Rules QMSrelated to MEDICAL DEVICES

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1. GENERALITIES

ThisRegulationdefines the supplementary and non-substitutiveproceduresapplied by QS for the certification of Quality Management Systems in additionto whathasalreadybeendefined in the General Regulation for the certification of Management Systems.

QS grants the certification in accordance with the requirements of ISO/IEC 17021-1:2015 to Organisationswhose Management System hasbeenrecognisedascomplying with all the requirements of ISO 13485:2016/ CEI EN 13485:2021.

1.1 APPLICABILITY

The scope of standard ISO 13485 indicatesthat the standard can be applied by:

− Organisationsinvolved in one or more life-cycleprocesses: including design andDevelopment, production, storage and distribution, installation or maintenance of aMedical device and design and development or provision of associated activitiesTechnical support example), and

− Suppliers or external parties providing products to suchorganizations, including services

Related to the QMS.

Itisnotexcludedthat the standard EN ISO 13485 can also be applied by othereconomicoperators in the supply chain (e.g. authorisedrepresentatives, importers, distributors, System assemblersetc).

2. STANDARD OF REFERENCE/REQUIREMENTS FOR CERTIFICATION

To obtaincertification from QS, a Quality Management System must initially and over time meet the requirements of ISO 13485 and the Additional standards provided by Accreditation Bodies.

QS grants the certification in accordance with the requirements of ISO/IEC 17021-1:2015 to Organisationswhose Management System has been recognise das complying with all the requirements of ISO 13485:2016/ CE EN 13485:2021.

Otherdocumentsapplied for the determination of the requirements:
IAF MD 9:2017 IAF - Mandatory Document for the Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485);
IAF MD 5:2015 - IAF Mandatory Document for Duration of QMS and EMS Audits
ISO/IEC 17000:2004 – Conformityassessment –General principles and vocabulary
EN ISO 14971:2012 - Medical devices - Application of risk management to medical devices
CEN/TR 17223:2018 – Guidance on the relationshipbetween EN ISO 13485:2016 and europeanmedical device
MEDDEV 2.4/1 rev.9 classification of medical device

The Quality Management System isfullyoperationalwhen, in addition to whatisestablished by the General Regulation for the Certification of Management Systems, actions havebeen put in place thatguaranteeconstancy in the way of production and In the quality of the products/services provided.

3. DEFINITIONS

Competent Authority: The authority or authoritiesresponsible for the supervision of the market and/or surveillance for the medicaldevices

Destination: The use to which the device isintended in accordance with the Manufacturer'sparticulars in the label, the package leaflet and/or the advertising material

Medical Device: Anyinstrument, apparatus, plant, substance or other product, used alone or in combination (including computer software used for properoperation) and intended by the manufacturer to be used in man to Purpose of diagnosis, prevention, control, therapy or mitigation of a disease; of diagnosis, control, therapy, attenuation or compensation of a wound or a handicap; of study, substitution or modification of anatomy or of a physiologicalprocess; of intervention on conception, which product doesnotexert the main action, in or on the human body, to whichitisdestined, by pharmacology-ci or immunologicalmeans or by metabolicprocessbutwhosefunction can be assisted by suchmeans.

Manufacturer: The natural or legalpersonresponsible for the design, manufacture, packaging and labelling of a device with a view to placing on the market in itsown name, irrespective of whethertheseoperations are performed by thissameperson or by a third party on hisbehalf.

Own Brand Labeller (OBL): meansmanufacturer OBL whoaffixits trade mark on a Medical Device alreadymarked CE by anothermanufacturer (OriginalEquipmentManufacturer, OEM), and then put it on the market in itsown name

3.1 CERTIFICATION APPLICATION

In Addition to the Rules set out in the General regulations QS Quality Services LTD, the Organization must communicate to QS:

- Anyelements of the reference standard whichitconsiders to be notapplicable to itsOrganisation or whichrequireinterpretation or adaptation, statingclearly the reasons for it.
- Classification of the DM and intended use

Together with the request for certification, or thereafter, the Organisation, in addition to the requirements of the General Regulation QS Quality Services Ltd, shallalso make available to QS a Manual of the Quality Management System whichincludes :

- The description of the processes and their interactions;
- The list of the mainlaws and/or regulationsapplicable to the product/service provided or necessary for the correctapplication of the Management System and compliance with them.

As A result of the application for certification, additional information may be issued in addition to thoseprovidedprior to the organization'scontent.

3.1 AUDIT 1 STAGE

The STAGE 1 Audit may be conductedthrough aauditof the documentationwhich the applicant makes available to the audit team, at the discretion of the technical department and takinginto account the complexity of the processes and the number of employees of the organization.

Stage 1 if high-risk medical devices are concerned, itisalwaysperformedat the organization (e.g. class II medical Device or class III). Es. MD 09/2015 at Point 9.2.3.1-GHTF C Moderate-high risk suchasLung Classic/bone fixationplate and GHTF D high risk suchas Heart valves/ImplantableDefibrillator – implantable DM).

In the case of lower risk activities (e.g. class I devices, or onlymaintenance or distribution services) Phase 1 can be carried out in a documentarymannerat QS, if the organisationprovidesall the documentation and Requested information.

Documentsshallgenerallycontain the information required to demonstrate the conformity of the product/process/service, the description of the means by which the organisationisable to demonstrate and monitor the conformity of its Product/Service/process (documented information, procedures, instructions, registrations) with respect to the requirements of the regulatorydocument, certificationrequirementsissued by QS and accreditation bodies, aswellasany Legal requirements and in accordance with point 10.6 of the General Regulation QS Quality Services Ltd.

In addition to whatisalreadydescribed, the Organisation must make available to the staff responsible for carrying out the Phase 1 audit:

• Product Documentationrequired to meet the regulatoryrequirements;

• ApplicableregulatoryRequirements;

• Anycertificationsissued by otherNotiefied Body or authority for the marketing of DM;

• Risk assessment Papers.

In particular, the management documentation, in addition to the standard ISO 13485, shallcontain a sufficientlydetaileddescription of the responsibilities, methods and registrationsimplemented for the management of the Organisation'sprocesses and How the compliance with essentialrequirementsishandled. Itshallalso report anyexclusions of the requirements of the standard, clearlyindicated and justified

Anydeficiencies and gaps in the documentationmay interrupt the Certification Iter, in the opinion of GDV, untiltheirresolution. Following the QS verification, the company sends a report identifyingany gaps, or, if so, suggestscontinuation of the verification activity. Fill in these gaps, the GdV manager schedules the verification in the field, communicating to the Organization the audit plan, with the details of the sites, the processes etc. to be assessed, aswellas the specificprogram of evaluation of the product/process/service.

3.2 OUTSOURCING

The evaluation procedure shall include an inspection in the Manufacturer's facilities and, wheredeemednecessary, by subcontractors or critical suppliers.

Where the organisationhasdecided to allocate the processesinfluencing the safety of medical devices outside the organisationitself, the audit activities may be extended to these outsourcers in order to verify the effectiveness of the system In theseorganizations.

Audits at suppliers may take place in the context of the initial audit and/or periodicmaintenance audits.

The choice of conductingthese audits willdepend on the influence of the outsourcer on the SG for DM quality, the relevance of whichwill be dictated by the evaluationanalysis and the QS assessments and the audit team.

Ownership of the SG'seffectivenesswillremain in the Organization. The non-availability of these suppliers to be auditedwill invalidate the possibility of certifying the sameOrganisation.

If the Organization is an OBL, itacquires the responsibility of the DM product, and must demonstratethatithasacquired the design, processes and conformityrequirements of the DM it markets in its system; You must provide QS with the following documentation:-copy of the contract with the OEM supplier;

-Copy of the OEM supplier's CE certificate;

-Copy of the OEM Supplier's labels and operatinginstructions;

-declaration of identicity with the product variants of the OEM Supplier;

-Technical documentation of the OEM manufacturer, which must meet the requirements of Directive 93/42/EEC; Regulation MDR 745-2017

-Quality System Documentation

The conformity audit on the OBL Manufacturerwillhaveasitspurpose the verificationthat:-the CE certification, obtained by the OEM Supplier, isvalid;

-The quality system appliedcomplies with the requirements of the Annex to Directive 93/42/EEC, chosen by the Manufacturer for the conformityassessment of the Medical Device.

4. RESPONSIBILITY

The company has the responsibility of conformity to the certificationrequirements and is the sole responsible for complying with all the provisions of existinglaws (community, national, local) and the technical norms and the fulfilmentthey derive.

The Certification body isresponsible for assessing the sufficientobjectiveevidence on which to base a certificationdecision

The company isresponsible for verifyingthat the customer hasassessedstatutory and regulatory compliance and can demonstratethat appropriate measureshavebeentaken in the event of non-compliance with the relevantlegislation and regulations, includingNotify the regulatory authority of anyincidencesrequiring reporting. In any case, the legislative conformityverification activities carried out by QS are notsubstitutive with those of legal and authorized control bodies.

Evenas a result of certification, the maintenance and evaluation of compliance with the legalrequirements are borne by the certified organization.

The certified organisation must promptlyinform QS of anyoccurrence of accidents, significantemergency situations (potential or real), notifications of legalproceedings or disputes by public authoritiessuchas to put In doubt the effectiveness or credibility of the management system.

5. MULTISITE

The requirements of the IAF MD 9 document do notallow the sampling process to be applied to sitesthat produce the design and production of medical devices.

The Multi-site approachisconsideredpossible in the differentsites with similarprocesses (e.g. packaging, sterilization, commercialization of alreadypackaged products)

6. ANANNOUNCED AUDIT OR SHORT NOTICE AUDIT

In addition to requirements of Clause 9.6.2.2, the surveillance programme shall include a review of actions taken for notification of adverse events, advisory notices, and recalls.

As already provided in the general Regulation, QS reserves the right to carry out audits at short notice or audit without notice where there is need. In the case of ISO 13485 certification It may be required for:

- External factors such as:
- The data available on post-marketing surveillance known to QS on the subject, indicate a possible significant deficiency in the quality management system,
- Or QS becomes aware of important information related to the security threat
- Significant changes occur that have been presented as required by the legislation or become known to QS, and that could affect the decision on the compliance status with the legal requirements of the customer

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

i. QMS – impact and changes

   a) New ownership

b) Extension to manufacturing and/or design control

c) 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.

d) 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)

e) 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

ii. Product related changes:

a) New products, categories

b) 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 o an existing scope limited to ultrasound equipment)

iii. QMS & Product related changes:

a) Changes in standards, regulations

b) Post market surveillance, vigilance