REGULATION FOR THE MANAGEMENT OF MEDICAL DEVICES TECHNICAL FILE

Document R-005
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INDEX

Rev.	*Modification*	*Elaboration*	*Approval*
May 2018	section 3.3 - Update Regulation UE 679/2016 – Data Protection	M. Magni (Medical devices certification manager)	R. Cusolito (Managing Director)

1. PURPOSE AND PREMISE

The procedure for the issue of a certification of conformity according to Directive 93/42/EEC Annex II, V or VI by ITALCERT occurs through not only the evaluation of the quality management system implemented by the manufacturer in compliance with the requirements of Directive 93/42/EEC Annex II, V or VI but also through the evaluation of the technical file (also identified as Device Master File or Technical Documentation), arranged by the manufacturer to demonstrate the compliance of medical devices to the essential safety requirements of Directive 93/42/EEC and subsequent amendments and additions.
As regards the certifications of medical devices Class III, ITALCERT will conduct a specific evaluation of the technical file and of any records of the design process implemented by the manufacturer, in order to issue a specific certificate of conformity according to Directive 93/42/EEC Annex II (point 4) also called EC DESIGN EXAMINATION certificate. This certificate is complementary to the certificate of conformity of the quality management system implemented by the manufacturer according to Directive 93/42/EEC Annex II (excluding section 4).
This Regulation defines the criteria for the Technical File (TF) management, that an organization requesting a certification of compliance with the requirements of Directive 93/42/EEC and subsequent amendments and additions for Medical Devices (MD), shall comply to obtain and maintain the medical devices certification issued by ITALCERT.
As regards the quality management system evaluation, please refer to the Regulation for CE Certification of Medical Devices (Quality System Certification of Medical Devices Manufacturers) R 003 issued by ITALCERT.

2. DEFINITIONS

Technical File (TF): the whole of the technical documents arranged by the organization to demonstrate the MD compliance with the essential safety requirements listed in Annex I of Directive 93/42/EEC and subsequent amendments and additions.
Customer: Organization that requires (or has obtained) the certification *(in some parts of this Regulation it may also be referred to as the "Organization" or "Manufacturer").*
For any other definition it will be applied what's defined in the certification standards, in ISO 9000, ISO 13485, ISO 19011 standards and in the Directive 93/42/EEC and subsequent amendments and additions.

3. MANAGEMENT OF THE TECHNICAL FILE BY ITALCERT

3.1. First sending of the documents and structure of the TF

Once the certification application and the certification process have been completed, the FT relative to the certified MD shall be transmitted to ITALCERT in electronic format, preferably in PDF format or other format that can not be modified by e-mail or wetransfer or on CD-ROM support. or other file transfer system (depending on file size) for its evaluation and analysis. Files in formats that allow to modify the contents are not accepted.
The files that make up the technical file shall be appropriately identified and named, in order to facilitate the identification of its configuration. In particular, the following is required:
- The supporting document of the documents structure must be identified, it shall have a clear identifier that allows it to be traced back to the DM or the DM family; the document revision status shall also be identifiable from the file name. (i.e.: TF product name rev xx).
- A list of attachments shall be prepared, with the relative index of revision of the attachments. It can be a separate document or a part of the main document mentioned above.
The file of each attachment shall have in the file name an element that allow to univocally and easily correlate it to the list of attachments in the main document of the technical dossier; moreover, it should also include an indication of the revision index (ex: ALL 4 component sheets rev. 2).

3.2. Evaluation of the Technical File

At the opening of the evaluation procedure, the name of the person in charge of the evaluation of the TF commissioned by ITALCERT is indicated to the organization. The organization has the right to request replacement, within a maximum of three working days, if there are motivated conflicts of interest.
ITALCERT reserves the right to subsequently replace the name of the person responsible for the evaluation of the TF. Where appropriate, the responsible for the evaluation of TF may ask ITALCERT for involvement in the TF assessment of additional experts and in particular of external clinical experts regarding the clinical evaluation of DM.
Also in this case the name of the external clinical expert, involved in the clinical data evaluation procedure is communicated explicitly to the organization requesting the certification and the organization has the right to request its replacement, within a maximum of three working days, if there are motivated conflicts. of interest.
During the evaluation process other ITALCERT resources are involved (clinical evaluation supervisor, final reviewer, decision maker). The names of these resources are not usually communicated to the organization, being internal resources or formally integrated into the ITALCERT organization chart.
The evaluation may result in various comments / observations that will be communicated in a formal way to the organization requesting the certification.

3.3. Changes after evaluations

The comments / observations shall be acknowledged by the organization through appropriate modifications and / or additions to the TF delivered for evaluation; any non-transposition of the comments / observations shall be motivated by the organization through a special cover letter, which shall promptly justify these motivations and provide the necessary evidences.
The TF, as amended following the implementation of the comments / observations, shall be identified either with new revision index and new revision date or with the same revision index of the draft sent but with indication of a new issue date subsequent to that indicated in the communication that formalizes the outcome of the evaluation.
The modified parts must be clearly identifiable and / or detailed in a letter accompanying the new revision of the document.
The procedures for identification and transmission of documents are the same as those for the first submission. It is possible for the manufacturer to re-transmit the technical file in its entirety or only in the modified parts. In any case, the list of attachments shall be updated each time one of the annexes that make up the FT is modified.
The TF sent to ITALCERT will be subjected to an additional evaluation, which may give rise to further comments / observations or lead to its approval.

3.4. Approval of the Technical file

Once the TF has been approved, ITALCERT communicates the relative approval to the organization by means of a special letter. This approval should however be considered as provisional, pending the review and the final decision referred to in the following point.
The TF shall be approved before conducting the stage 2 audit of the quality management system in accordance with Annex II or V or VI of Directive 93/42 / EEC and subsequent amendments and additions.
If this condition can not be achieved, the conduct of the stage 2 audit can only take place upon explicit approval of the DM sector manager and only if there is clear evidence that the evaluation of the TF has not given rise to critical comments / observations, generated by significant differences with respect to the essential safety requirements established in Directive 93/42 / EEC and subsequent amendments and additions.
In any way, the certification practice can not be taken to the subsequent stages of final review of the practice and of a final decision on the issue of certification before the approval of the TF.

3.5. Final review and decision making

It is necessary to point out that the certification procedure has to concluded by a phase of final review of the practice, by experts different from those involved in the evaluation activities. The review may lead to requests for further changes to the TF, although it has been previously approved.

The final review precedes the final decision for the issue of the certification.
These phases are conducted by internal resources of the ITALCERT structure.

3.6. Sending back of the approved technical file

Once the certification has been issued, the TF is returned to the organization exclusively in digital format by e-mail or "Wetransfer" or CD-ROM (depending on the file size) or other file transfer system and exclusively in PDF format or other non-editable format.
The TF, including all its attachments, will show the following watermark in the header on the left: "FT n. xx - name - rev. xx of the yyyy-mm-aa approved by Italcert - transmission protocol number xxxx / yy-zz / yy of yyyy-mm-dd "and will be protected by ITALCERT by means of alphanumeric password to prevent changes. This format will be the only document recognized as a work tool and valid for regulatory purposes.

4. UPDATING OF THE TECHNICAL FILE

After having obtained the Certification, the manufacturer undertakes to:
- start the production of the DM in compliance with what is described and established in the approved FT and in accordance with the approved quality management system.
- communicate in advance to ITALCERT any request for modification of the FT.

It is also possible that ITALCERT requests the modification of the TF following:
- any type of request for modification, extension or reduction of the certificate,
- standards and / or legislative changes occurred,
- further evaluations carried out on the TF (for example, during certification renewals)

The changes made to the TF shall be transmitted to ITALCERT in the same way as for the first evaluation of the TF, so that they are submitted for evaluation and subsequent approval.
Following the new approval of TF ITALCERT, the approval of the TF changes will notify to the organization by means of a specific letter of release.
If the changes are related to an application for extension or reduction of the certificate, the certificate in question will be reissued with the appropriate changes.
Following the new approval, the Manufacturer must proceed to send the approved Technical File including all its attachments, and it will be returned to the organization in the manner described in paragraph 3 above.
With regard to the certification of medical devices Class III, all changes to the design process previously approved (EC design examination certificate) shall be subjected to an additional approval by ITALCERT, wherever such changes may affect the conformity to the essential requirements of Directive 93/42/EEC or may affect the conditions laid down for the use of medical devices or whether there is an explicit request for change, extension or reduction of the object of certification by the manufacturer. ITALCERT will communicate this additional approval by a review of the EC design examination certificate previously issued.
In any case the manufacturer, is responsible for the completeness and accuracy of the TF.
The modified and outdated parts shall be stored by the organization, according to the procedures provided within its own quality management system.

5. DEROGATIONS

Notwithstanding the operative procedures for the management and transmission of the technical file by the organization requesting the certification of DM, provided for in this regulation; paper handling with the relative dry stamping of the technical dossier as provided for in previous versions of this regulation may only be allowed, only in exceptional cases, following a documentary request from the organization with precise reasons and only following the explicit approval of ITALCERT.

6. CONFIDENTIALITY AND DATA PROTECTION

According to Regulation UE 2016/679 and to applicable Italian legislation about Data Protection, the personal data provided by the owner to ITALCERT will be processed by ITALCERT (internal staff and external collaborators/professionals involved - the latter designated as external data processing managers) exclusively for the purpose of ensuring the correct execution of the contractual relationships and of the management of the service.

In relation to the aforementioned purposes, the processing of personal data takes place through IT, manual and telematic tools with logics strictly related to the purposes themselves and, in any case, in order to guarantee the security and confidentiality of the data. The provision of the customer's personal data is therefore essential in relation to the proper conduct of contractual relationships with the consequence that any refusal to supply them will determine the impossibility for ITALCERT to proceed with the same relationships.
The data of the Organization may be communicated by ITALCERT, as far as their respective and specific competence is concerned, to Bodies and in general to any public and private entity, as well as to the internal designated subjects, responsible and in charge of data processing, as well as to those external parties responsible and / or appointed by ITALCERT to whom the communication is necessary for the execution of the services provided by ITALCERT, and with respect to whom there is an obligation or need for communication for ITALCERT.
The personal data (for example: company name, address, VAT number, name of the contact persons, telephone and fax numbers, email addresses) are collected and processed by ITALCERT with the exclusive purpose of managing and coordinating the planned activities according to this regulation and in order to carry out administrative / accounting procedures. The data related to products / services (Audit Reports, Manuals, Evaluation Documents, etc.) are collected and processed in order to comply with the requirements that ITALCERT shall fulfill as an Accredited Body.
When applying for a certification, ITALCERT will provide the Customer with information about EU Regulation 679/2016 and the Italian legislation applicable to Data Protection, as a consequence the Customer may give his consent to the processing of data.
Not all the required information are detailed in this regulation.
Remember that:
- the "Data Controller" is ITALCERT S.r.l., in the person of the Legal Representative, address: Viale Sarca 336, Milan (ITALY)
- The Customer has the right, at any time, to have access to his personal data processed by ITALCERT, for example in order to request its updating, correction or integration, without prejudice to the obligations and provisions of law that bind ITALCERT as Notified Body for the conservation of specific information.
The provided data are collected by ITALCERT for the unique purpose of carrying out administrative / accounting procedures and to comply with the duties requested by Competent Authorities for Medical Devices.
Following the issue of the certification, the customer data are entered in a special "Register of Certified Companies". Furthermore, all the information concerning the certificates issued, renewed, limited, suspended or revoked are by law due to the Competent Authorities for Medical Devices. This information may be also made available to any applicants who request ITALCERT with a written request.
ITALCERT guarantees also the confidentiality of all information that will be collected during the audits, including the results recorded in the audit reports. The persons, in charge by ITALCERT are also bound by specific confidentiality restrictions in relation to all the information they will be aware of during the certification process.

7. ACCEPTANCE AND UPDATE OF REGULATION

The customer applying for certification formally accepts the contents of this Regulation by signing the AGREEMENT and APPLICATION for CERTIFICATION. In case of future updates and changes, ITALCERT will make available the Regulation on its web site www.italcert.it and will notify the customer by fax, registered letter R.R. or e-mail. The customer has 60 days to formally communicate the lack of acceptance of the amendments. This communication will cause the withdrawal of the certification. After 60 days without communications from the customer, the new edition of the Regulation R-005 will be deemed accepted for silent consent.