global requirements, local procedures and relevant translations may be created, but these should not contradict global policies and procedures for the UKAS/RvA ISO 13485 Scheme.

Oversight of critical locations may take a number of forms and the responsibility for managing this oversight falls to the relevant interested parties.

Accreditation	Main location	Critical location
UKAS	UK	Japan
RvA	The Netherlands	UK

Responsibility	UKAS and RvA Global Scheme Managers / GQA (Global Quality and Accreditation) Team
Ensure BSI's QMS Process and BSI' Procedures and Forms related QMS audit processes meet the accreditation requirements of the IAF (IAF-MDxx) Mandatory Documents, ISO 17021, RvA's BR004, SAP-C000 & SAP-C021. Attendance of relevant staff / relevant input to management meetings Attendance and/or receipt of QMS auditor update training sessions (e.g. annual update training).	GQA (Global Quality and Accreditation) Team
Review of internal audit findings.	Global Medical Devices Compliance and Risk
Review of third-party audit findings.	GQA Team and Global Medical Devices Compliance and Risk
Review of quality performance data at management review.	GQA Team and Global Medical Devices Compliance and Risk
Review of commercial performance at management meetings.	Medical Devices Commercial management team

Outputs from these reviews will be documented in the relevant associated records, such as competence records, internal audit records, management review meetings and other meetings as relevant.

6 Accreditation & Impartiality Requirements

The scheme is a UKAS and RvA accredited scheme and standard BSI rules of impartiality apply per GP009 & MDP1200.

BSI employees and external resource auditors will have signed a confidentiality/impartiality agreement on employment and external resource personnel will also have signed an agreement that includes a confidentiality clause.

7 Competence Requirements

The competence of all personal involved in the ISO 13485 certification auditing process are defined

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in the MDF3315 (PF145 / A657) form which must be completed for an application, qualifying or requalifying review of any scheme code. All codes shall be applied for using a GF013 form supported with a completed MDF3315. A copy of the GF013 and MDF3315 is held with the code holder and the registrar. The requalification requirements for scheme codes is covered in the BSI core auditor development processes and the best fit code system.

Those personnel involved in the ISO 13485 certification process shall be competent for the functions they perform.

Function	Responsibility	Code / Qualification
Global UKAS/RvA 13485 scheme manager	Oversees the global accreditation and certification processes. The Global Scheme Manager is responsible for ensuring that the policies and rules documented within this manual are complied with throughout BSI and for ensuring that BSI is aware of updates and revisions to ISO 13485, the regulatory and accreditation framework and audit and certification practices. The Global Scheme Manager shall ensure an internal audit determining the effectiveness of the operation of the scheme is conducted at least once per annum.	Experiential, accreditation requirements, or holder or past holder of P13485 - ISO13485
Regional scheme management: Nominated regional staff in critical locations	Oversees the implementation, operation and maintenance of the rules and policies of the global scheme at the regional and local level.	Experiential or holder or past holder of P13485 - ISO13485. Typically, this person may be a country manager, a member of the GQA team or an experienced scheme manager of a similar scheme, as deemed appropriate.
Marketing	Retain responsibility for pricing, selling and strategic and tactical marketing throughout the product lifecycle. This is carried out under the control of the respective regional VP.	n/a
Sales	Responsible for the handling of enquiries and the development of applications (Company Information Forms (CIF)). Responsible for ensuring that applications and potential changes to certificates are communicated to the UK/NL (for customers worldwide) or Critical Location teams for contract review.	C328. Awareness of relevant procedures, manuals, certificate structure and accreditation issues
Regional Planning & Administration	Regional administrators are responsible for delivery of the administrative elements of the scheme within their own local area.	Awareness of relevant procedures, manuals, certificate structure and accreditation issues
Product / Scheme Manager / certification specialist	In countries where this role exists, this role will be responsible for supporting the contract review process and preparing documents for the certification decision process.	Awareness of relevant procedures, manuals, certificate structure and accreditation issues
Compliance and risk	Responsible for ensuring all the regulatory and accreditation requirements are complied with.	Accreditation requirements
Audit Team	Responsible for the delivery of certification audit against the policies and procedures included and referred to in this manual.	Listed on the auditor register, P13485 - ISO13485
Certification Reviewers &	Responsible for the independent review of the certification/ recertification audit and the certification/ recertification decision.	C170 – UKAS C213 – RvA

Function	Responsibility	Code / Qualification
Certificate Decision Makers		

7.1 Competence Requirements - Overview

Required types of knowledge and skills for personnel involved with the ISO 13485 activities. IAF-MD9 Annex B specifies the type of knowledge and skills that a CAB has defined for specific functions in addition to knowledge and skills per *ISO/IEC 17021-1 Annex A* such as language skills appropriate to all levels within the client organization, note-taking & report writing skills, presentation skills, interviewing skills, audit management skills.

7.2 Auditor competence

Auditors will be qualified and requalified using the standard process described in GP035. The requirements for achieving P13485 - ISO13485 are described in GP011. In addition, external resource auditors also require their external resource contract and the relevant contract novations (see MDP3400) to be uploaded to their PointGlobal profile by the local registrar for skill code P13485 - ISO13485 to be assigned.

- For an Auditor qualifying-review, the auditor shall have demonstrated successful participation in a minimum of four audits for a total of at least 20 days under direct local observation, 50% of which shall be against accredited ISO 13485, 50% may be against accredited ISO 9001. This will have included the entire process of auditing medical device quality management systems, including review of documentation and implementation, risk management of applicable medical devices, parts or services (see IAF-MD9 Table A.1.7) and audit reporting.
- For a Lead Auditor qualifying review the auditor shall have experienced an audit team leader role under the supervision of a Lead Auditor in at least three ISO 13485 audits, one of which may be the qualifying review.

As well as general audit and ISO 13485 competence, it is expected that auditors will have an appreciation of the role of ISO 13485 in the regulation of medical devices worldwide, including knowledge of the basics of the International Medical Device Regulators Forum (IMDRF) (formerly called GHTF) model.

Additional requirements for CE Marking are covered in MDP4520. Additional requirements for any schemes based on ISO13485 (e.g. MDSAP) are covered in the respective scheme manuals.

7.2.1 Regulatory background

An appreciation of the role of the following is expected:

- Knowledge of generic quality management system practices;
- Knowledge of the legal framework of regulations and the role of a Certification Assessment Body;
- Knowledge of the CABs ISO 13485 processes
- Risk Management
- Adverse incident processes

7.2.2 Medical device background

Auditors are recruited with a view to holding sufficient background or knowledge of the use of medical devices to appreciate the hazards of their use. This will be demonstrated via resume/CV.

This may include qualifications in:

- biology or microbiology
- chemistry or biochemistry
- computer and software technology
- electrical, electronic, mechanical or bioengineering
- human physiology
- medicine
- pharmacy
- physics or biophysics

Any advanced knowledge necessary is covered when auditors progress to CE Marking audits and is outside the scope of this document.

7.2.3 Manufacturing background

Sufficient background or knowledge of product realization processes either related to medical devices or in other industries, to appreciate the methods and materials involved and the potential complications associated with their use, related to the T code held. Typically, 4 years of medical device or related experience at a finished goods manufacturing location or subcontractor or supplier of product services or repair or service of products.

7.2.4 English language requirements

Language skills both oral and written to allow:

- conduct of audits in English (including the provision of all related audit documentation in English). Whilst the audit may also be conducted in the local language, all documentation and key correspondence must be in English. The only exception to this is audits conducted by BSI Japan as critical location for the UKAS scheme in their local territory, where the audit does not include EC or MDSAP certification.
- receipt and understanding of all relevant training provided in English;
- effective verbal and written communication in English with clients, BSI colleagues and regulators.

7.2.5 Maintaining competence

Ongoing monitoring of competence will be managed via MDP3500.

Full time auditors should be expected to deliver a minimum of 20 days of ISO 13485 audit annually to maintain competence. For other staff for whom assessing is not their full-time role, maintenance of P13485 - ISO13485 should equate to 10 days assessing annually, of which up to 50% may consist of delivering QRs, observing trainees, witnessed audits and unannounced visits. For staff delivering key ISO13485

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activities, such as certificate decision makers, report reviewers or scheme managers, this may be increased to 75% and also include ISO13485 certificate decisions or report reviews (3 equivalent to 1 audit day). Other combinations may be possible, and exceptions must be reviewed for risk on a case by case basis.

Requalification witnessed audit must be ISO13485. Where possible, requalification should be done using on-site qualifying reviews. However, a remote review is possible where challenges exist, such as difficult geographic constraints and travel bans or for staff who deliver key ISO13485 activities, such as certificate decisions, report reviews or scheme management. Remote requalification must be performed on ISO13485 audit reports. If the auditor is CE qualified, please refer to MDP3300 for additional requalification requirements.

7.3 Audit team competence

All audits must be allocated to staff with the correct competency as defined by the best-fit code methodology and as recorded on SAP. Best Fit Codes are allocated to the client to ensure the correct resource can be identified for the audit team.

Over the audit cycle the requirements of all P/T/S codes must be met. For ISO 13485 audits each visit must be carried out by an auditor holding code P13485 - ISO13485. Where a single T code is allocated to the client each visit must be carried out by an auditor holding that code. Where more than one T code is allocated to the client the T code requirements must be met over the audit cycle. If an auditor on the team does not hold the T-code(s), care should be taken to ensure that the audit plan reflects the balance of skill within the team. Topics such as design, product test/release and risk management are unlikely to be appropriate to non-code holders.

Where P37/07 is allocated to an ISO 13485 client, this requirement must be met at least once over the audit cycle or more frequently as specified by the Main Location (UK / NL) or its critical location office (See section 5). P37/07 is the skill code allocated to clients who manufacture sterile product or who perform contract sterilization activities or activities where microbiological cleanliness is of importance. Holders of P37/07 must also hold P13485 - ISO13485, as qualified auditors.

7.4 Client best fit codes:

All ISO 13485 clients must have skill code P13485 - ISO13485 assigned to them on PointGlobal. In addition, auditors also require an appropriate T code which best fits the client's scope of certification. This includes clients who outsource processes (e.g. virtual manufacturers).

The following T codes are mainly used for ISO 13485 clients:

- T04 – metal based medical devices
- T05B – software
- T06 – electro-medical devices
- T34 – chemical based medical devices
- T37D – device-drug combination medical devices, IVD's, medical devices utilising active coatings, wholly/mainly absorbed materials, or incorporating human blood derivative / animal tissue (this will normally be used in combination with one of the other T codes and IVD manufacturers will typically be allocated code S IVD ISO 13485)
- T37E - Clients where a process specific t code is not required. This may include the manufacture of parts and provision of services (IAF-MD9 Table A.1.7), where a specific t code is not deemed

necessary. More typically this includes distribution, packaging, transportation and medical device consulting services but may also apply to calibration, maintenance or other services.

- T37E & P37/07 – contract sterilization companies and sterile services
- T38B – textile based medical devices
- T38F – rubber and/or plastic based medical devices

Additional T code(s) may also be applied depending on the complexity of the client's operations. Where more than one T code is applied to a client the surveillance programme should be such that each code is used at least once in the certification cycle. The main T code should be used at least once in the certification cycle and during reassessment. For medical devices utilising tissues of animal origin,

↖ should be removed?

For medical devices incorporating specific substances/technologies, additional audit guidance and requirements may be provided by technical specialists and scheme managers. For medical devices utilising technologies not specified in this section, nanomaterials or micromechanics, the code corresponding to the general underlying material or technology will be assigned (such as T04 or T06). For devices utilising tissues of animal origin or incorporating derivatives of human blood, T37E may be applied where P37/05HAT (Processing of materials of human or animal origin) has already been applied. For devices utilising biological active coatings and/or materials being wholly or mainly absorbed, T37E may be applied where P37/05B (Biotechnology – biologically active, absorbed or dispersed materials) has already been applied.

Clients who manufacture sterile medical devices or who manufacture devices that will be sterilized will also be assigned code P37/07 (microbiology and sterilisation).

SIVD 13485 – will be applied to IVD manufacturers. If the company only distributes IVD's and does not perform any additional processing of them this code shall not be assigned, and the audit can be conducted by any ISO 13485 qualified auditor. If additional activities such as change to use, repackaging or relabelling are conducted then the S code should be applied.

8 Licence Coding

Certificate Number Prefix	Description
MD	Medical Device – UKAS or RvA

Certificates are issued with the "MD" prefix indicate UKAS or RvA accredited ISO 13485 certification. The relevant accreditation logo, and only one per certificate under UKAS or RvA must be used with the appropriate prefixed certificates.

The 4-date certificate format is used in common with other BSI management system certificates. However, for certificates transferred from another registrar the "original registration date" will be the date of the first issue of the BSI certificate.

9 Audit program, audit planning & determination of audit duration

Based on MDP7300 / MDP4200 an Audit Program (Stage 1, Stage 2, Surveillance Audits / Continuing Assessment Visits, Recertification Audits) and Audit Plan for each audit will be established for each client. For the determination of the Audit durations the methodology described in MDP7300 / MDP4200 (MDF8823 when applicable) will be used. In the case of a client holding both UKAS/RvA certification and

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MDSAP certification, the longer duration will apply. MDP7300 also covers clients who hold ISO 9001 certification.

9.1 Sampling

Where a client holds or applies for a multi-sited certificate, sampling can be used at the initial **audit** stage and for planning surveillance audits. A site cannot be listed on a certificate if it does not receive a visit based on agreed sampling frequencies. Sampling rules defined in GP016 should be used for guidance, however the following exceptions should be noted:

- UKAS and RvA 13485: No sampling of design and/or manufacturing sites
- All clients on recertification by reassessment Option 2: All sites must have a recertification audit prior to the certificate being renewed.

For multi-national organisations with site(s) in P.R. China, an independent standalone sampling plan specifically for site(s) located in P.R. China is required in accordance with GP033.

10 Certification processes

The processes for certification follow standard Global procedures, as listed on page 3 of this document, except where specific exceptions or clarifications have been made below:

Process	Remark
Application to Signed Agreement	All requirements are covered in MDP7300 / MDP4200. In case of UKAS 13485 Certification, it should be noted that before a proposal (new or existing business) is sent to a client it must be reviewed by the UK or Japan to ensure that the scope is appropriate to ISO 13485, to confirm the duration is correct and to determine the skill codes (P and T codes) required by the audit team, including any specialist skills. The application documentation must include the standard terms and conditions in respect of this scheme and a determination of which accreditation body will be used. In the case of RvA 13485 Certification, RvA contract and scope review will be performed by the BSI-NL in Netherlands or BSI-UK as critical location. No additional contract review or signed contract is required for existing clients for re-certification.
Transfer	If the transfer includes CE mark, then CE requirements will supersede standard transfer processes.
Scope Extension & Reduction	Scheme managers (where applicable) must approve the changes before they take place. Additional time will be quoted for extensions.
Multi-site certification	Scheme managers (where applicable) will decide any appropriate sampling rules to apply, with input / suggestion from the auditor and others as applicable (sales etc).
Audit Planning	Additional <i>Audit Planning</i> requirements covered in section 9.
Audit Delivery	Additional Audit requirements covered in section 10.

Process	Remark
Audit Reporting	Up until April 2019, 2 hrs off-site Healthcare Planning and Reporting Time was allowed for Surveillance, Recertification and Pre-Transfer Reviews. After April 2019 a separate half day block charging methodology is used for all audit types which may be on or off-site at the auditor's discretion. Reports should be issued within 5 working days.
Nonconformity Management	Additional NC / CAP requirements covered in section 11.
Certification Decision	See section 12.

10.1 Pre-certification assessment

No significant change from GP027. P13485 - ISO13485 shall be held, but there is no T-code or P37/XX code requirement, although this would be considered good practice where possible.

10.2 Stage 1 audit

Stage 1 is the first part of the Initial Certification Audit. The generic audit plan for stage 1 audits should be uploaded to PointGlobal and care should be taken to ensure that the scope, objectives and audit criteria are included.

As per GP027, both major and minor non-conformities may be raised at this audit. If auditors are making a recommendation to proceed to stage 2 and a major non-conformity has been raised, a justification must be clearly documented. Options under these circumstances may be to repeat the stage 1 or ensure good confidence that the issue will have been addressed by the time of Stage 2 (for example lack of Management Review or Internal Audits at Stage 1 means these areas must be covered at Stage 2). Additional time may be needed to close out large numbers of non-conformities.

Outcomes for the audit are:

- Recommend to proceed to stage 2;
- Recommend further audit – stage 1 will need to be repeated;

The stage 1 audit report should contain a clear plan for the stage 2. If during the audit, any concerns are raised as to the applicability of the proposed scope, advice should be sought from a relevant scheme manager or the Global 13485 scheme manager.

10.3 Stage 2 audit

Stage 2 Audit is the second part of the Initial Certification Audit. The requirements are as per GP027, with the following exceptions:

The plan from the stage 1 should be reviewed prior to the audit and re-issued if any significant changes are planned, such as a change of date/duration, presence of observers, new/modified processes, scheme manager briefing note instruction etc. Good practice is to include a small amount of reporting each day to avoid the last day of the plan being predominantly reporting oriented.

There are four possible outcomes from the audit:

- Recommendation for certification, no corrective action plan required (in this case no non-conformances have been raised).
- Recommendation for certification with a corrective action plan required from the organisation in writing (in this case non-conformances have been raised but are not major).
- Certification not recommended. Further audit recommended but limited to reviewing specific areas or issues where major non-conformities have been identified.
- Certification not recommended. Further audit recommended, a full re-assessment of the system as non-conformance has been identified on such a scale that the system is judged to be ineffective. Discussion should be taken with the scheme manager (if applicable) under these circumstances, as the use of this last outcome triggers the cancellation process and the client will need to reapply.

The stage 2 audit report should contain a clear three-year Audit Program and Audit Plan for the first surveillance visit. The report format should follow GD211 guidance and follow the MDF4523 template.

10.4 Surveillance audit (SA) / Continuing assessment visits (CAV)

In addition to GP027 requirements, such visits shall also contain:

- A review of actions taken for notification of adverse events, advisory notices and recalls

The plan should be reviewed prior to the visit and re-issued as specified in section 10.3.

Outcomes are as described in section 10.3 above.

Reporting for surveillance Audit Visits is per MDP7300 / 4200. If another scheme is included, e.g. ISO 9001 and a single report is being prepared, the reporting time includes all of the audit days. Reports should generally be submitted to the customer within 5 working days. Reports must follow the format specified in section 10.3.

Audit durations must be checked against MDP7300/MDP4200 (MDF8823 when applicable) at **every** visit and any discrepancies documented and justified. Durations will depend on the recertification method chosen, see section 10.5. Clients will be informed on the calculated Audit Duration and the related justification.

10.5 Re-certification audit (RA)

Re-certification should be conducted following the normal requirements and **audit** practice referenced within the global procedure GP027.

- IAF-MD9 (Annex D) via procedure MDP7300 / MDP4200 (MDF8823 when applicable) is used to determine audit durations. This is used when calculating the days required to conduct audits against ISO 13485 in order to ensure that days allocated reflect as accurately as possible the complexity of the locations to be assessed.
- An important element of the re-certification Audit is to review and confirm that current BSI **audit** planning and auditor allocation remains appropriate particularly in relation to T code, employee numbers and impartiality. This review and the resulting conclusions must be clearly included in the recertification report. Auditor rotation must be applied per GP027. However, if other scheme visits are combined, e.g., CE or MDSAP, then the strictest impartiality requirements take precedence.
- Outcomes are as for section 10.3

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- Note – if the client also holds an EC Certificate, the data from the renewal of either/both voluntary certificates may be used to feed information into a review of the CE marking certificate.

10.6 Audit program

For each client an audit program will be established starting with the Initial Management Systems Certification Audits, i.e., Stage 1 Audit plus Stage 2 Audit followed by the subsequent Certification audits. Based on the Audit time of the Initial Audit, the audit time of the subsequent audits (e.g. Surveillance Audit, Continuing Assessment Visit, Recertification Audit) are defined.

For its Audit Program, a Client can choose between the following two options:

10.6.1 Option 1: Strategic Review (OPT1) – Currently being phased out

- As of July 2019, this option is not to be applied to new ISO 13485 clients. At the next recertification audit by strategic review, OPT1 clients are to have an OPT2 cycle documented in the report 3-year plan and are to be set up with this new OPT 2 certification cycle in PG.
- If a client had originally opted for CAV and Recertification by strategic review (Option 1) * under the UKAS ISO13485 scheme, the client is required to receive at least one visit per annum with a recertification audit by strategic review in the third year. Audit durations should be checked in the appropriate table of MDP7300.

10.6.2 Option 2: Reassessment Review (OPT2)

This is the default certification cycle format and is required for all new clients and clients undergoing renewal from July 2019. The client is required to have one surveillance visit per year and a reassessment in the third year. Surveillance visits should be scheduled such that the total duration over each year is about 33% of the initial audit duration.

The reassessment will replace the surveillance visit in the third year and its duration should be about equal to 66% of the Initial Certification Audit. This should be reconfirmed against MDP7300 / MDP4200 at the time of the reassessment visit.

Table 10.6.2.1: Audit Duration as percentage of the Audit Duration during Initial Certification Audit

Option:	YEAR 1	YEAR 2	YEAR 3
#1: Strategic Review (currently being phased out)	CAV: 50%	CAV: 50%	RA Option1: 50%
#2: Reassessment Review	CAV: 33%	CAV: 33%	RA Option2: 66%

NOTE: This table is to show the principle only. Durations must be determined based on tables in MDP7300 or MDP8823 when applicable

10.7 Extension to scope audits

Requests for extension to scope audits come in two main forms or a combination of both, i.e. to add additional location(s) to the registration without amending the actual scope of registration or to add additional activities to the scope of registration. In all cases, extension to scope audits should be treated as Stage 2 audits and GP027 followed relating to information confirmation and planning. The duration of an extension to scope audit should be calculated and planned based upon durations in MDP7300, taking into account the employee numbers involved for any additional locations or activities. Audit resource requirements for the extension to scope audit should be the same as for a certification audit, Stage 2.

10.8 Special audits / short notice audits

Special audits may be required when:

- a) external factors apply such as:
 - available post-market surveillance data on the subject devices indicate a possible significant deficiency in the quality management system
 - significant safety related information.
- b) significant changes occur which could affect the decision on the client's state of compliance with the regulatory requirement.
- c) Close out of a major non-conformity.

The following are examples of such changes which could be significant when considering that a special audit is required, although none of these changes should automatically trigger a special audit:

QMS – impact and changes:

- a) New Regulations and revision in (QMS) Standards that impact the processes of the Quality Management Systems
- b) new ownership
- c) extension to manufacturing and/or design control
- d) new facility, site change 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)
- e) new processes, process changes 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)
- f) QM management, personnel modifications to the defined authority of the management representative that impact:
 - quality management system effectiveness or regulatory compliance
 - the capability and authority to assure that only safe and effective medical devices are released
- g) product related changes:

- new products, categories
- 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).
- Post market surveillance, vigilance reports

An unannounced or special audit may also be necessary if there are justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

If appropriately justified, a major non-conformity close out and report may be conducted remotely, depending on the nature of the non-conformity.

10.9 Transfer audits

The standard requirements of GP031 apply with the following exceptions:

- Auditors must hold C050 and P13485 - ISO13485. Where a single T code is allocated to the client each visit must be carried out by an auditor holding that code. Where more than one T code is allocated to the client the T code requirements must be met over the remaining audit cycle.
- Where a CE Mark certificate is included in the transfer, the requirements of CE Marking will be added to the QMS audit. See MDP4120 and MDP6100.
- Under some circumstances, contact with the previous registrar may be delayed until the final stages of the process, to prevent premature cancellation of the certificates.
- Reported off-site where the visit is conducted on-site.

10.10 Internal review

In addition to the requirements of GP046, Medical Devices procedure MDP3500 *Monitoring of competences training and exchange of experience* shall be followed on a sampling basis, confirming that completed reports reflect that the requirements stated within this manual have been correctly followed and that the information available in the reports is satisfactory.

An annual internal audit of the scheme shall be carried out by Compliance & Risk to the reference documents ISO 17021 / ISO 13485 / IAF-MD5 & IAF-MD9 in accordance with the global internal audit procedure GP025.

10.11 BSI UK to NL Notified Body Transition

In all audits where a BSI-NL CE certificate has been migrated from BSI-UK, auditors must verify and document the status of the labelling plan for update of NB number from 0086 to 2797.

11 Reporting, records and non-conformity management

Audit reports shall be GD211 compliant and follow the Healthcare model e-report template, MDF4523. Whilst the audit may be conducted in the local language, all documentation and key correspondence must be in English. The only exception to this is audits conducted by BSI Japan as critical location for the UKAS scheme in their local territory, where the audit does not include EC or MDSAP certification.

The following documentation shall be uploaded to PointGlobal:

- **audit** detail reports (GF011), (may be omitted in desktop and NCR close-out audits);
- opening and closing meeting checklists MDF4521;
- the report;
- corrective action plan, where non-conformities are issued;
- acceptance of corrective action plan;
- Z1 signature sheet confirming receipt of the audit (not the report);
- audit plan, if previous plan is missing or requires amending.

Non-conformities are raised in accordance with GP027.

Client corrective action plans are required for every audit, where nonconformities have been raised, including when non-conformities are unable to be closed. Client corrective action plans are requested and managed in accordance with MDP4520. Corrective action plan templates can be found in MDF4800 and should be used in order to enable customers to meet their regulatory obligations.

The client's corrective action response shall be in writing, received by the due date specified in the audit report, and shall include, in English;

- a description of the nonconformity and its unique reference number
- details of the correction
- result of investigation of the root cause of the nonconformity
- details of the proposed corrective action to prevent reoccurrence, the person responsible for implementation and the date by which it will be implemented.

12 Remote auditing using information and communication technology (ICT)

As a general principle audits should take place on-site. Where remote (offsite) auditing is duly justified and documented in PG, the following general guidelines apply:

Remote auditing must be permitted by all applicable regulatory schemes in the audit scope (e.g. CE and MDSAP) for the audit type and to the extent delivered. A stage 2 must take place at client site(s). Precluding locations associated with high risk devices, a stage 1 **audit** may be conducted remotely. In all cases the objectives of a stage 1 audit must be met which include evaluating site specific conditions (information generally provided by a site tour).

Where remote auditing using ICT (e.g. WebEx, email) is justified, planned and incorporated into a certification cycle, this should be in accordance with GP145 and to the extent permitted by applicable regulatory schemes in the audit scope or contract (e.g. CE and MDSAP physical visit requirements as per

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MDP4520 and MDP8810). For remote audits other than transfers and NCR close-outs, the lead auditor must contact the client and complete form GF058 in accordance with GP145 as part of the audit planning process. Suitable justifications for remote audits other than transfers and NCR close-outs include extraordinary events or circumstances. Suitable sites/audits include those without physical processes in the audit scope (such as sales, software development or virtual manufacture) where activities are considered low risk.

13 Certification process

13.1 Issue

This document only covers the ISO 13485 certification process and where an audit contains other schemes, such as ISO 9001, separate processes are implemented. These are outside the scope of this document. The principles of GP005 shall apply.

For clients based in the US and EMEA, the scheme manager will prepare documentation to support the client's application and submit for ISO 13485 Certificate Decision Making (DM 13485) review via Darwin. Independent certification reviewers, qualified per section 7, review & approve the application.

For audits by BSI Japan under the UKAS scheme, in the local territory, a locally documented certificate review process is established.

For the remainder of APAC (including Australia and New Zealand), local administrators will submit a certificate decision request to the ISO 13485 Certificate Decision Making (DM 13485) group via the PSPanel1Reg inbox. Certification reviewers will issue the MDF8820 as part of the review and approval process, which shall in turn be uploaded to PG by local administrators.

Certificate reviews are guided by the checklists in MDF8820 but should consider as a minimum:

- A quotation for initial audits and extension to scopes, approved by the scheme manager or qualified independent reviewer and the client;
- A signed contract for initial audits;
- A check of audit durations and qualification of auditors, including the use of a lead auditor on team visits;
- Appropriate audit documentation uploaded to Point Global;
- The content of the report and audit detail reports (ADRs / A7s) reflect the proposed scope and full coverage of the requirements;
- A review of the certificate scope to ensure it falls under the scope of ISO13485 or to ensure that the device in scope is considered a medical device in at least one geographic territory, appropriate wording and coverage (see guidance below); appropriate use of the accreditation mark and signatory; correct dates and addresses;
- Where cleanliness is of critical significance, or sterile and/or cleanrooms are mentioned in the scope, a microbiology audit has been performed;

13.2 Scoping guidance

ISO13485 certification demonstrates an organisation's ability to provide medical devices (defined as such by at least one global regulatory jurisdiction) and related services that consistently meet customer and applicable regulatory requirements. The scope of certification represents the extent and boundaries of this certification. The scope phrasing should generally take the format:

Scope = activities + medical device technical area or product categories + (for application/intended use/context)

Where standard activities can include design and development, manufacture, installation, provision of maintenance services, translation or distribution services for example.

The Technical Areas described in *Appendix A* should be consulted to help define the scope of certification applicable to:

- Finished medical devices
- Manufacturing of parts which are not categorized as finished medical devices (raw materials, components and subassemblies)
- Associated activities and services for example distribution, transportation, maintenance or calibration services (note that organisations providing calibration services should be accredited to ISO/IEC 17025).

Inclusion of "for" and the medical device application, intended use or context of the activity should be considered where this is not evident in the technical areas or product categories indicated. High risk activities such as "sterile", "implantable" or involving special substance (table A.1.6) should be clearly indicated where not self-evident.

There should be no use of subjective or marketing terminology. Some terminology is accepted industry practice but can cause ambiguity, such as 'life sciences'. Where the use of this terminology is thought to be appropriate, clear justification and linkage to a medical device application should be recorded on the contract review documentation. Priority shall be placed on the clarity of scope phrasing and multiple sentences in the above format may be necessary to accurately reflect certification activities. Where other schemes are involved such as MDSAP, it would be appropriate to align the scopes with the requirements of these schemes as applicable.

Specific consideration needs to be given to the use of 'manufacture' in the case of a virtual manufacturer. As of July 2019, the terms "control of" or "outsourced" will be gradually phased out. If the manufacturer cannot demonstrate that they have full control of the process in accordance with clauses 4.1.5 and 7.4, for example in the same way that a virtual manufacturer for CE marking should be able to, then their scope should reflect that of a distributor of medical devices.

13.3 Issue of certificates referencing the harmonised "EN" version of ISO13485

We can issue ISO 13485 certificates referencing both the international and harmonised versions of the standard (*ISO 13485 & EN ISO 13485*) under UKAS and RVA accreditation only to:

- Clients which hold CE certification and / or place devices on the market in Europe (as default if they have a UKAS ISO 13485 certificate)
- Clients making a request for a UKAS or RVA accredited *ISO 13485 & EN ISO 13485* certificate

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For clients that do not hold CE certification (e.g. class I device legal manufacturers or client not in themselves legal manufacturers yet involved in the placement of product/services on the EU market), a top-level check of EU directive or regulation compliance (as applicable) must have been undertaken or be specified via a briefing note to be performed at the next routine audit. This will typically include product/economic operator registrations, technical documentation, vigilance, UDI/labelling, as applicable.

13.4 Cancellation and suspension

Where there is no scheme manager involvement, the global procedure GP005 shall apply for both voluntary and BSI initiated actions.

For scheme manager lead territories, MDP4800 and MDF4802 shall apply.

In all instances, the critical consideration shall be to obtain the clients wishes in writing and to record any correspondence leading up to the final decision.

Clients should always be advised of the appropriate use of logos under these circumstances and template letters in MDF4800 should be used.

Appendix A: IAF MD8/9 Medical Device Technical Areas

Technical areas in Table A.1.1 – 1.6 are applicable to finished medical devices whereas scoping for services related to medical devices or manufacturing of parts which are not categorized as finished medical devices is detailed in Table A.1.7.

Table A1.1: NON-ACTIVE MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Non-active Medical Devices	General non-active, non- implantable medical devices	<ul style="list-style-type: none"> Non-active devices for anaesthesia, emergency and intensive care Non-active devices for injection, infusion, transfusion and dialysis Non-active orthopaedic and rehabilitation devices Non-active medical devices with measuring function Non-active ophthalmologic devices Non-active instruments Contraceptive medical devices Non-active medical devices for disinfecting, cleaning, rinsing Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) Non-active medical devices for ingestion
	Non-active implants	<ul style="list-style-type: none"> Non-active cardiovascular implants Non-active orthopedic implants Non-active functional implants Non-active soft tissue implants

	Devices for wound care	<ul style="list-style-type: none"> Bandages and wound dressings Suture material and clamps Other medical devices for wound care
	Non-active dental devices and accessories	<ul style="list-style-type: none"> Non-active dental devices/equipment and instruments Dental materials Dental implants

Table A1.2: ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Active Medical Devices(Non-Implantable)	General active medical devices	<ul style="list-style-type: none"> Devices for extra-corporal circulation, infusion and haemopheresis Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
		<ul style="list-style-type: none"> Devices for stimulation or inhibition
		<ul style="list-style-type: none"> Active surgical devices
		<ul style="list-style-type: none"> Active ophthalmologic devices
		<ul style="list-style-type: none"> Active dental devices
		<ul style="list-style-type: none"> Active devices for disinfection and sterilization
		<ul style="list-style-type: none"> Active rehabilitation devices and active prostheses
		<ul style="list-style-type: none"> Active devices for patient positioning and transport

		<ul style="list-style-type: none"> Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
		<ul style="list-style-type: none"> Software
		<ul style="list-style-type: none"> Medical gas supply systems and parts thereof
	Devices for imaging	<ul style="list-style-type: none"> Devices utilizing ionizing radiation Devices utilizing non-ionizing radiation
	Monitoring devices	<ul style="list-style-type: none"> Monitoring devices of non- vital physiological parameters Monitoring devices of vital physiological parameters
	Devices for radiation therapy and thermo therapy	<ul style="list-style-type: none"> Devices utilising ionizing radiation
		<ul style="list-style-type: none"> Devices utilising non-ionizing radiation
		<ul style="list-style-type: none"> Devices for hyperthermia / hypothermia
		<ul style="list-style-type: none"> Devices for (extracorporeal) shock-wave therapy (lithotripsy)
	Active (non-implantable) medical devices other than specified above	

Table A1.3: ACTIVE IMPLANTABLE MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Active Implantable Medical Devices	General active implantable medical devices	<ul style="list-style-type: none"> Active implantable medical devices for stimulation / inhibition Active implantable medical devices delivering drugs or other substances Active implantable medical devices substituting or replacing organ functions
	Implantable medical devices other than specified above	

Table A1.4: IN VITRO DIAGNOSTIC MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/ Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing	
	In Vitro Diagnostic Instruments and software	
	IVD medical devices other than specified above	

Table A1.5: STERILIZATION METHODS FOR MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Sterilization	Ethylene oxide gas sterilization (EOG)	
	Moist heat	
	Aseptic processing	
	Radiation sterilization (e.g. gamma, x-ray, electron beam)	
	Sterilization method other than specified above	

Table A1.6: DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Devices incorporating/utilizing	Medical devices incorporating medicinal substances	
	Medical devices utilizing tissues of animal origin	
	Medical devices incorporating derivatives of human blood	
	Medical devices utilizing micromechanics	
	Medical devices utilizing nanomaterials	
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	
	Medical devices incorporating or utilizing specific substances /technologies/elements, other than specified above.	

Table A1.7: PARTS AND SERVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Parts or services.	Raw materials	Raw metals, plastic, wood, ceramic
	Components	Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic
	Subassemblies	Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions
	Calibration services*	Verification/confirmation services for measuring instruments, tools or test fixtures
	Distribution services	Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices.
	Maintenance services	Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.
	Transportation services	Trucking, shipping, air transportation service in general.
	Other services	Consulting services related to medical devices, packaging services, etc.
*Organizations providing calibration services should be accredited to ISO/IEC 17025		

Appendix B: Policy for addressing clause 4.2.3 in ISO 13485:2016

Scope

If any requirement in [Clauses 6, 7 or 8](#) of this International Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system.

4.2.3 Medical device file

For each medical device type or medical device family, the organization shall establish and maintain one or more files either *containing or referencing* documents generated to *demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements*.

The content of the file(s) shall include, but is not limited to:

- a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;
- b) specifications for product;
- c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;
- d) procedures for measuring and monitoring;
- e) as appropriate, requirements for installation;
- f) as appropriate, procedures for servicing.

Background

Note the italics portion above. If the client is NOT a medical device legal manufacturer, then compliance to applicable regulatory requirements does NOT include European medical device/in vitro diagnostic directives and regulations for example. Therefore, organisations which are NOT legal manufacturers only have to demonstrate that their products meet the requirements of the standard and local general product liability/safety regulations that already exist. This should already be in place to meet the requirements of 7.5.1 and 7.2.1.

Policy

Documentation to address this clause should demonstrate that the client has thought about how the requirements of ISO13485 apply to their product offering.

The document should contain **or reference** relevant information listed in the clause by including examples such as:

- Hazard and safety information, including disposal/recycling
- How the product is monitored for conformance ie a quality plan: (eg incoming inspection, in-process checks, final release, despatch checks)
- Reference to manufacturers websites that contain specifications, instruction manuals, service/installation guides and MSDS
- Examples of or links to any additional instructions / labelling provided;
- Links to catalogue material that contains product information;
- Service provision specifications and contractual obligations;
- Dose mapping and validation reports;
- SOPs, work instructions, recipes and sampling plans;
- Customer specifications and contracts or quality agreements;
- Batch records

The organisation of this information should be in a logical fashion and consideration of 'groups' of similar products may be appropriate. Eg for a distributor of a diverse range of products to the medical industry, categories such as electrical goods, chemicals, textiles, etc may be appropriate.