REGULATION FOR CE CERTIFICATION OF MEDICAL DEVICES

(Quality System Certification of Medical Devices Manufacturers)

Document R-003

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

This Regulation lays down the modalities followed by ITALCERT for the management of the CE certifications of medical devices in relation to the conformity assessments of the quality management systems foreseen by Annex II, Annex V and Annex VI of the Directive 93/42/EEC and subsequent amendments and additions.
Further details, such as cheap fares, not specified in this Regulation, are defined in the Agreement of Certification issued for each specific customer.
ITALCERT is a notified body authorized by the Italian Ministry of Health for the issuance of certifications above mentioned and therefore it is subject to compliance with the rules laid down in legislative and regulatory applicable documents.
Medical devices and evaluating process, for which ITALCERT is notified, are contained in appropriate legislative decrees of authorization issued by the Italian Ministry of Health.

2 DEFINITIONS

For the purposes of this procedure, the following definitions apply:
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: Non-compliance of a requirement that represents a significant limitation of the Management System compliance with the reference standard.
Non-Conformity Class 2: Any non-compliance of a requirement that is not configurable as Class 1.
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 to as "Organization" or "Manufacturer").*
For any other not mentioned definition is as defined in the certification standards and in standards ISO 9000, ISO 13485, ISO 19011 and in Directive 93/42/EEC.

NOTE: to facilitate the correct identification of the standards listed below, they are reported as "EN ISO xxxx," following the terminology used such as harmonized standards.

3 PRINCIPLES OF CERTIFICATION

3.1 Certification process

The process to issue a certification of conformity to Directive 93/42/EEC Annex II, V or VI by ITALCERT is through the evaluation of the technical file (also identified as Device Master File or Technical Documentation) prepared by the organization applying for the certification to demonstrate the conformity of medical devices to the essential safety requirements of Directive 93/42/EEC and through the evaluation of the quality system implemented by the same organization in accordance with the requirements of Directive 93/42/EEC Annex II or V or VI. About the technical file management, please refer to the Regulation for the Technical File Management of Medical Devices R 005 of ITALCERT.

3.2 Sampling

The certification process mainly involves the collection of information at the customer's head office, evaluating some applicable examples. The audit is by nature an activity performed by sample and the customer must refrain from using improperly the outcome of audits.

3.3 Independence and impartiality

ITALCERT is required to comply with the rules established by legislative and normative documents applicable to its activities. In particular, ITALCERT is required to guarantee the principles of independence and impartiality. As a result, ITALCERT cannot offer support services intended as business consulting.

3.4 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.

3.5 Free access to the operational sites

The customer who started the certification needs to ensure to the auditor of ITALCERT the free access to its operational premises and to the documentation concerning its own quality system to perform different types of audits planned within the certification, in accordance with Directive 93/42/EEC. Such free access must be guaranteed even by the customer’s outsourcers, where they play a crucial activity for compliance of the devices manufactured. Therefore, the customer must provide for this in the contracts and /or in the agreements provided with its own outsourcers.

Whether to visit the country where the customer is located is necessary a specific visa, will be laid down specific contractual provisions and documents with the customer, so that ITALCERT could visit this country at any time. These specific contractual provisions and documents will be prepared and also extended to the customer’s basic subcontractors and suppliers.

The customer must also allow the access to the observers designated by Control / Accreditation Bodies in the performance of their monitoring and control duties of the activities performed by ITALCERT, as Inspection and Certification Body and Notified Body. The presence of these observers will always occur by accompanying the staff of ITALCERT. The notification of the presence of these observers could take place with a minimum notice (up to 5 days), or even without notice in case of presence during the "unannounced audits ", except where this may be a reason for non-acceptance of their presence by the customer. Failure to accept the presence of these observers by the customer determines the interruption of the certification process started or the suspension of the certificate (if already issued); the process or the certificate (if already issued) will be permanently interrupted / revoked whether the refusal at issue persists.

3.6 Communications towards ITALCERT about the maintenance of production

Whether the production of the devices subject to certification is interrupted for a certain period, the customer must inform ITALCERT updating also when such production will be restored.
Whether during an unannounced audit is not available any example of medical devices produced or in production, without this event has been previously communicated to ITALCERT, it determines the repetition of the audit itself, as detailed below.

4 STARTING OF THE PRACTICE

4.1 Request for quotation

Any customer can request a quotation for the certification process of a medical device. Some information is necessary to arrange the quotation and the customer must make it available to ITALCERT. The information will be evaluated by ITALCERT to determine whether the medical device, for which the certification is required, falls within the definition of medical device set out in Directive 93/42/EEC and subsequent amendments and additions and also to determine whether the organization has identified a correct classification of the medical device in accordance with Annex IX of Directive as well as an appropriate evaluation procedure.
Showing the certification process and including a section about the audit program and one about the amounts provided, the quotation will be arranged according to the information received by the customer; whether the information sent is incorrect, ITALCERT will perform a new practice review, and if appropriate, an update of the audit program and economic conditions. If such inaccuracies are particularly critical, ITALCERT may be deemed to rescind the certification agreement unilaterally.
The audit program is arranged according to internal procedures of ITALCERT, following the guidelines available for such activities.

4.2 Acceptance of quotation and formalization of the agreement

Following the acceptance of the quotation by the customer, the certification practice is opened and the following documents are transmitted to the customer:

a) this regulation R 003
b) the regulation for technical file management R 005
c) the regulation for the use of the mark R 002
d) the certification agreement
e) the “application for certification” form (Directive 93/42/EEC)

The agreement must be returned signed for acceptance. The application must be signed and returned filled out in detail. Without the above documents, ITALCERT will not be able to start any activity related to the certification process.
At the opening of the practice, the customer is given the name of the Audit Team Leader expected for the certification audit. The customer has the right to request the replacement, within a defined time, if there are motivated conflicts of interest. ITALCERT nevertheless reserves the possibility to replace afterwards the Audit Team Leader.

5 CONDUCTING AUDITS - GENERAL PRINCIPLES

5.1 Reference requirements

The customer’s quality system evaluation follows the instructions laid down in Directive 93/42/EEC in accordance with applicable Annex (II, V, VI). To evaluate the quality system conformity, ITALCERT relates

only to the harmonized standard EN ISO 13485, therefore the customer's quality system must be set and implemented in respect of this standard.
The customer's quality system must also consider the requirements laid down by Directive 93/42/EEC and by the harmonized standards that may apply. In particular, the customer's quality system must provide a risk management process in compliance with EN ISO14971 standard requirements.
The customer has to draw up and issue a Quality Manual, giving evidence, even brief, of how the quality system ensures the compliance with the requirements set by standard EN ISO 13485. Whether the sections of the Manual do not follow the numbering of standard requirements, it must include a correlation table between the regulatory requirements and the sections of the Manual.
The Quality Manual must also point out the presence (or absence) of processes entrusted to third parties (outsourcing) and must indicate the type and extent of checks carried out on these processes.

5.2 Audit operating procedures

The definition of the dates of audits is agreed by the secretariat of ITALCERT together with the customer, according to the customer's availability and the auditors in charge.
The date of audit execution and the Audit Team composition are formally notified (by fax or e-mail) to the customer. The customer has the right to request the replacement of one or more members of the Audit Team, within a defined time, if there are motivated conflicts of interests.
About 5 days before the audit, ITALCERT sends to the customer an audit plan, with the operational detail, specifying the sequence of activities related to processes and to regulatory reference standards. The plan always includes an opening meeting, during which the customer may request clarification or suggest any operational changes to the plan. The plan always provides a closing meeting, during which the Audit Team presents the results of the audit, explaining to the customer the context of the identified reliefs. The plan cannot be formalized in case of unplanned surveillance audit.
The audits are conducted at the customer's head office (or head offices if applicable); they may be held even outside the customer's head offices to verify the performance of activities included within the subject of certification; for example, installation activities at the customer's head offices fall in this area. During the audit the Audit Team will collect information needed to express its own opinion on the management system through:

- examination of the customer's documentation
- interviews with staff
- evaluation of examples about activities carried out previously (on documentary basis) or current activities during the audit.

The customer must ensure the Audit Team the opportunity to examine examples of activities carried out for all processes/products for which the certification is required, including those processes/products performed outside the customer's premises. For this reason, the customer must ensure the access to all its departments and the opportunity to interview any person employed in activities, related to the certification request.
Where applicable, before the Audit, the customer must notify to ITALCERT a list of external activities (e.g. installations) verifiable during the audit, including location, type of activity and state of progress.
If deemed appropriate and necessary ITALCERT may, at its sole discretion, require to check the management system of the customer's outsourcers at their head offices; such verification may be considered as unplanned audit (extra) or be included in the planned audit time, to sole discretion of ITALCERT. The lack of opportunity for ITALCERT to verify the management system of a customer's outsourcer can be considered as sufficient cause by ITALCERT to determine a negative result as regards the issue of certification or be cause of suspension of the certificate issued.
At the end of each audit, the Audit Team Leader releases a report (hereinafter referred to letters "RRC DM") in which NC, recommendations and observations are formalized.

5.3 Management of findings detected

For each NC, the customer is asked to notify to ITALCERT within 15 days the assessment of the causes of NC and what measures will be implemented in order to eliminate the NC, in the expected time of implementation; ITALCERT may consider not acceptable a time of implementation exceeding 90 days. Corrective actions must be related to the causes and should consider the possibility that the promptly detected NC may also be present even in other similar situations.
The corrective actions suggested are evaluated by ITALCERT; the outcome of the assessment is formally communicated to the customer, including any additional requests.

Normally ITALCERT requires the evidence, even by an extra (unplanned) audit if appropriate, of the implementation of the NC grade I within 90 days from the date of audit, while the implementation of the NC grade II will be verified during the following audit. However, according to different situations, ITALCERT can apply, formally notifying the customer, a different management of the verification of the corrective actions taken by the customer.
The closure of the NC requires the verification that the suggested corrective actions have been implemented and that they are effective. In the event that the Audit Team does not have evidence of implementation of corrective actions planned in response to the detected NC, the grade level of NC can be increased from grade II to grade I.
Not solving **Non-Conformity Class 1,** detected during stage 2 assessment audits within the required time, will result in a refusal of certification.
Not solving **Non-Conformity Class 1,** detected during surveillance audits within the required time, will result in suspension of the certificate.
The recommendations are not binding; however, the customer must handle them in documented form, implementing appropriate improvement and/or preventive actions or, otherwise, documenting the arguments in support of the non-implementation of subsequent actions. The relevant documentation is normally verified during the following audit; ITALCERT may require, by formal request to the customer, documented evidence of recommendations management before the following audit.
The observations, related to change requests of system documentation, must be taken over within the next audit, unless otherwise communicated by ITALCERT.

6 TYPES OF AUDIT

6.1 Types of expected audits

During the certification process and its subsequent maintenance, ITALCERT provides for the following types of audits:

- Certification Audit stage 1
- Certification Audit stage 2
- Planned surveillance Audit
- Renewal Audit
- Unplanned surveillance Audit (extra)
- Unannounced Audit

All audits are carried out against payment for customer, according to the fares specified in the certification agreement.

6.2 Certification Audit Stage 1

The audit stage 1 has the following purposes, as detailed below:

a) verify that the customer's management system documentation properly covers the system requirements provided by EN ISO 13485, as applicable to devices covered by the application for certification and to the assessment procedure required, and that includes a risk management process according to standard EN ISO 14971;
b) verify that the customer has implemented all procedures provided by standard EN ISO 13485, as applicable to devices subject of certification request and to the assessment procedure required;
c) verify the customer's level of knowledge and understanding about the legal and regulatory requirements that the quality system must take charge;
d) collect the necessary information about the type of devices for which the certification request was submitted, the production processes and customer's locations as well the regulatory matters to apply;
e) evaluate the level of preparation for the audit stage 2, checking if the internal audits and review of the management system have been planned and carried out and if the level of implementation of the management system provides adequate reliability that the customer is prepared for the audit stage 2;
f) draw up/confirm/change the planning of stage 2 defining any appropriate details (such as the location of external activities to verify);
g) ensure that the customer has set up one or more technical files for the medical devices of which it is the manufacturer.

The audit stage 1 is always carried out in case of new certification. It is also carried out in cases where a customer, which already has a certificate issued by ITALCERT, submits a new certification request for other medical devices that provides for the issuance of a further new certificate.
Normally the audit stage 1 is carried out at the customer's head office; in specific cases this audit, or part of it, cannot be carried out at the customer but, for example, at the head office of ITALCERT. In the event of customers requiring to ITALCERT the certification of devices previously marked by other Notified Body, ITALCERT reserves the possibility not to carry out the audit stage 1 or to perform it not at the customer's head office.

6.3 Certification Audit Stage 2

The purpose of the audit stage 2 is to evaluate the implementation, including its effectiveness, of the customer's management system. The audit stage 2 must take place at the customer's head office(s). Part of the audit should also be carried out at the supplier/s's headquarter/s considered as critical/s, according to the audit plan.
During the audit, the Audit Team has to:
• collect evidences about the compliance with all applicable requirements, both regulatory and legislative;
• verify that the system ensures the operational control of processes and that records assure the traceability, when expected or required;
• verify that the quality system ensures the ability over time to provide compliant products to the approved technical specifications (technical file);
• verify that the customer has implemented a monitoring, measurement and recording system as well a management system review, some key targets and goals, which necessarily provides also the conduct of internal audits carried out by competent staff, as well as the management review.
The Certification Audit Stage 2 shall be carried out preferably within 6 (six) months from stage 1 but not later than 12 months; once this time has elapsed, ITALCERT will have to perform certification audit stage 1 again.
In case the costumer is not available to carry out the certification audit stage 2 audit within 12 months from the execution of certification audit stage 1, ITALCERT will be able to close the certification procedure following a written notice by registered letter. This closure of the file shall be seen as a REFUSAL of the certification and shall be formally communicated to the Competent Authority according to current laws.

6.4 Planned surveillance Audit

Surveillance audits are carried out at the customer's premises, in order to maintain confidence that the certified management system continues to meet the requirements specified. Part of the audit might be also carried out at the supplier/s's headquarter/s considered as critical/s, according to the audit plan.
ITALCERT carries out at least one planned surveillance audit in a year. In any case, the first surveillance audit must be conducted no later than 12 months from the audit stage 2. For this reason, ITALCERT normally plans the first planned surveillance audit at a distance of 10 months from the audit stage 2.
The non-compliance with the rules about the planned surveillance audit performance, for customer's unavailability, involves the suspension of the certificate.

6.5 Renewal Audit

The certification renewal occurs as a result of a renewal audit (or recertification), whose purpose is to ensure that the efficacy of the whole management system has been maintained, in light of internal and external changes, as well as its continued relevance and applicability to the subject of certification and that the management system has actually contributed to the achievement of the customer's policy and targets.
The renewal audit is planned and conducted to evaluate the continued fulfilment of all requirements of the relevant normative document. The purpose of the recertification audit is to confirm the maintenance of compliance and the effectiveness of the whole management system as well as the maintenance of its usefulness and applicability for the purpose of certification.
This audit considers the management system performances during the certification period; therefore, the customer must make available to the Audit Team all data and/or information covering the duration of the certificate, subject of renewal.
Exceptionally, ITALCERT can carry out a renewal audit in two stages (1 and 2), for example in case of significant changes in the management system, or about the customer, or in the operational context of the management system (e.g. changes in the legislative context or customer's requests about extensions/variations of the field of certification).

The renewal audit is normally planned at least two months before the expiry of the certificate.
The manufacturer in any case shall submit a written application of renewal request using the form provided, within 3 months from the date of expiry of the expiring certificate.
Concerning the management of the reliefs found during a renewal audit, it remains essentially valid as given in previous point 5.3 of this Regulation, specifying that in case of NC grade I, the procedure of renewal cannot be taken forward as long as the manufacturer will have solved these NC grade I and so it is responsibility of the manufacturer to give evidence even before the 90 days normally deemed acceptable by ITALCERT for their resolution, due to the timing normally foreseen in the management of the renewal audit. ITALCERT anyway will formally agree with the manufacturer on the modalities of verification of the NC grade I resolution (e.g. through the transmission of documented evidences or through extraordinary audit). Finally, we point out that, if not subjected to a formal renewal yet, the expired certificate of conformity cannot be used by the manufacturer, which therefore cannot proceed with the placing on the market of new medical devices listed in the certificate.

6.6 Unplanned surveillance Audit

Unplanned audits can be resolved by ITALCERT in the following cases:

- request for extension of certification by the customer;
- particularly critical situations requiring an increase of field monitoring by ITALCERT;
- particularly serious reports by the "customer's system" of the certificated customer;
- particularly serious reports from the market (e.g. "incident reports/failure incidents") relating to medical devices, subject of certification;
- reports and/or specific requests of the Ministry of Health/Competent Authority;
- need to examine the management system of a customer's outsourcer (subcontractor);
- need to examine processes or customer's and/or critical suppliers' premises outside the usual audits planning;
- failure to send of corrective actions following the detected NC;
- failure to evidence of implementation of the actions planned following the detected NC;

The unplanned surveillance audits can be performed in a simplified manner, according to their purpose, and may not provide a detailed audit plan.

6.7 Unannounced Audit

At least every three years ITALCERT carries out an unannounced audit, in accordance with the procedures defined below. ITALCERT may, at its sole discretion, consider to increase the minimum number of unannounced audits, based on the following criteria:

- risks of medical devices subject to certification;
- presence of frequent non-conformities on products, identified during the planned surveillance audits;
- presence of specific information that gives reasonable suspicion about the non-conformity of the devices and of the manufacturer's quality system;
- refusal to receive an unannounced audit.

The manufacturer cannot have a prediction, even approximately, about the planning of the unannounced audits.
The unannounced audit lasts for a minimum of 1 day and is carried out by an Audit Team consisting of at least two persons.
The unannounced audit is carried out at the customer's cost, according to the contracts and agreements between the parties.
The unannounced audit generally takes place at the manufacturer's premises. However, ITALCERT may, at its discretion, carry out such audit at the premises of the customer's outsourcers, where they play a critical activity for compliance of the devices manufactured. Therefore, the customer must provide for this possibility in the contracts and /or agreements provided with its own outsourcers.
Within the context of the unannounced audit the audit team will check an adequate sample of the ongoing production, verifying its conformity to the technical file and to regulatory requirements. When deemed appropriate for a complete verification of conformity of products made, the Audit Team may require to take a sample of products to be tested at a laboratory chosen by ITALCERT.
The cost of such tests will be charged to the customer.

At the request of the Audit Team, the customer may have to perform or re-perform the tests on the products sampled (in-process and / or final) in presence of the auditors of ITALCERT.
In addition, the Audit Team should verify whether the quality system applied is in line with the approved quality system and the applicable regulatory requirements.
In general, the requirements for the management and the conducting of unannounced audits, as well as on the modalities of the tests to be performed or at the manufacturer or at critical supplier or at external laboratory qualified by ITALCERT, are listed in the Annex III of the COMMISSION RECOMMENDATION of September 24, 2013 (2013/473 / EU).
The customer cannot refuse to accept an unannounced audit.
Where the Audit Team has not the opportunity to sample examples of products made, without the customer has previously communicated to ITALCERT that these products are no longer object of production, the audit should be repeated subsequently.
By its very nature, the unannounced audit does not provide for the transmission of an audit plan or the prior notification of the Audit Team to the customer. Therefore, it is not possible for the customer to recuse in advance the Audit Team. Where the customer has real and objectively proven reasons of conflict of interest with the Audit Team, may formally challenge this situation within 3 days after the conduct of the audit. Where such reasons are found objectively consistent, and therefore deemed acceptable by ITALCERT, the audit will be canceled and repeated later; in addition, the audit itself will not be invoiced to the customer.
The refusal to receive an unannounced audit involves the immediate suspension of the current CE certifications.
For the reactivation of the certification an unplanned audit must be carried out successfully (as in the previous paragraph), that, however, does not replace the unannounced audit, which should be recovered.
In addition, the refusal to receive an unannounced audit should be a reason to increase the number of audits of this type, expected in three years.
The persistence of the state of suspension of the certification will determine the revocation of certifications, in the manner provided for in this Regulation.

7 RELEASE OF CERTIFICATE

7.1 Issue of certificate

The certificate of conformity is made up of two parts:

- the certificate itself, with the identification of the manufacturer, the registered office and operational head offices, the annex followed in the certification process, dates of issue, current/renewal issue and expiry;
- an annex containing all the necessary information to enable a unique traceability and link between medical devices, subject of certification and devices placed on the market.

The certificate has a maximum duration of five years. ITALCERT reserves the right to issue a certificate with duration less than five years if its validity is related to another certificate issued to another manufacturer, with whom the customer of ITALCERT has signed an OBL agreement.
The change of the Annex to the certificate does not modify the expiration date of the certificate.
The certificate of conformity is issued after a final review stage of the practice and after a final decision on the release, based on the documentation collected during the audits and only after the approval of the Technical Documentation arranged by the organization requiring the certification to demonstrate the conformity of medical devices to the essential safety requirements of Directive 93/42/EEC and subsequent amendments and additions.

The stage of final revision of the practice may have the following results:

a) give a positive opinion to bring the practice towards a subsequent stage of final decision on certification;
b) give a negative opinion to bring the practice towards a subsequent stage of final decision on certification, as long as have been implemented a series of actions that must be formally communicated to the customer;

For example the actions that can be requested to the manufacturer are:

- require additions/revisions to Technical Documentation previously approved, in particular as regards the documentation of compliance with the essential safety requirements, the risk management documentation, the clinical evaluation documentation, the information for use;
- give evidence of specific procedures/instructions/documents of the customer's quality system as result of corrective actions planned by the manufacturer, following the reliefs issued during the audit or change and/or further integrate specific procedures/instructions/documents of the quality system.

Any further specific actions required to the manufacturer must necessarily be taken and absolved by the organization applying for certification, before the practice can be then submitted to the subsequent activity of final decision for the certification issue.

The stage of final decision may have the following results:

c) deliberate the issue of the certificate;

d) deliberate the issue of the certificate requiring specific actions to the customer after the release;

e) deny the issue of the certificate.

For example the actions that can be requested to the manufacturer are:

- request to conduct an unplanned surveillance audit;
- request to anticipate the first planned surveillance audit expected;
- request to implement a mandatory action following a recommendation detected during the audit;
- request specific actions to the manufacturer, for example about post-market surveillance and post-market approval clinical investigation.

In case of negative opinion in relation to the certification issue, the reasons of the decision and the modalities to re-submit an eventual new application will be communicated to the manufacturer.

During periods of non-validity of the certificate (expired certificate, not issued, suspended, revoked, etc..) the customer cannot commercialize medical devices, subject of the certificate.
Once verified the misuse of the certification, ITALCERT takes measures to prevent it and to protect, even by publication, its own interests (warning, suspension or revocation of certification, legal actions), as well as proceeding with adequate communication to the Competent Authority.

7.2 Marketing of certified medical devices

The customer can place on the market the devices subject of certificate only after issuance of the certificate by ITALCERT. These devices must have to bear the CE mark, in accordance with the requirements of Directive 93/42/EEC, accompanied by the number 0426, that is the approval number of ITALCERT as Notified Body.
The customer must guarantee and undertake to ensure that the medical devices placed on the market with the CE symbol and the identification number 0426 are:

- uniquely correlatable to a specific Technical File approved by ITALCERT;
- produced in full compliance with such Technical File;
- correlatable to a specific declaration of conformity;
- correlatable to the specific certificate of conformity issued by ITALCERT.

7.3 Change, extension, reduction of the certificate

The customer may request a change, extension or reduction of the medical devices listed in the Annex to its certificate.
This request must be expressed by giving written notice on the Certification Request form. Depending on the type of change, ITALCERT may request the performance of a specific audit.
Following each type of change request, extension or reduction of the certificate, ITALCERT must however receive evidence of any changes to Technical Documentation arranged by the organization and previously approved, for a new evaluation. Following the approval of the Technical Documentation and the possible conduct of a specific audit, with its positive outcome, ITALCERT will communicate to the organization the approval of change, extension or reduction of medical devices listed in the Annex to its own certificate, through a review of the same Annex or through a special discharge letter, if the approval is related to medical devices already in the Annex to the current certificate.

Following each type of request for change, extension or reduction of the certificate, ITALCERT has however the possibility to review and update, as appropriate, the audits plan in terms of duration, and consequently to update the related fares.
Changes of name and address of the organization will necessary require a revision of the certificate.

8 REQUEST FOR SHIFTS OF PLANNED AUDITS

ITALCERT communicates in advance to the customer the period of the next planned audit expected.
Any shift may be requested by the customer, provided that:

a) the obligation to conduct at least one audit in a year is guaranteed;
b) the customer requests the shift in a formal way, if this shift exceeds 2 months, giving further evidence of having implemented the corrective actions proposed for the management of NC, if applicable;
c) the shift does not lead to an interval exceeding 18 months between two consecutive audits.

ITALCERT nevertheless reserves the possibility not to accept the requested shift.
In case of request for shift of a renewal audit, it is necessary to consider that the duration of the certificate cannot be extended beyond the expiration date.

9 SUSPENSION, REVOCATION, RECESS OR LIMITATION OF CERTIFICATION

9.1 Suspension

The suspension of certification may be generally considered when:

a) the customer's management system has persistently or seriously failure to meet the certification requirements, including requirements for the effectiveness of the management system;
b) the customer does not allow the conduct of surveillance or renewal audits at the frequencies required;
c) it is not possible to carry out audits at the customer's outsourcers, as requested by ITALCERT;
d) the customer does not send on time to ITALCERT the corrective actions planned against the NC detected;
e) the customer is not up to date with payments;
f) the certified customer has voluntarily requested the suspension;
g) the customer has failed to communicate to ITALCERT the change of its registered office and/or its operational sites;
h) the customer has placed on the market CE marked medical devices not conformed to the approved technical file;
i) liquidation / bankruptcy of the customer;
j) the customer refused to receive an unannounced audit.

The adoption of suspension of the certification is formally communicated to the customer by registered letter R.R., with fax in advance if possible. In the communication, ITALCERT indicates the condition for the reestablishment of certification and the maximum time provided (however not exceeding 6 months).
During the suspension period, the customer cannot place on the market the medical devices covered by the certificate.

9.2 Revocation

The revocation may be applied by ITALCERT in the following conditions:

a) failure to resolution, within the stipulated time, of the elements that have led to the suspension;
b) repetition of conditions referred to in different points of the previous paragraph;
c) cessation of activity by the customer.

The order of revocation is communicated by registered letter R.R., with possible anticipation by fax. Following the revocation, the customer cannot place on the market the devices covered by the certificate in question.

9.3 Recess

In case of recess of the certificate, the customer must give written notice to ITALCERT, by registered letter R.R. pointing the date from which the customer waives the certificate and consequently will no longer mark CE, with the identifier of ITALCERT, the medical devices subject of certification. ITALCERT also reserves the possibility to conduct an unplanned surveillance audit in order to verify the maintenance of the quality management system, compliance with the requirements of Directive 93/42/EEC Annex II or V or VI with effect from the last surveillance audit until the date of recess of the certificate. In case of

unavailability of the customer to support this audit, ITALCERT reserves the possibility to make appropriate communications to the Competent Authority.
Following the recess, the customer cannot place on the market the devices covered by the certificate in question and must return the original certificate to ITALCERT.

9.4 Limitation of the scope of certification

ITALCERT reserves the possibility to limit the certificate subject and/or the list of devices mentioned in Annex when:

a) there are medical devices no longer produced and marketed from more than 2 years;
b) the customer's quality system does not meet critically and repeatedly the requirements applicable to such categories of devices;
c) on customer request.

Before implementing a limitation of the scope of certification, ITALCERT notifies the customer giving it the opportunity to argue.

10 CERTIFICATION REFUSAL

Once a formal application for certification has been already presented to ITALCERT by the manufacturer, a certification refusal shall be formally communicated to the manufacturer and to the Competent Authorities in case that the manufacturer has been found not to be able to solve the non-conformities documented during the evaluation process of the quality management system or during the evaluation of the technical dossier.
It is agreed that this impossibility to solve the non-conformities can be attested by the fact that after 18 months from the communication of the result of the first evaluation of the technical dossier, any resolution has been no longer provided or that the technical dossier has come to the fifth additional assessment without obtaining an approval.
It is also agreed that this impossibility to solve the non-conformities can be attested by the fact that the manufacturer was not able to give evidence of the resolution of a Grade I NC, detected during the stage 2 assessment audit, in general within 90 days from the conduct of the audit and in any case no later than 6 months.
Once a formal application for certification has been already presented to ITALCERT by the manufacturer, a certification refusal shall be also formally communicated to the manufacturer and to the Competent Authorities in case that, during the evaluation process of the technical dossier, an incorrect placement of the product within the definition of medical device (Article 1 of Directive 93/42/EEC) is communicated to the manufacturer, as a consequence of elements that in the preliminary assessment phase were not been brought to the attention of ITALCERT or as a consequence of the meanwhile evolution of the regulatory framework.
Once a formal application for certification has been already presented to ITALCERT, a certification refusal shall be notified as a consequence of a voluntary renunciation by the manufacturer to continue with the evaluation procedure.

11 MULTISITE CERTIFICATES

In the event that the customer produces medical device in multiple operational sites, each of them will always be examined during each audit, except for the audit stage 1.

12 TRANSFER OF CERTIFICATION

The customer may request to ITALCERT to certify one or more medical devices already subject of the certificate issued by another Notified Body.
The applicable regulations do not allow the "transfer" of a CE certificate. The customer in this case must apply for new certification to ITALCERT, contextually to a declaration of the certificate cancellation in force with the other Notified Body, starting from a defined date.
In these cases, ITALCERT normally conducts an audit considered as "renewal audit" at the customer's head office together contextually to the evaluation and subsequent approval of the technical documentation arranged by the customer.

13 TRANSFER OF INFORMATION TOWARDS ITALCERT

The customer, once achieved the certification, must promptly inform ITALCERT in case of:

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

In the event of proven failure to communicate of such information, ITALCERT may resolve upon, according to the criticality reported, to:

- conduct an unplanned audit;
- implement the suspension of the certificate issued.

14 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.

15 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.

16 CERTIFICATION OF MEDICAL DEVICES ALREADY CERTIFIED BY OTHERS MANUFACTURERS

In case that a manufacturer (hereinafter referred as “buyer”) applies for the certification of a medical device that is already certified with exactly the same intended use by another manufacturer (hereinafter referred as “supplier”), that is manufactured by the supplier on behalf of the buyer, however with the intention of putting it on the market under his own name, ITALCERT shall conduct an evaluation procedure only if the following requirements are satisfied:

- it must be verified the presence of a contract/agreement between the supplier and the buyer, in which the mutual responsibilities are clearly defined;
- it must be provided clear and irrefutable evidence of the certification obtained by the supplier and that such certification is not derived from another similar procedure;
- it is necessary for the buyer to submit a complete technical file to ITALCERT according to Directive 93/42/EEC or it necessary that the technical file includes within it references and / or attachments to the technical file prepared by the supplier; this technical file, also including any documents prepared by the supplier, shall necessarily be delivered and evaluated in its entirety by

ITALCERT; it is also permitted that any specific part drawn up by the supplier may be delivered to ITALCERT directly by him and not by the buyer for reasons of confidentiality; in any case, even these documents must be evaluated by ITALCERT and without their positive evaluation it will not be possible to continue with the subsequent phases of finale review and decision making.

ITALCERT will conduct an evaluation procedure in accordance with the requirements of this Regulation.

Any certificate of conformity issued by ITALCERT to the buyer is however subordinated anyway to the validity of the certificate of conformity issued by ITALCERT or by another Notified Body to the supplier. In case of suspension and / or withdrawal of the supplier's certificate, the certificate will be simultaneously and immediately suspended and / or withdrawn to the buyer.

17 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.