Handbook for clients
CERTIFICATION PROCESS

Conformity assessment of medical devices according to Regulation (EU) 2017/745

Institute for Testing and Certification, Inc. Czech Republic

1 Introduction

This handbook informs customers of the Institute for Testing and Certification, Inc. ("ITC") about the conformity assessment process of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council ("MDR"), as performed at ITC.

ITC is designated by the designating authority Czech Office for Standards, Metrology and Testing as a Notified Body No. 1023 (hereinafter referred to as NB 1023) to perform conformity assessments of medical devices before their placing on the market of the European Union and the European Free Trade Association (EFTA).

ITC carries out conformity assessment activities for those medical devices that fall within the scope of its designation. The scope of the ITC designation is available in the Notified Bodies Database (NANDO) created and maintained by the European Commission (https://ec.europa.eu/growth/tools-databases/nando/).

Regulation (EU) 2017/745 on medical devices is directly applicable in all EU and EFTA Member States. A product that has successfully passed the NB 1023 conformity assessment process under this Regulation may therefore be placed on the market in any EU and EFTA Member State.

NB 1023 offers conformity assessment processes according to Annex IX and XI of the MDR, the conformity assessment according to Annex X is not included within the scope of the NB 1023 designation.

2 Inquiry

An enquiry is any preliminary question (in the form of a face-to-face discussion, telephone contact, email, or paper document) concerning the competences, procedures and prices relating to a medical device to be placed on the EU market.

Enquiries are managed and recorded by the ITC Medical Device Certification Department Secretariat. The responsible person in the Secretariat (administrator) shall provide a response to the enquiry received within 5 working days at the latest. The response shall include information on the earliest possible date for the start of further communication and a link to the ITC website, where downloadable forms are available and the conformity assessment process is described.

The medical device manufacturer (hereafter referred to as the "client") shall send a completed Preliminary Questionnaire (FM- 19-05-01 Preliminary Questionnaire for Potential MDR Clients) to ITC along with the following additional documents

- a document containing a description of the medical device and its intended use;
- instructions for use of the device;
- copies of valid MDD, MDR and QMS certificates (if any);
- a diagram of the organisational structure of the manufacturer's company and, where applicable, its subsidiaries;
- copies of valid QMS certificates held by critical process subcontractors.

The questionnaire form is available for download on the ITC website:
https://medical-devices.itczlin.cz/en

The completed questionnaire can be delivered by the client by email, mail or in person to the contact below:

Institute for Testing and Certification, inc.
Medical Device Certification Department

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Contact details - medical device certification department:

Ing. Tomáš Závišek (Head of the Medical Device Certification Dept.)
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The required languages of the questionnaire and the documentation to be submitted are Czech, Slovak and/or English.

Upon receipt of the completed preliminary questionnaire and the required documents, the administrator will check the completed data and attached documents for completeness and formal correctness. If any information is missing, the potential client will be asked for its completion or correction.

The manufacturer shall inform ITC whether the application has already been lodged with another notified body; if so, whether the manufacturer withdrew his application before the decision of that notified body or whether the application was rejected by that notified body.

Upon receipt of the duly completed questionnaire, supplemented by the required documentation, the appointed worker will prepare a proposal of price quotation for the required conformity assessment procedure.

3 Pre-registration phase

The pre-registration phase involves a detailed review of the preliminary questionnaire and the documents provided. The aim of this review is to confirm the qualification and classification of the product proposed by the client. If, on the basis of the pre-verification, the ITC staff member considers that the qualification and/or classification information in the preliminary questionnaire has been incorrectly filled in by the client, he/she will ask the client for additional justification or, where appropriate, for a change in the qualification or classification determined. If the manufacturer does not sufficiently substantiate his qualification/classification proposal with relevant data, the administrator shall invite the manufacturer to proceed according to Article 51(2) of the MDR and request the manufacturer to contact the competent authority (CA) for an opinion on the qualification/classification of the product.

4 Project planning and quotation

Based on the documents submitted and confirmation of product qualification and classification, a project leader is assigned to the inquiry being addressed and is responsible (at this stage of the project) for confirming the conformity assessment procedure requested by the manufacturer, establishing a sampling plan for the technical documentation (if multiple product groups are the subject of the application and if ITC decides to apply sampling) and establishing a project plan.

A sampling plan shall be drawn up for Class IIa and IIb medical devices. For implantable medical devices of Class IIb (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors) sampling shall not apply and the assessment of the technical documentation of each device shall be carried out.

Based on the knowledge of the number of documentation samples assessed during the primary certification and in each year of the certificate validity, the project leader will establish an overall Project Plan for the entire certification period (maximum 5 years), including the assessment of technical documentation, initial audits and surveillance activities.

The client will receive information on the acceptance/rejection of the enquiry and (in positive case) the quotation within 10 calendar days after receipt of the duly completed preliminary questionnaire, or additional justification of qualification and classification, if applicable, or after delivery of a valid opinion of the competent authority.

5 Registration and application

If the client rejects the quotation or does not confirm it within 14 days, the enquiry is terminated without registration.

If the client accepts the quotation, the manufacturer's registration obligations (in the EUDAMED database) are verified, namely the assignment of the single registration number (SRN) and, in the case of Class III devices and Class IIb implantable devices, the assignment of the basic UDI-DI. If the registration obligations are not fulfilled, the process is suspended and the manufacturer is asked to remedy the situation.

If the registration requirements are met, the client will receive a form of Application for conformity assessment from the NB 1023 administrator for completion (alternatively, the form can be downloaded from the ITC website: https://medical-devices.itczlin.cz/en). The duly completed and signed application must be sent to ITC either in paper or scanned form within 7 days. At the same time, the manufacturer is asked to sign the General Framework Agreement GFA-MDR (form AG-19-05-01), without which the certification process cannot start. If the client has already concluded a GFA-MDR with NB 1023 (for previous conformity assessment processes), it is not necessary to conclude this agreement again.

The application received by the ITC is reviewed for formalities and in case of deficiencies the applicant is invited to complete or correct the application.

Once the application has been reviewed, the project is registered and the manufacturer receives access data to the Web Interactive Medical Device Application and Review (WIDAR), which serves as an annex to the application containing data on the device and quality system under assessment, as a communication tool between the manufacturer and the ITC, and as an interim report on the review of the technical documentation.

The manufacturer shall complete all required data in the WIDAR application and deliver the complete technical documentation to the ITC within 30 days of receipt of the login data. Once the required data has been completed and the cycle is closed, the entered data is locked and the manufacturer is only able to view the application, at the same time the application is made available to NB 1023 personnel who can add comments on individual items.

The procedure for operating the WIDAR application is described in a separate "Handbook for clients - WIDAR".

If the manufacturer fails to make the WIDAR application available within the above time limit, he is notified to arrange for a remedy within an additional 7 days. If even this deadline is not met, the application will be rejected.

The technical documentation to be sent by the manufacturer following the completed data in the WIDAR application shall be prepared in accordance with the requirements of Annex II and Annex III of the MDR.

A separate application for conformity assessment including the completed WIDAR application shall be submitted for each class of medical device.

6 Review of the application

In the first stage of the application review, the qualification and classification of the device is assessed in detail against the technical documentation submitted. If the review of the application, which at this stage is already supported by the technical documentation, results in a change of qualification, the conformity assessment process shall be terminated by rejecting the application.

At the same time, other aspects that could lead to the rejection of the application are examined, namely

- Ineligibility of NB 1023 to consider the application under the approved scope of designation;
- there are facts in the file which could give rise to a conflict of interest and compromise impartiality or independence;

- the inapplicability of the conformity assessment procedure chosen by the manufacturer to the device concerned;
- the application contains several classes and/or categories of medical devices for which a separate applications must be submitted;
- The limited capacity of NB 1023 staff to provide all required activities does not provide the prerequisites for certification within an acceptable time interval;
- The manufacturer did not truthfully disclose that he had submitted a previous application to another NB and had withdrawn it or had been refused;
- the manufacturer has not remedied the defects in the application that were brought to its attention;
- the manufacturer has not made the annex to the application (WIDAR) available to the ITC within the required time after submission of the application and has not responded to the ITC's urging, so that the application is incomplete;
- the manufacturer has not signed and/or has refused to sign the current version of the GFA-MDR (AG-19-05-01).

A review of the above aspects may lead to an update of the project plan and quotation.

If the review of the application does not identify any obstacles to the initiation of the conformity assessment process, a copy of the application signed by the ITC reviewer is sent to the manufacturer and ITC proceeds to establish the contractual relationship.

7 Conformity assessment contract

Based on the overall project plan, a long-term contract is prepared, covering all activities carried out during the initial certification and for the entire duration of the certificate (maximum 5 years). The contract includes references to the sub-contracts under which NB 1023 will carry out the individual activities.

The conclusion of the long-term contract and the sub-contract and the payment of the agreed contractual amount formally and technically initiates the conformity assessment process.

If the manufacturer withdraws the application during the conformity assessment, i.e. after signing the contract and before the notified body decides on certification, the process is completed and an entry is made in the appropriate section of the EUDAMED database.

8 Review of technical and clinical documentation

Scope of review of technical and clinical documentation by risk class:

- The review of the technical and clinical documentation shall not be performed for medical devices of risk **classes Is, Im and Ir** where the notified body's activity is limited to the assessment of the quality management system restricted to the aspects related to sterility assurance, aspects related to metrological requirements and aspects related to the reusability of the surgical instrument.
- For **Class IIa** medical devices**, Class IIb non-implantable devices and Class IIb implantable devices that are** sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, a sampling assessment of the technical and clinical documentation shall be performed using the selected sampling procedure (if sampling was applied by NB 1023 when the project plan was established). If the sampling procedure was not applied in the project plan, an assessment of each device shall be performed.
- For **Class IIb** implantable medical devices not **listed in the previous paragraph, a** review of the technical and clinical documentation for each device shall be carried out.
- For **Class IIb non-implantable active** medical devices **intended to administer and/or remove of drugs**, a review of the technical documentation is performed on a sampling

basis (if sampling was applied by NB 1023 in the development of the project plan), but a review of the clinical documentation and submission of the CEAR (Clinical Evaluation Assessment Report) to the Commission is performed for each device.

- For **Class III** devices, a review of the technical and clinical documentation of each device shall be performed.

The WIDAR web application is used to review technical and clinical documentation. The project leader together with the assessment team will review, comment on and evaluate all relevant items in the WIDAR application that have been completed by the manufacturer.

The assessment of the technical and clinical documentation is carried out as follows:

1) Review, commenting and evaluation of all relevant items in the WIDAR application by a team of assessors (includes project leader, product assessors, in-house clinicians, clinical experts, technical experts, etc.).
2) Formal conclusion of the first round of NB 1023 documentation review and making the WIDAR web application available to the manufacturer. The manufacturer is allowed to correct only the parts (fields in the WIDAR application) where deficiencies were found.
3) Input of information by the manufacturer on the corrections made in the technical and clinical documentation file. Submit the completed WIDAR application for NB 1023 review along with the complete updated technical and clinical documentation.
4) Review, commenting and evaluation of corrections to identified deficiencies by the team of assessors. If the corrections are found to be sufficient, a certificate is recommended (for a period not exceeding 5 years) and a second round of documentation review is formally completed with a positive statement. Otherwise, the second round of review is formally concluded with a negative result and the manufacturer is requested to make corrections.
5) Input of information by the manufacturer on the corrections made in the technical and clinical documentation file. Submit the completed WIDAR application for NB 1023 review along with the complete updated technical and clinical documentation.
6) Review, commenting and evaluation of corrections to the identified deficiencies by the team of assessors. If the corrections are found to be sufficient, a certificate is recommended (for a period not exceeding 5 years) and the third round of documentation review is formally completed with a positive statement. Otherwise, the third round of review is formally concluded with a negative result and a statement is issued with a recommendation not to issue a certificate (3rd round of assessment).

Note : The manufacturer has the option to request a 4th round of assessment, which will be carried out by NB 1023 at an additional cost to the agreed price of 60% of the price for the initial assessment of the technical and clinical documentation. The 4th round is the final round and will result in either a recommendation to issue a certificate or a refusal to issue a certificate.

8.1 Specific additional procedures

The additional procedures are intended for certain product groups, namely

- Class IIb active medical devices for the administration or removal of medicines and Class III implantable medical devices (see section 8.1.1 below);
- medical devices containing a medicinal substance (see section 8.1.2 below);
- medical devices containing substances absorbable or dispersible in the human body (see section 8.1.3 below).

8.1.1 Class IIb active medical devices for the administration or removal of medicines and Class III implantable medical devices

For Class III implantable devices and active devices intended for the administration or removal of a medicinal product and classified in Class IIb according to Annex VIII, Rule 12, the clinical evaluation consultation procedure shall apply according to Article 54(1) of the MDR

(the conclusions of the clinical evaluation assessment carried out by NB 1023 shall be consulted with the expert group of the European Commission). Clinical evaluation consultation is not applicable in the case of

- recertification;
- the medical device has been placed on the market by the same manufacturer under the MDR or under Directive 93/42/EEC and only modifications have been made to it which do not adversely affect the benefit/risk ratio;
- a Common Specification CS has been issued for the clinical evaluation principles of the device.

NB 1023 shall inform the Commission and the competent authorities through the EUDAMED database whether the clinical evaluation consultation procedure will be applied or whether one of the above exemptions will be applied.

If any of the above exceptions apply, the TD (Technical Documentation) must include:

- a complete list of changes made to the device;
- justification and evidence that the changes made to the device will not adversely affect its benefit/risk ratio.
- Where the requirements of the Common Specification (CS, if any) are applied, the manufacturer shall also provide a complete list of changes to the device and evidence that the requirements of the Common Specification have been met.

If the evidence submitted is not sufficiently convincing, the exception shall not apply.

The Panel shall either inform the notified body within 21 days that it will not provide a scientific opinion or issue a scientific opinion within 60 days. If the scientific opinion is not provided within 60 days, the opinion of the expert group shall be considered as positive.

8.1.2 Medical devices containing a medicinal substance

For medical devices containing as an integral part one or more substances which, when used separately, may be considered as a medicinal product within the meaning of Article 1(2) of Directive 2001/83/EC, and the effect of these substances is only ancillary to the effect of the device, NB 1023 shall follow the procedure in Article 52(9) and Annex IX(II), point 5.2 of the MDR, which describes the consultation procedure for scientific opinion on the quality and safety of the medicinal substance used. NB 1023 shall request the so-called "consulted authority" to verify the usefulness of such medicinal substance. The consulted authority may request additional information or documents. In such a case, NB 1023 shall invite the manufacturer to explain or submit the relevant documents.

In case an opinion has already been issued under Directive 93/42/EEC for the same product, the previous opinion of the competent authority must be submitted together with the complete dossier for the medicinal substance. If there have been no changes to the medicinal substance, its manufacturing process, the way in which the substance is incorporated into the medical device, the medical device itself, or the relevant documentation since the last consultation (whether primary or post-consultation), the NB 1023 shall issue a statement of these facts and submit it to the consulted authority together with the dossier for the medicinal substance.

The consulted authority shall provide a scientific opinion within 210 days.

Before making any changes in relation to the medicinal substance integrated in the device, in particular changes related to the manufacturing process, the manufacturer must inform NB 1023 of these changes. In this case, the expert opinion of the consulted authority is also required (this requirement applies for the whole certification cycle, i.e. for the entire period of validity of the issued certificate).

In the case where the combination of a medical device and a medicinal substance falls under the jurisdiction of Directive 2001/83/EC (see Article 117 of the MDR), the competent authorities designated by the Member States under this Directive or the EMA shall assess the whole as

a medicinal product, but NB 1023 shall issue an opinion on compliance with the GSPR (General Safety and Performance Requirements, Annex I of the MDR) of the part of the medicinal product that is a medical device. For this purpose, NB 1023 requires the manufacturer to provide technical documentation in a similar scope and structure as for the conformity assessment of a medical device fully subject to the MDR. Clinical documentation is not required as the clinical evaluation of a medicinal product, part of which is a medical device, is assessed by the competent authority or the EMA. In this case, the output of the NB 1023 is an opinion on the assessed part, not a final report and/or certificate.

8.1.3 Medical devices containing substances absorbable or dispersible in the human body

For medical devices that are composed of substances or combinations of substances intended to be introduced into the human body through a body orifice or by application to the skin and which are absorbed by the human body or locally dispersed in the human body, the procedure in Annex IX(II), point 5.4 of the MDR shall apply. The assessment shall evaluate absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions.

For devices or products of metabolism which are systematically absorbed by the human body to achieve their intended purpose, NB 1023 shall request a scientific opinion from the consulted authority on the compliance of the device with the relevant requirements of Annex I to Directive 2001/83/EC.

The consulted body shall provide a scientific opinion within 150 days.

8.2 Validation of the SSCP Safety and Clinical Function Data Summary

The technical documentation for all implantable devices and all Class III devices (except custom-made devices or devices undergoing clinical trials) shall include a Summary of Safety and Clinical Performance (SSCP) prepared by the manufacturer in accordance with Article 32 of the MDR.

The content of the SSCP and its validation process is based on Article 32 of the MDR and MDCG Guideline 2019-9.

The timing of SSCP validation is dependent on the classification of the device under assessment:

- for Class III medical devices and Class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the validation of the SSCP draft shall be performed as part of the review of the documentation submitted with the application;
- for IIb implantable devices not covered by the previous paragraph and for IIa implantable devices intended for placement in teeth according to Annex VIII, Rule 8 of the MDR, at least one SSCP draft shall be validated before the certificate is issued, all other drafts shall be validated at least once during the certificate cycle.

8.3 Evaluation of the regularly updated PSUR safety report

The technical documentation for all Class IIa, IIb and III devices shall include a Periodic Safety Update Report (PSUR) prepared by the manufacturer in accordance with Article 86 of the MDR.

In the case of Class IIa and IIb implantable devices and Class III devices, the results of the PSUR evaluation are entered into the EUDAMED database.

8.4 Review of documentation for systems and procedure packs

Manufacturers – persons who assemble systems or procedure packs of medical devices that are not subsequently sterilised shall fulfil their obligations by drawing up a statement that they have verified the compatibility of the devices and any other products in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions, that they have packaged the system or procedure pack and supplied relevant information to users.

In the case of sterilisation of systems or procedure packs of devices for the purpose of placing them on the market, the persons carrying out such sterilisation shall use one of the procedures set out in Annex IX or the procedure set out in Annex XI, Part A of the MDR. The application of those procedures and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged.

9 Review of quality management system documentation

The technical documentation files also include the QMS documentation.

In the case of conformity assessment based on a quality management system and on assessment of the technical documentation (see Annex IX, point 2 of the MDR) or conformity assessment based on product conformity verification - production quality assurance (see Annex XI, Part A of the MDR), NB 1023 also examines the following information and documents that are part of the application for conformity assessment:

- the name of the manufacturer and the address of his registered place of business and any additional manufacturing sites covered by the quality management system;
- the name of the authorised representative and the address of his/her registered place of business (in the case of an authorised representative lodging the application instead of the manufacturer);
- all relevant information on the device or group of devices covered by the quality management system;
- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system;
- a draft of an EU declaration of conformity (see Article 19 and Annex IV of the MDR) for the device model covered by the conformity assessment procedure;
- documentation concerning the manufacturer's quality management system (see Article 4.2 of EN ISO 13485);
- a documented description of the procedures in place to fulfil the obligations arising from the quality management system and the undertaking by the manufacturer in question to apply those procedures (see clauses 4.2 and 5.1 of EN ISO 13485);
- a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures (see clauses 4.1.4, 4.2, 5.1, 5.4.2, 5.6, 6.1 and 8 of EN ISO 13485);
- the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with vigilance obligations (see Articles 87-92 of the MDR), (see Articles 8.2.1 and 8.5.1 of EN ISO 13485);
- a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with vigilance obligations (see Articles 87-92 of the MDR), including the manufacturer's commitment to use these procedures (see Articles 8.2.1 and 8.5.1 of EN ISO 13485);
- documentation related to the clinical evaluation plan (see Article 7.3.7 of EN ISO 13485);
- a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

The quality management system documentation provided by the manufacturer must contain all the elements, requirements and provisions adopted by the manufacturer for his quality management system, which must be systematically arranged in the form of a quality manual and relevant procedures.

The quality management system documentation shall include:

- in the case of conformity assessment according to Annex IX of the MDR, the requirements set out in Annex IX, point 2.2(a) to (e)

- in the case of conformity assessment according to Annex XI of the MDR, the requirements set out in Annex IX, point 2.2(a), (b), (d) and (e)

The submitted documentation of the quality management system is examined during the technical documentation review phase, the validity and implementation of the defined procedures is then checked during on-site audits.

10 Initial audit

The initial audit of the manufacturer's quality management system is subject to a positive outcome of the technical documentation review and the issue of a technical documentation review report and a clinical evaluation review report, or a favourable opinion of the consulted bodies.

The initial (certification) audit is conducted by a qualified team of auditors approved for the area. The duration and scope of the audit are communicated to the manufacturer via the Audit Plan. The audit shall be carried out at the manufacturer's premises and, if necessary to ensure effective control, at the premises of its suppliers or subcontractors of critical processes.

Critical processes purchased from critical subcontractors include:

- product design and modification;
- determination of material specifications;
- purchase and control of input materials and components;
- the manufacture of a device or parts of a device affecting the safety or functionality of the device;
- assembly of the device;
- primary packaging;
- sterilization;
- software validation;
- testing of the device in the contract laboratory for the purpose of output control and release of products or batches thereof
- marking and labelling of the product (labels).

The purpose of the audit at the premises of the subcontractor and/or supplier is in particular:

- verification of the effectiveness of the manufacturer's control over the subcontractor or supplier to ensure that the required conditions of the product or service purchased are met, regardless of the length of the contractual chain between the supplier or subcontractor and the manufacturer;
- an assessment of the supplier's ability to provide a product or subcontractor's ability to provide a service that consistently meets the manufacturer's specified requirements, including quality requirements.

Supplier/subcontractor audits are conducted as part of the manufacturer's purchasing process audit. The supplier/subcontractor audit assesses the implementation of the requirements placed on the supplier/subcontractor by the manufacturer as specified in the contract between the two parties. The adequacy of this agreement, including its scope, shall be assessed as part of the manufacturer's quality system audit.

Any non-conformity identified in an audit of a supplier/subcontractor is documented as a non-conformity against the manufacturer's quality system.

The outcome of the audit is the "Report from audit of Quality Management System" (RP-19-30-01), which contains recommendations for NB 1023.

11 Decision-making on certification

Once the conclusions of the assessment of the technical and clinical documentation, as well as the results of the certification audit, are available, the project leader will submit the output

documents to the ITC decision council, which will decide whether to issue or refuse the certificate. In case of a positive opinion, a certificate is issued with a maximum validity of 5 years.

12 Post-certification surveillance and monitoring

After the decision to grant certification and the issuance of the first version of the relevant certificate, NB 1023 shall initiate surveillance activities concerning the certified device, its manufacture and the information obtained after placing the device on the market. These include periodic audits, unannounced audits* or short notice audits**, reviews of technical documentation samples for Class IIa and IIb devices, testing of devices, validation of updates to the Summary of Safety and Clinical Performance (SSCP), review of Periodic Safety Update Reports (PSUR), evaluation and disclosure of these reports to competent authorities for implants and Class III devices, checking compliance with UDI requirements, and addressing suggestions from authorities and other subjects regarding product quality and safety.

The general rights and obligations of the manufacturer after granting of the certificate are subject to the general framework agreement GFA-MDR, which is signed before the conformity assessment process starts. The individual surveillance activities carried out in cooperation with the manufacturer are specified in the form of partial contracts issued immediately before the start of the activity, and in the case of an unannounced audit, such audit is carried out at any time within 365 days after the date of conclusion of the partial contract.

* Unannounced audits shall be carried out to check the day-to-day compliance of the manufacturer's procedures and processes with the requirements of the quality management system approved by the notified body NB 1023. The notified body shall carry out random unannounced audits of each certificate holder at least every 5 years (see Annex IX, Chapter I, point 3.4 of the MDR), and the timing of unannounced audits should be unpredictable for the manufacturer (see Annex IX, Chapter I, point 3.4 of the MDR). If devices present a high risk or devices of a given type are frequently non-compliant, or if specific facts lead to suspicion of non-conformity of devices or non-conformity on the part of the manufacturer, then the frequency of unannounced audits is increased to once every 2 years. NB 1023 shall carry out unannounced audits at the prescribed frequency for the period of the validity of the certificates issued in accordance with the established long-term audit programme.

** Audits announced at short notice (extraordinary audits) are carried out on the basis of information and suggestions received from the manufacturer, users or competent authorities, where it is necessary for this information to be verified on site at the manufacturer. These include:

- information on the occurrence of a serious incident; device problem - (malfunction, deterioration of function, failure) of the device that occurred after its placing on the market (e.g. PMCF or post-market surveillance); health effects - clinical signs and symptoms or conditions of the affected person that occur as a result of a serious incident with the device placed on the market
- changes in production process/technology;
- change of production site;
- change of critical supplier;
- changes affecting the quality system, production or product assurance;
- complaints and other suggestions from users or operators.

This audit focuses only on the area to be verified. The interval between the notification and the audit shall allow the manufacturer to prepare the required data and information, but its length shall not allow the rework of a non-conforming QMS. Normally this interval is no longer than 7 days.

13 Certificate validity confirmation and status changes

Surveillance activities carried out at the place of manufacture and/or in cooperation with the manufacturer are concluded either by confirmation of the validity of the certificate or by a change in the status of the certificate (suspension, renewal or withdrawal of the certificate, limitation of the scope of the MD covered by the certificate), possibly linked to specified conditions, including the imposition of time-bound measures on the manufacturer.

14 Approval of changes

The manufacturer shall, in accordance with Annex IX(I), point 2.4, inform the notified body in advance of any intention to change substantially the quality management system or the range of devices covered by the certificate. According to Annex IX(II), point 4.10, the manufacturer shall also inform the notified body in advance of any intention to modify the approved MD in a way that could affect the safety and performance of the device or the conditions prescribed for use of the device.

The manufacturer's obligations are enshrined in the GFA-MDR contract, where the manufacturer undertakes to notify ITC of its intention to make any changes to the system, the scope of the devices covered by the certificate and the design of the MD. ITC will then decide whether the changes are significant or insignificant and whether the change should be approved by issuing a supplement to the EU Quality Management System Certificate, a supplement to the EU Quality Assurance Certificate or to the EU Technical Documentation Assessment Certificate.

15 Recertification

Recertification (the validity of the certificate can be repeatedly extended for further periods not exceeding an interval of 5 years, see Article 56(2) of the MDR) must be requested by the client in the same way as for the initial conformity assessment, but the application must be made at least 9 months before the expiry of the certificate to be replaced by a new certificate. This period shall be extended to 12 months in the case of devices containing a medicinal substance, devices composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body, Class IIb active devices for the administration/removal of medicinal products and Class III implantable devices.

In the case of a positive certification decision, the certificate shall not normally be assigned a new code number, but the original certificate code number shall be used, distinguished by a version number. The term 'Recertification' is then indicated in the certificate history section in relation to this version.

16 Transfer of certificates between notified bodies

The transfer of a certificate between notified bodies may occur in two cases, namely

- change of notified body at the initiative of a manufacturer who has decided to terminate his contract with a notified body (Article 58 MDR - voluntary change of notified body)
- restriction, suspension or withdrawal of the designation of the notified body (Article 46 MDR - changes to designation and notification)

In both of the above situations, a tripartite contract is required where the parties to the contract are the two notified bodies (the withdrawing and the incoming) and the manufacturer requesting the transfer. From the date specified in the tripartite contract, the incoming notified body takes over responsibility and carries out all surveillance and monitoring activities.

17 Attachments

Annex 1 - Scheme of the certification process

Annex 1 Diagram of the certification process