REGULATION FOR CE CERTIFICATION OF MEDICAL DEVICES

Regulation UE 2017/745

Document R013

INDEX

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November 2021	4	First surveillance timing update	D. Mauri (Certification Manager)	G. Leonardi	R. Cusolito (CEO)
08/08/2024	5	§5.2, 6.4, 6.5 – clarification of surveillance frequency, §12 – clarification on critical suppliers; §13 – clarification for PSUR submission General revision of the index (paragraphs numbers).	D. Mauri (Certification Manager)	G. Leonardi	R. Cusolito (CEO)

1. PURPOSE AND PREMISE

This Regulation lays down how ITALCERT manage CE certification procedure of medical devices in relation to Annex IX chapter I and II and Annex XI Part A of Regulation UE 2017/745 (hereinafter “MDR”).
Further details, as fees, not specified in this Regulation, are defined in specific Agreement issued for each specific customer.
ITALCERT is a Notified Body authorized by the Italian Ministry of Health and therefore it is subject to compliance with the rules laid down in legislative and regulatory applicable documents.
The list of Medical Devices for which ITALCERT is designated is part of specific legislative decrees issued by the Italian Ministry of Health.

2. DEFINITIONS

For the purposes of this procedure, the following definitions apply (as per ISO 17021-1):
Requirement: Need expressed in the reference standard for certification or due to it.
Non-Conformity (NC): Non-compliance of a requirement.
Non-Conformity Class 1 (major): Failure to satisfy a requirement that affects the ability to achieve the expected results and the occurrence of which represents a significant limitation of compliance to MDR.
Non-Conformity Class 2 (minor): Any failure to satisfy a requirement that does not affect the ability to achieve the expected results and that in general cannot be configured as Class 1 (major).
Recommendation (REC): Non-binding indication of improvement and/or consolidation areas of the management system. Reports of situations that can potentially generate NC, belong to this area.
Observation: Situation related to one or more documents of the management system which, though not a non-conformity, requires an updating and/or change of the document itself.
Customer: Organization that requires (or has obtained) the certification *(in some parts of this Regulation it may also be referred as "Organization" or "Manufacturer").*
Technical File (FT): set of all the technical documentation used to demonstrate compliance with general safety and performance requirements listed in Annex I of MDR.
Common Specifications (SC): set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

For any other not mentioned definition please refer to standards ISO 9000, ISO 13485, ISO 19011 and MDR.

NOTE: *to facilitate the right identification of the standards listed below, they are reported as "EN ISO xxxx,".*

3. PRINCIPLES OF CERTIFICATION

3.1. Certification process

The certification process goes through the evaluation of technical file (also identified as Device Master File or Technical Documentation), issued by the manufacturer in order to demonstrate medical device conformity to general safety and performance requirements of MDR, and through the assessment of quality management system against MDR Annex IX chapter I or II and Annex XI Part A requirements.

In case of specific medical devices with specific intended uses Annex IX chapter II apply and the evaluation of technical documentation will lead the issue of EU technical documentation assessment certificate (MDR annex IX chapter II).

3.2. Language

Technical documentation and quality management system documentation must be in Italian. English can be accepted under manufacturer explicit request.

3.3. Certification

Certification activity requires, as a key step, collection of information at the manufacturer’s premises, on the basis of application examples. Audit is by its nature carried out on a sample basis, so its results cannot be improperly used by manufacturer.

3.1. Independence and impartiality

ITALCERT is required to comply with the rules established by applicable legislative, normative and regulatory documents. In particular, ITALCERT is required to guarantee independence and impartiality. ITALCERT cannot offer services intended as business consulting.

3.2. DATA PROTECTION – Regulation UE 679/2016

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.

3.1. Free access to the operational sites

Customer must guarantee to ITALCERT auditor free access to their operating offices and to the documentation relating to their quality management system in order to properly carry out the different types of audits as part of the certification process.

Free access must also be guaranteed by outsourcers and "critical suppliers". For this reason, customer must have in place specific contracts and/or agreements with its outsourcers.

If customer is located in a country that requires visa in order to pass borders, specific contractual provisions and documents will be established allowing ITALCERT to visit that country at any time. These specific contractual provisions and documents will also be extended to outsourcers and "critical suppliers".

Customer must also allow the access of observers of the Designating and Competent Authority in order to allow them to carry out monitoring activities of ITALCERT as a Notified Body

Observers will always be accompanied by ITALCERT staff. Notification of the presence of such observers could take place with minimum notice (up to 5 days), or even without notice in case of presence during "unannounced audits". Please note that this cannot be a reason for non-acceptance by the customer of their presence. Non-acceptance of the presence of such observers by the customer lead to the interruption of the certification process started or the suspension/withdrawal of the certificate (if already issued).

3.2. Communications to ITALCERT about production maintenance

If the production of the certified devices is interrupted for a certain period, customer must inform ITALCERT. Communication must be provided when the production will be re-established as well.
Where the production of the certified devices is managed on a non-continuous basis (order-based production), customer must inform ITALCERT about any existing production.
If, during an unannounced audit no medical devices are available, neither already produced nor in production, and if no specific communication was provided to ITALCERT, the audit will be repeated as detailed below.

4. ASSESMENT STARTING

4.1. Quotation request

Any customer can apply for a quotation of medical device certification assessment. To prepare the offer, customer must provide to ITALCERT specific requested information.
Information will be evaluated by ITALCERT in order to confirm: the proper qualification of the product as medical device, as defined in MDR; the right classification of the device as per Annex VIII of MDR; the appropriateness of the chosen assessment procedure route.
The quotation resumes the assessment procedure route, the audit program and the applicable rates. The quotation is issued on the basis of the information provided by the customer. If such information will be found not correct, new data review and, if appropriate, an update of the offer will be necessary.
If such inaccuracies are considered critical, ITALCERT may withdraw the certification contract unilaterally.
Audit program is defined following ITALCERT procedures and applicable guidelines as well.

4.2. Quotation acceptance and contract

After quotation acceptance the customer, certification procedure can start and the following documents are sent to the customer:

a) this regulation R 013
b) contract
c) application form

Contract must be sent to ITALCERT duly signed. Application form must be sent to ITALCERT filled and duly signed. Signed contract and signed application form are mandatory documents required in order to start the assessment procedure.

For each activity of the assessment process, ITALCERT inform the customer about resources involved (name of the technical experts and auditors). Customer has the right to ask for substitution, within a defined timeframe, in presence of justified conflicts of interest. ITALCERT, however, reserves the right to replace

auditors and technical experts involved in the assessment process in case of doubt about their adequacy or in case of their unexpected unavailability.

5. PERFORMANCE OF AUDITS - GENERAL PRINCIPLES

5.1. Requirements

Assessment of quality management system follows the provisions of applicable Annexes of MDR. For the purposes of assessing the conformity of the quality management system, ITALCERT refers to EN ISO 13485 standard. Therefore, quality management system must be set up against this standard.
Customer's quality management system must also take into consideration requirements of MDR, applicable harmonized standards and applicable common specifications.
In particular, customer's quality system must include a risk management process in compliance with the requirements established by EN ISO 14971 standard.
Customer must issue a Quality Manual that describes how quality system ensures compliance EN ISO 13485 requirements. If chapters of the manual do not strictly follow the requirements notation of the standard, Quality Manual must include a cross-reference table between standard requirements and manual's chapters.
Quality Manual must also identify outsourced processes (outsourcing) and must clarify type and extent of controls implemented on these processes.
Quality Manual must clearly identify EN ISO 13485 non-applicable requirements and MDR non-applicable requirements as well.
Quality Manual must be self-supporting and must contain references to procedures and operating instructions. Controlled document list must be provided.

5.2. Interval between audits

According to Regulation EU 2017/745, the interval between one audit and the next must not exceed 12 months. The first surveillance audit must be carried out no later than 12 months from the date of issue of the certificate
ITALCERT will consider the possibility of merging into a single surveillance / renewal audit several certificates issued to the same manufacturer. Consequently, some audits could be carried out in advance respect the scheduling.
Generally, scheduled surveillance audits are communicated to the customer with adequate advance notice.
Failure to comply with the conditions relating to the execution of the planned surveillance audit, for reasons related to unavailability of the customer, leads to the suspension of the certificate.

5.3. Operating procedures - audits

Audit dates are agreed by ITALCERT secretariat accordingly with customer, taking into consideration customer and auditors availability.
Audit dates and audit team composition are formally communicated (by fax or e-mail) to the customer. Customer has the right to ask the substitution of one or more members of the Audit Group, within a defined timeframe, in presence of justified conflicts of interest.
About 5 days before the audit, ITALCERT provide to the customer detailed audit plan (operational details, activities) in relation to processes and requirements to be assessed.
Audit starts with an opening meeting, when customer can ask for clarifications about the planned activities or ask for changes to the plan itself.
At the end of the audit, during the closing meeting, Audit Group communicate the audit outcomes, clarifying the findings. The audit plan may not be formalized in the case of unannounced audits / unscheduled surveillance audits.
Audits are carried out at the customer's premises; moreover, audits can also take place outside the customer's premises to verify the activities of the certification scope (e.g. production processes carried out by outsourcers and installation activities).
During the audit, Audit Group will collect the information required in order to formalize an opinion about the quality management system through:

- documentation examination
- interviews with the staff
- evaluation of examples of activities previously carried out (on a documentary basis) or activities in place at the time of the audit

Customer must ensure to the Audit Group the possibility of assess examples of activities carried out for all the processes/products included in the certification scope, including processes/products carried out outside the customer's premises. For this reason, Customer must ensure access to all its departments and must ensure the possibility to interview the staff involved in the activities related to the certification scope.
Where applicable, customer must inform ITALCERT in advance about external activities (e.g. installations) that can be verified during the audit, including location, type and progress of the activity carried out.
If deemed necessary, ITALCERT may request to verify the customer's outsourcer management system; this can be considered as an unscheduled audit (extraordinary) or considered as part of the scheduled audit time, at the sole discretion of ITALCERT.
If ITALCERT is not allowed to verify the quality management system of an outsourcer, suspension of the issued certificate as well the impossibility to issue a certificate could occur.
At the end of each audit, Team Leader of the Audit Group issues an audit report (called “RRC MDR”) in which NCs, recommendations and observations are formalized.

5.4. Findings management

For each NC customer must communicate to ITALCERT within 15 days an evaluation of the causes of the NC and the actions to implement in order to solve the NC, with an expected implementation time; ITALCERT may consider an implementation time exceeding 90 days unacceptable.
Corrective actions must be related to the causes and should consider the possibility that the non-conformity detected may also be present in other similar situations.
Proposed corrective actions are evaluated by ITALCERT; the outcome of the assessment is formally communicated to the customer, including any additional requests.
As a general rule, ITALCERT requires evidence of the implementation of Class 1 NCs within 90 days from the audit (or, if deemed appropriate by means of an extraordinary – unscheduled – audit), while the implementation of Class 2 NCs is examined during the subsequent audit.
However, in specific cases, ITALCERT could apply a different approach for the corrective actions verification.
Elimination of NC requires the verification that the proposed corrective actions have been implemented in an effective manner. In absence of proper implementation of the proposed corrective actions, NC classification (gravity) can be raised up, from Class 2 to Class 1.
Failure in the resolution of Class 1 NCs detected during stage 2 assessment audits within the agreed time will result in a refusal of certification.
Failure in the resolution of Class 1 NCs detected during surveillance audits within the agreed time will result in a suspension of the certificate(s).
Recommendations are not binding; however, customer must manage them in a documented way, implementing appropriate improvement and/or preventive actions or, alternatively, demonstrating that no actions are deemed necessary. Relevant documentation is usually verified during the next audit; ITALCERT, however, has the right to request at any time, before the next audit, documented evidence of the management of the recommendations.
Observations related to requests for changes to quality management system documents must be taken over within the subsequent audit, unless otherwise communicated by ITALCERT.

6. AUDIT TYPE

6.1. Type of audit

As part of the certification process and its subsequent maintenance, the following audits types apply:

- stage 1 certification audit
- stage 2 certification audit
- surveillance audit (planned)
- renewal audit
- unscheduled surveillance audit (extraordinary)
- short-notice audit
- unannounced audit

All audits are at customer’s charge, accordingly to the rates defined in the certification contract.

6.2. Stage 1 certification audit

Stage 1 audit has the following purposes, as detailed below:

a) verify that the quality management system documentation meets the requirements of EN ISO 13485, as applicable to the devices covered by the certification application and to the applicable assessment procedure of EU Regulation 2017/745, including a risk management process compliant with EN ISO 14971;
b) verify that the customer has issued all the procedures required by EN ISO 13485, as applicable to the devices covered by the certification application and to the applicable assessment procedure of EU Regulation 2017/745;
c) verify the customer knowledge of mandatory and regulatory requirements, covered by the quality management system;
d) obtain all the necessary information regarding the type of devices covered by the certification application, production processes and customer's locations, as well as the applicable regulatory aspects;
e) assess the preparedness for the stage 2 audit. Internal audits and management system review must be planned and carried; quality management system implementation must provide adequate confidence about client preparedness for the stage 2 audit);
f) draw up/confirm/modify stage 2 scheduling, defining details where appropriate (such as the location of the external activities to be verified);
g) verify the technical documentation management and that the information provided to ITALCERT about the different technical files are actually consistent with what was planned and under evaluation by specific technical experts appointed by ITALCERT.

Stage 1 audit is always carried out in the case of new certification. It is also carried out if a customer who already has a certificate issued by ITALCERT submits a new application for certification for other medical devices that provides for the issue of a new additional certificate.
As a general rule, stage 1 audit is carried out at the customer's premises; in some particular cases this audit, or a part of it, may not be carried out at the customer's premises, but, for example at the ITALCERT headquarters. In the case of customers who request ITALCERT certification of devices already previously marked by another Notified Body, ITALCERT reserves the right not to carry out the stage 1 audit or to carry it out not at the customer's premises.

6.3. Stage 2 certification audit

Purpose of stage 2 audit is to evaluate the implementation, including its effectiveness, of the customer's quality management system. Stage 2 audit must take place at the customer's site(s). Part of the audit may also be carried out at the headquarters of the critical supplier(s), as defined in the audit program.
During the audit, the Audit Group must:

- obtain evidences of compliance to all applicable requirements, both regulatory and legislative as well;
- verify that the quality management system guarantees operational control of the processes and the traceability records, where this is foreseen or necessary;
- verify that the quality management system ensures the ability over time to supply products in compliance with the approved technical specifications (technical file);
- verify that the customer has implemented a system for monitoring, measuring, recording and reviewing the management system, key objectives and targets, which necessarily also includes internal audits carried out by competent personnel and the management review.

Stage 2 audit must preferably carried out within 6 (six) months from stage 1 but not later than 12 months; after this time ITALCERT will have to carry out a new stage 1 again.
In case the customer is not available to carry out the stage 2 audit after 12 months from the stage 1, ITALCERT have the right to close the certification procedure following a formal written notice through written communication transmitted by email or by registered letter R.R. This will be considered as a REFUSAL of the certification and will be formally communicated to the Competent Authority as applicable (ELECTRONIC SYSTEM - art .57 EU REGULATION 2017/745).

6.4. Surveillance audit (planned)

Surveillance audits are carried out at the customer's premises. Scope of surveillance audit is to verify the continuous compliance of the certified quality management system to the specific requirements, based on the specific conformity assessment procedure requested by the customer.
Part of the audit may also be carried out at the headquarters(s) of the critical supplier(s) or at external offices (eg installation activities), as per the audit program.
ITALCERT usually carries out at least one planned surveillance audit per year.
In any case, the first surveillance audit must be carried out no later than 12 months from the date of issue of the certificate. For this reason, ITALCERT normally schedules the first surveillance audit after 10 months from the date of issue of the certificate.
Second surveillance audit shall be scheduled within 12 months after the previous one and so on for subsequent audits. In general, planned surveillance audits are communicated to the customer well in advance.
Failure to comply with the conditions relating to the execution of the planned surveillance audit, for reasons related to unavailability of the customer, leads to the suspension of the certificate.
For class III medical devices, the planned surveillance audits referred to in Annex IX(I) also include a test on the approved parts and/or materials that are essential for the integrity of the device, including, where applicable, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

6.5. Renewal audit

Renewal of the certification requires a renewal (or recertification) audit. Purpose of renewal audit is to verify that the efficiency of the quality management system as a whole has been maintained, taking into account internal and external changes, verify that the quality management system still remains relevant and applicable with respect of the scope of certification and that the quality management system has effectively contributed to the achievement of the customer’s policy and objectives and has allowed the continued satisfaction of all legislative requirements.
Renewal audit takes into consideration the performance of the quality management system over the certification period; therefore, the customer must make available to the Audit Group data and/or information that cover the whole duration of the certificate subject to renewal procedure.
In exceptional cases, ITALCERT may carry out the renewal audit in two stages (1 and 2), for example in case of significant changes of the quality management system, changes to the customer organization or changes of the operational context (e.g., changes in the legislative context or requests by the customer for extensions/variations of the certification field).
Renewal audit is usually planned at least two months before the certificate expires, according to paragraph 5.2 of this regulation.
In any case, manufacturer must submit a written request for the renewal using the appropriate application form within 10 months from the certificate expiry date.
With regard to the management of the outcomes (findings) of a renewal audit, paragraph 5.4 of this regulation applies. In case of a Class 1 NCs, the renewal procedure cannot continue until the manufacturer has solved these Class 1 NCs. Therefore, considered the time normally required for the management of the renewal procedure, it is manufacturer’s responsibility to solve all the NCs even before the deadline normally considered acceptable by ITALCERT and fixed in 90 days.

In any case, ITALCERT will formally agree with the manufacturer about how verify the resolution of Class I NCs (e.g., through the transmission of documents or through an extraordinary audit).
In the case of a request for postponement of a renewal audit by the customer, it is necessary to take into account that the duration of the certificate cannot be extended beyond the expiration date.
Finally, we specify that if not yet subject to formal renewal, the expired certificate of conformity cannot be used by the manufacturer, who therefore cannot make available on the market any new medical devices covered by the certification.

6.6. Unscheduled surveillance audit and Short-notice audit

Unscheduled audit can be performed in the following cases:

- critical situations that require an increase of the on-site monitoring by ITALCERT
- no transmission of corrective actions following NCs

- no implementation of corrective actions proposed in order to solve the NCs
- serious reports from vigilance system
- specific reports and/or requests from the Ministry of Health/Competent Authority
- need to assess the quality management system of an outsourcer (subcontractor)
- need to assess customer and/or critical supplier processes or locations outside of the normal audit schedule
- request for extension of certification scope

Unscheduled surveillance audits can be performed in a simplified manner, depending on the purpose, and may not include a detailed audit plan.
In cases of well-founded doubt about the certification, especially when ITALCERT becomes aware of particularly serious reports from the vigilance system or following specific reports and/or requests from the Ministry of Health/Competent Authority, during unscheduled surveillance audits or short-notice audits ITALCERT has the right to carry out tests on the products at the customer headquarters, or take products to carry out tests at qualified laboratories with the same methods that are described in the following paragraph "unannounced audits". The cost of carrying out these tests is borne by the customer.

6.7. Unannounced audit

At least every five years, ITALCERT carries out an unannounced audit, as defined below. ITALCERT may, at its sole discretion, deem to increase the minimum number of unannounced audits, based on the following criteria:

- risk of medical devices subject to certification
- presence of frequent non-conformities on products found during scheduled surveillance
- presence of specific information that raise reasonable doubt on the conformity of the devices and on the manufacturer's quality management system
- refusal to receive an unannounced audit

Manufacturer cannot be aware of the scheduling of unannounced audits.
Unannounced audit has a minimum duration of 1 day and is carried out by an audit team consisting of at least two people.
Unannounced audit is charged to the customer, accordingly to the rates defined in the certification contract.
Unannounced audit generally takes place at the manufacturer's premises. However, ITALCERT may carry out this audit at the premises of the customer's critical outsourcers and suppliers, where they carry out a critical activity for the purposes of the compliance of the manufactured devices. Therefore, customer must have in place specific contracts and/or agreements with its outsourcers laying down this availability.
During the unannounced audit, audit team will verify the conformity of medical devices in production in relation to the specific technical file and to the MDR requirements as well.
If deemed appropriate for a complete verification of the conformity of the manufactured devices, the audit team may take a sample to be tested in a laboratory duly qualified by ITALCERT. Tests will be charged to the customer.

Tests can also be performed directly at the customer's premises, supervising and recording the activities performed by duly qualified personnel of the manufacturer, if the manufacturer has adequate testing equipment.
Alternatively, or in addition to the above sampling, ITALCERT can test samples of the customer's medical devices taken directly from the market to verify that the manufactured device complies with the technical documentation. In this case tests will be carried out in a laboratory chosen and duly qualified by ITALCERT. Tests will be charged to the customer.
Furthermore, audit team must verify whether the applied quality system is in line with the approved quality system and with the applicable mandatory requirements (documented in the specific technical files).
Customer cannot refuse to receive an unannounced audit.
If no medical devices are available, neither already produced nor in production, and if no specific communication was provided to ITALCERT, the audit will be repeated.
The unannounced audit does not require the transmission of the audit plan nor notification to the customer. It is therefore not possible for the customer to deny the audit team in advance.
In case of conflict of interest with the audit team, customer has the right to contest the situation within 3 days of the audit. If the reasons are evaluated as objectively consistent and therefore deemed acceptable

by ITALCERT, the audit will be cancelled and repeated; in addition, the audit will not be charged to the customer.
Refusal to receive an unannounced audit leads to the immediate suspension of existing EC certificates.
To reactivate the certification, an unscheduled audit must be carried out with a positive outcome. Unscheduled audit cannot be considered in substitution of unannounced audit.
Furthermore, the refusal to receive an unannounced audit may be led to increase of frequency of this kind of audits.
If the certification suspension will persist, ITALCERT will proceed with the certificates withdrawal, as specified in this regulation.

7. TECHNICAL FILE (TF) EVALUATION

7.1. First transmission of the documentation and TF structure

Once the specific application form has been completed and the certification process has been started, every TF must be sent to ITALCERT for assessment in electronic format, preferably in PDF format or other not editable format by e-mail or wetransfer or on CD-ROM support or other file transfer system (depending on the size of the files). Editable files are not accepted.

Files of technical file must be clearly identified, for proper identification. In particular:

- A supporting document of the whole structure must be identified, with a clear reference to the medical device or family; in addition, the revision status of the document must also be identifiable from the file name. (e.g. TF product name rev. xx).
- A list of attachments must be supplied, with specific revision index. It can be a stand-alone document or a part of the main document.
- Files of any attachments must named in a way that allows clear identification; in addition, it should also report an indication of the revision index (e.g. ANN 4 component data sheets rev. 2).

technical file must necessarily cover all the requirements of EU Regulation 2017/745 and all the applicable harmonized standards / common specifications requirements.
Specific information about TF structure and contents are provided in the document IL068 “MDR Technical Documentation White Paper”.

7.2. Technical file evaluation

Once the assessment procedure starts, name of the responsible person appointed by ITALCERT for TF evaluation is communicated to the organization. The organization has the right to request its replacement, within three working days, in case of justified conflicts of interest.

ITALCERT however has the right to subsequently replace the assessor. If necessary, assessor may request to ITALCERT to involve additional experts in the evaluation of the TF, particularly external clinical experts as regards the clinical evaluation. Also in this case, explicit communication is sent to the organization, that has the right to request its replacement, within three working days, in case of justified conflicts of interest.
During the evaluation process, other resources (clinical evaluation supervisor, final reviewer, decision maker) are involved. Identity of these resources is not generally communicated to the organization, as they are internal resources or formally integrated into the ITALCERT organization chart.
The assessment process may rise various comments/observations that will be communicated to the organization.

7.3. Changes following evaluation

Comments/observations must necessarily be solved by the organization through changes and/or additions to the TF; any non-acceptance of comments/observations must be motivated by the organization through a specific communication and by means of justified evidences.
TF modified following the implementation of the comments/observations, must be identified either with a new revision index and new revision date or with the same revision index as the draft sent but with an indication of a new issue date.
Changed parts must be clearly identified and/or detailed in a letter accompanying the new revision of the document.

Identification methods and documents transmission methods are the same as for the first sending. It is possible for the manufacturer to re-submit the whole technical file or only the modified parts. In any case, the list of attachments must be updated every time.
The new TF will be subjected to an additional evaluation, which may rise to further comments/observations or lead to its approval.

7.4. Technical file approval

Once the TF is approved, ITALCERT send to the organization specific communication. However, this approval must be understood as provisional. Further final review and final decision are required, as referred to in the following chapters.
TF must be approved before conducting the stage 2 audit of the quality management system, in accordance with Annex IX chapter I of EU regulation 2017/745 and Annex XI part A of EU regulation 2017/745 (where a certificate referred to in Annex X of EU regulation 2017/745 does not exist).
If this condition cannot be achieved, the conduct of the stage 2 audit can only take place upon explicit approval of the Head of the medical device sector. In this case, if any critical comments/observations raise from the TF assessment after stage 2 audit, ITALCERT reserves the right to carry out a new audit.
In any case, the certification practice cannot be gone through subsequent final review and final decision stages before the approval of the TF.

8. ISSUE OF THE CERTIFICATE

8.1. Certificate first issue

Certificate of conformity consists of two parts:

- the certificate, with identification of the manufacturer, its registered office and operating offices, MDR annex, issue date, current issue/renewal/expiry dates
- an attachment with all the information allowing traceability and link between medical devices subject to certification and devices placed on the market.

The certificate has a maximum duration of five years.
Further changes to the attachment to the certificate does not change the expiry date of the certificate.
Certificate of conformity is issued after a final review and final review of the procedure, on the basis of the documentation collected during the audits and only following the approval of the Technical Documentation demonstrating conformity of the medical devices with the essential safety and performance requirements of EU regulation 2017/745.

Final review may have the following outcomes:

a) Give a positive opinion for the subsequent stage of final decision about the certification
b) Give a negative opinion for the subsequent stage of final decision. In this case specific actions must be implemented by the customer

For example, actions that can be requested from the manufacturer include:

- additions/revisions to the previously approved Technical Documentation, especially as regards the documentation of compliance with the essential safety and performance requirements, risk management, clinical evaluation, information for use.
- provide evidence of specific procedures/instructions/documents of the customer's quality management system, as evidence of the management of specific corrective actions, or modify and/or further integrate specific procedures/instructions/documents of the quality management system

Any further specific actions required to the manufacturer must be managed and fulfilled before the application can then be subjected to the final decision about the certification.

Final decision phase may have the following results:

a) approve the certificate issue
b) approve the certificate issue, with specific requests required to the customer after the issue
c) deny the certificate issue

For example, actions that can be requested to the customer include:

- unscheduled surveillance audit
- anticipation of the first scheduled surveillance audit
- evidence of the management of specific recommendation raised during the audit
- specific actions regarding, for example, post-marketing surveillance and post-market clinical investigations.

In case of a negative outcomes related to the certificate issue, reasons for this decision will be communicated to the manufacturer, along with the information required in order to submit again a new application.

During non-validity periods of the certificate (certificate expired, not issued, suspended, withdrawn, etc.), customer cannot make available on the market the medical devices covered by the certificate.

ITALCERT, having ascertained the incorrect use of the certification, takes appropriate measures to prevent it and to safeguard, including through publication, its interests (warning, suspension or revocation of certification, legal actions), as well as the necessary communications to the Competent Authority
In case of incorrect use of the certification, ITALCERT will takes appropriate measures in order to prevent the situation and in order to safeguard its interests (warning, suspension or withdrawal of certification, legal actions), along with all the specific communications to Competent Authority as well.

8.2. Placing on the market of medical devices

Customer can place on the market devices only after the issuance of the certificate by ITALCERT. Devices must bear the CE mark, in compliance with the requirements of EU Regulation 2017/745, along with the number 0426, which is ITALCERT identification number as a Notified Body.

Customer must ensure that the medical devices placed on the market with CE symbol and the identification number 0426 are:

- uniquely linked to a specific technical file approved by ITALCERT
- have been produced in compliance with the approved technical file
- related to a specific declaration of conformity
- related to the specific certificate of conformity issued by ITALCERT

8.3. Approved technical file

Once the certification has been issued, the approved TF is sent to the customer exclusively in PDF format or other non-editable digital format, by e-mail or "Wetransfer" or CD-ROM (depending on the size of the files) or other file transfer system, including ITALCERT *cloud* system. In this case, TF is shared in a specific folder protected with password (sent in separate communication) with 5 working days validity, at the end of which the documentation will be removed from the cloud.
The approved TF is in any case stored in the ITALCERT data base and it will be considered the only valid document for regulatory purposes.

9. TECHNICAL FILE UPDATES

After obtaining the Certification, manufacturer undertakes to:

- start the production of the medical devices in compliance with what is described and established in the approved TF and in compliance with the approved quality management system
- communicate in advance to ITALCERT any TF request for modification

ITALCERT has the right to requests TF modification in case of:

- customer request of modification, extension or reduction of the certificate scope
- regulatory and/or legislative changes that have occurred
- further analyses carried out on the TF (e.g. during certification renewals)

Changes to the TF must be communicated to ITALCERT in the same way as for the first assessment. Changes are subjected to assessment process. In case of positive outcome, ITALCERT will communicate to the customer the approval of the TF changes.

If the changes are related to an application for extension or reduction of the certificate scope, the certificate in question will be reissued with duly changes.
Following the new approval, Manufacturer must therefore proceed to send the approved Technical File including all its attachments. It will be managed as described in section 7.3.

With regard to the certification accordingly to Annex XI chapter II of MDR, in any case all design changes, and therefore the technical file and its annexes already approved (EU technical documentation assessment certificate) must be subject to a complementary approval by ITALCERT, if said changes may affect compliance with the essential requirements of MDR or the use of the certified medical devices or in case of an explicit customer request for changes, extension or reduction of the certification scope. ITALCERT will communicate this approval through a revision of the EU technical documentation assessment certificate previously issued.

Manufacturer is in any case responsible for the completeness and correctness of the TF. The changed and outdated parts must be archived by the customer, accordingly to his quality management system.

10.CHANGES, MODIFICATIONS, EXTENSION, REDUCTION OF THE CERTIFICATE SCOPE

Customer must inform ITALCERT about the following changes:

- change of the approved quality management system(s) or change of the medical device range covered by the system
- change of the approved design for the device
- change of the intended use of the device or change of any the statements about it
- change of the approved device type
- change of any substance incorporated or used for the manufacture of a medical device, subjected to the specific assessment procedures as defined in point 4.5.6. of Annex VII of EU Regulation 2017/745

Changes must be approved by ITALCERT before their implemented by the customer, through assessment of technical documentation and/or through scheduled or unscheduled audits.

Specific application form must be provided to ITALCERT. Based on the type of change, ITALCERT may require the specific audit.

For any type of modification, extension or reduction of the certificate scope, customer must provide to ITALCERT the changed technical documentation, previously approved, for a new assessment.

Following the approval of the technical documentation and, if applicable, after a specific audit with relative positive outcome, ITALCERT will communicate to the organization the approval of the modification, extension or reduction of the certification scope through a revision of the certificate or through specific approval communication, if the approval is related to medical devices already covered by the valid certificate.
Following any type of request for modification, extension or reduction of the certificate scope, ITALCERT may review and update, if appropriate, the audit program and consequently update the relative rates.
Changes to the organization's company name and addresses will necessarily require a revision of the issued certificate.

11.CERTIFICATE RENEWAL - RECERTIFICATION

To start a renewal procedure, customer must submit a written request using the appropriate application form within 6 months from the expiry date of the certificate. If the manufacturer does not take care to respect this deadline, ITALCERT will still be able to accept the renewal application by way of derogation and therefore conduct an evaluation procedure for the renewal of the certification but cannot guarantee that the renewed certificate will be issued before its expiry date.

With regard to the certificate accordingly to EU Regulation 2017/745 annex IX chapter II, ITALCERT will start a completely new assessment procedure of each technical file relating to the specific certificate, as required for a first certification.

With regard to the certificate accordingly to EU Regulation 2017/745 annex IX chapter I and EU regulation 2017/745 annex XI part A, ITALCERT always proceed with a complete new assessment of each technical file relating to the specific certified, as required for a first certification; this is not applicable if the certificate accordingly to EU regulation 2017/745 Annex XI part A is accompanied by valid EU type-examination certificate as per Annex X of MDR.

It should be noted that for the renewal of the EU technical documentation assessment certificate (EU Regulation 2017/745 annex IX chapter II) is required to provide to ITALCERT a summary of the changes and scientific results relating to the device, including:

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

12.CRITICAL SUPPLIER

The supplier is an organization, or natural person, that provides a product and/or service and that is external to the manufacturer's Quality Management System. The term supplier is also used to refer to the "sub-supplier".

“Critical supplier” is that supplier of materials, components or services which may affect the safety and performance of the overall medical device and which cannot be verified by the manufacturer. By way of example, but not limited to, are considered critical: design process suppliers, supplier of production processes whose output element cannot be verified by the manufacturer, supplier of special processes (sterilization, packaging, etc ...), software supplier.

During the first certification and renewal, ITALCERT establishes the necessity to perform audits at critical suppliers’ premises. Data about suppliers are collected through the application form. The truthfulness of such data is manufacturer responsibility.

As a general rule, critical suppliers are always included in the audit program. However, it is considered possible not to carry out audits at outsourcers premises in the following cases:

Case 1

- The supplier has a quality management system certified by ITALCERT, for activities/processes/products/services related to the medical device under assessment, accordingly to ISO 13485 Regulation 2017/745 Annexes IX or XI.

Case 2

The following conditions are met:

- The supplier has a quality management system certified by another CAB or NB, for activities/processes/products/services related to the medical device under assessment, accordingly to ISO 13485 Regulation 2017/745 Annexes IX or XI;
- The manufacturer keeps the supplier under control (non-exhaustive examples: through appropriate audits, taking into consideration the medical device risk; through controls on the supplied products.

Case 3

In case of testing laboratories or calibration centers, the supplier has ISO 17025 accreditation or certification according to Good Laboratory Practices.

For sterilization and surface treatment services, suppliers with a quality management system certified by an accredited Certification Body and whose work are widely consolidated are not included in the audit program.

During the surveillance audits, the team leader in charge evaluates the list of critical suppliers of the manufacturer and verifies its capacity to control them. If critical situations are detected, the team leader will indicate in the audit reporting documents the need to schedule specific surveillance audits at suppliers' premises.

13.PERIODIC SAFETY UPDATE REPORT (PSUR)

In case of implantable medical devices or class III medical devices, the manufacturer shall submit the periodic safety update report (PSUR) to ITALCERT, accordingly to Article 86 and taking into consideration the MDCG 2022-21. PSURs shall be assessed by ITALCERT, and this assessment will be uploaded in EUDAMED. In the absence of fully functioning of EUDAMED, the manufacturer shall submit PSURs directly to ITALCERT, along with the form MDR61 (to be requested to ITALCERT). If the manufacturer fails to submit PSURs, ITALCERT reserves the right to suspend and/or limit the certificates issued.

For new devices certified according to Reg. 2017/745 and not previously certified according to Directive 93/42/EEC, certification date is considered as the start date of data collection and the anniversary of the certification of the device is considered as the end date of data collection. PSURs shall be provided to ITALCERT accordingly, as per Article 86.

In case of "legacy devices", already certified accordingly to Directive 92/42/EEC and which obtain certification accordingly to Reg.2017/745 after 26/05/2022 (one year from MDR date of application), the start date of data collection for the MDR device must coincide with the end date of data collection of the PSUR issued for the "legacy" device. PSURs shall be provided to ITALCERT accordingly, as per Article 86.

For all other types of medical devices (as specified by art.86 of MDR) certified by ITALCERT, the manufacturer makes available the periodic safety update report (PSUR) for the necessary assessments at least during the scheduled surveillance audits.

14.SUSPENSION, WITHDRAWAL OR LIMITATION OF THE CERTIFICATION

14.1. Suspension

Suspension of the certification can be generally adopted in cases where:

a) customer's quality management system has persistently or seriously failed to meet the certification requirements, including the requirements for the effectiveness of the management system
b) customer does not allow the proper conduction of surveillance or renewal audits
c) it is not possible to perform audits at the customer's outsourcers, when requested by ITALCERT
d) customer does not provide to ITALCERT the corrective actions related to NCs within the expected time frame
e) customer is not up to date with payments
f) customer has voluntarily requested the suspension of the certificate
g) customer has not communicated to ITALCERT changes of its registered office and/or its operational headquarters

h) customer has placed on the market CE marked medical devices that do not comply with the approved technical file
i) selling assets of the customer
j) customer refuse to receive an unannounced audit

Certificate suspension is formally communicated to the customer through written communication transmitted by email or by registered letter R.R. In the communication ITALCERT indicates the condition for the re-establishment of the certification and the maximum time allowed (in any case not exceeding 6 months).
During the suspension period, customer cannot market the medical devices covered by the certificate.

14.2. Withdrawal by ITALCERT

Withdrawal by ITALCERT applies in the following conditions:

a) failure to solve the cause of the suspension, within the established time
b) reiteration of the conditions listed in the previous paragraph, when the certificate is already suspended
c) termination of business by the customer (in this case there is no prior suspension)

The withdrawal is communicated by registered letter or certified e-mail. Following the withdrawal, customer cannot market devices covered by the certificate in question.

14.3. Withdrawal by the customer

In the event of a renunciation of the certification or its renewal, customer must inform ITALCERT in writing about the intended withdrawal date through written communication transmitted by email or by registered letter R.R. Starting from that date the customer will no longer CE mark the devices with ITALCERT identification number.
ITALCERT reserves the right to conduct an unscheduled surveillance audit, in order to verify the maintenance of the compliance of the quality management system with the requirements of the EU regulation 2017/745 annex IX chapter I or of the EU regulation 2017/745 annex XI part A from the date of the last surveillance audit up to the withdrawal date. In case of unavailability of the customer for this audit, ITALCERT reserves the right to make appropriate communications to the Competent Authority

Following the withdrawal, customer cannot place on the market devices covered by the certificate in question.

In the event that a customer renounces to the certification issued by ITALCERT in order to transfer the certification to another Notified Body, ITALCERT requires the following information:

- the date on which the certificates issued by the outgoing notified body become invalid;
- the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;
- the transfer of documents, including confidentiality aspects and property rights
- the date after which the conformity assessment tasks of the outgoing notified body is assigned to the incoming notified body
- the last serial number or lot number for which the outgoing notified body is responsible

In the event that ITALCERT was not promptly informed about the above information, it reserves the right to immediately withdraw the certificate.

14.4. Certification scope limitation

ITALCERT reserves the right to limit the certification scope and/or the list of devices certified if:

a) there are medical devices that have been no longer produced and placed on the market for more than 3 years
b) customer quality management system does not meet the applicable requirements for all the medical device range
c) upon specific customer request

Before implementing a limitation of the scope of certification, ITALCERT inform the customer, giving him the right to produce any answers.
The limitation is communicated by registered letter or certified e-mail. Following the limitation, the customer cannot place on the market devices subject to the limitation itself.

15.REFUSAL OFCERTIFICATION

If, during the assessment process of the quality management system or during the assessment of the technical file non-conformities are documented and if the manufacturer is not able to solve them, a refusal of certification will be formally communicated to the manufacturer and the Competent Authorities.

It is agreed that this inability to solve non-conformities related to the technical documentation can be confirmed if:

- after 18 months from the communication of the formal outcome of the first evaluation of the technical file the manufacturer is unable to provide any resolution
- a fifth additional evaluation of the technical file has been reached without obtaining an approval, within a time limit of 24 months

It is also agreed that this inability to solve non-conformities can be attested by the fact that the manufacturer is unable to provide evidence of the resolution of a Class 1 NC detected during the stage 2 assessment audit in general within 90 days from the audit and in any case no later than 6 months.

If, due to regulatory and legislative updates or due to data not disclosed by the manufacturer at the earlier stage of the application, the qualification of the products doesn't meet with the definition of medical device (Art. 2 of MDR), a refusal of certification will be communicated to the manufacturer.

Refusal of certification could also be notified following a voluntary refusal by the manufacturer to continue with the assessment process.

16.MULTISITE CERTIFICATES

In the case that the customer manufactures the medical device in multiple operating locations, each of them will always be examined at each audit, except for the stage 1 audit.

17.CERTIFICATION TRANSFER TO ITALCERT FROM OTHER NOTIFIED BODY

Customer can ask to ITALCERT to certify one or more medical devices already subject to a previous certificate issued by another Notified Body.
In this case, customer must submit an application for a new certification to ITALCERT, together with a declaration related to the withdrawal date of the certificate issued by the other Notified Body.

Manufacturer must provide to ITALCERT the following information:

- the date on which the certificates issued by the outgoing notified body become invalid
- the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material
- the date after which the conformity assessment tasks of the outgoing notified body is assigned to the incoming notified body
- the transfer of documents in order to allow the assessment procedure, including confidentiality aspects and property rights
- the last serial number or lot number for which the outgoing notified body is responsible

In these cases, ITALCERT usually carries out an audit configured as a "renewal audit" at the customer's premises and the technical documentation assessment.

18.TRANSFER OF INFORMATION TO ITALCERT

Once the certification has been obtained, customer must inform ITALCERT in the case of:

a) changes to the registered office and / or company name;
b) changes to contact addresses and production sites;
c) significant changes to the management system and production processes;
d) changes in outsourcer suppliers of critical and significant production processes;
e) changes made to the approved technical files;
f) reports of incidents relating to the devices subject to certification.
g) production interruptions of the certified devices

In case the above information are not promptly provided, ITALCERT may decide, based on the criticality found, to:

- carry out an unscheduled audit
- suspend the issued certificate

19.APPEALS

The customer may appeal against a decision taken by ITALCERT in relation to its own certification through written communication transmitted by fax or by registered letter R.R. To be eligible, the application must:

a) contain a description of the disputed decision;
b) be supported by a clear and detailed reason;
c) be transmitted to ITALCERT within 30 days from the date of the notified decision, subject of the appeal.

Upon receipt of the appeal, ITALCERT formally communicates to the customer within 7 days if the application was deemed to be eligible or not and, in case of eligibility, the date by which a decision will be taken (within 30 days of receipt of receiving the appeal).
The eligible appeals are evaluated by a Resolution Committee, independent from the staff involved in the actions that led to the decision subject of the appeal.
The decisions taken on the appeal by the Resolution Committee, on which no further appeal can be presented, are communicated to the customer by fax and / or registered letter R.R.

20.COMPLAINTS

The customer can make a complaint to ITALCERT for the activities relative to its own certification.
ITALCERT formally manages any complaint received in writing (letter, fax or e-mail address); any verbal complaint will be handled in a documented way, if deemed appropriate.
The management of the complaint provides:

a) written response (letter, fax or e-mail) within 7 days of receiving the complaint, with the analysis of the complaint and any actions planned for its management, with the relative timing;
b) written response (letter, fax or e-mail) at the completion of the actions provided.

21. COMMUNICATIONS WITH ELECTRONIC SYSTEM - art .57 EU REGULATION 2017/745

ITALCERT is responsible for upload the information regarding the single certificate of conformity issued accordingly to EU Regulation 2017/745 into the European database/electronic system referred to in Article 57 of EU Regulation 2017/745, along with the following information:

- changes and additions / extensions implemented to the single certificate,
- suspended certificates, as well as those made valid again,
- the certificates withdrawn
- the restrictions imposed on certificates
- renewed certificates
- certificates refused

22.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-003 will be deemed accepted for silent consent.