Summary of changes

- The validity of certificates and the period for carrying out unannounced audits changed to five years.
- The time that guarantees auditor's independence is reduced to three years
- Changed deadlines for the implementation of the following procedures: submission of technical documentation in a sampling procedure, closing of a procedure in case corrective actions are not implemented within 18 months
  Changed procedure for notification of changes

1 Introduction

This publication is intended for manufacturers and suppliers of medical devices who want to get an EC Certificate of Conformity according to the directive concerning medical devices (MDD 93/42/EEC). The publication explains the conditions for certification and illustrates the entire procedure, from the application for certification to the issue of an EC Certificate of Conformity. It also contains information on certificate maintenance, its withdrawal or cancellation, on confidentiality and handling of complaints.

SIQ operates medical device certification as a “third party”, i.e. an institution independent of influences from both - manufacturers and suppliers as well as customers and users. SIQ’s independence is ensured by its status (SIQ is registered as a not-for-profit institute) and by its appropriate corporate management and certification management. Certification activities are supervised by the Board of Certification Body representing the interests of public, commerce and industry associations, as well as interests of SIQ’s services customers.

The aim of the certification procedure is to examine and assess the compliance of a medical device with the relevant requirements applicable to it and to issue an EC Certificate of Conformity in case of compliance. The decision on the issuance of the certificate is in responsibility of the Notified Body Commission.

2 Basic principles of operation

2.1 Certification policy

- SIQ offers its certification services to everyone who shows interest.
- SIQ, i.e. its bodies and its personnel, treats and will treat equally all the applicants, irrespective of their geographical position, size, turnover, type of business, etc., and without neglecting anyone in any way.
- SIQ maintains its international recognition in the field of certification. SIQ endeavours to achieve recognition of its certificates of conformity in Slovenia and abroad.
- SIQ ensures impartiality and an organizational structure provides that the personnel, in its everyday activities, are not under influence of anybody having a direct commercial interest in certification and that no conflict of interest will arise. SIQ has established mechanisms to resolve potential conflicts of interest.
- Certification activities are performed in accordance with the requirements of the ISO/IEC 17021 and ISO/IEC 17065 standards, as well as MDD 93/42/EEC directive, including related, valid legislation, and MEDDEV and NBOG guidelines and instructions.
- SIQ fees for services are based on the SIQ Council's principles for formulating fees.
- The fees for services are formulated so as to enable SIQ to cover its operating costs and investments in technical and expert development of the activity.
- SIQ also ensures its impartiality in providing its services by refraining from providing advice in establishment and/or maintenance of the conformity of management systems and medical devices with reference documents.

2.2 Rules for certification personnel

The certification personnel, auditors and experts follow relevant Slovene, European and/or international standards, as well as regulations, procedures and instructions of SIQ, which regulate the work in this area.

The certification personnel, auditors and experts are guided by the following principles and bind themselves:

- To act in a confidential and impartial manner in relation to SIQ, as well as in relation to any other organization involved in the assessment and certification activities they perform themselves or are performed by the staff for which they are in charge;
- To inform SIQ of any connection with an organization in which they are about to perform an assessment and certification before taking on any function in relation to the assessment and certification in the organization;
- Not to have performed any consulting activities in the organization in three consecutive years prior to the assessment and certification;
- Not to accept from this organization any order for work in the field of management systems or related to medical devices in period of two years after the conclusion of the assessment and certification;
- Not to advertise their co-operation with SIQ while providing consultancy or raise the organization's expectations to be treated differently or favourably during the audit due to their co-operation with SIQ;
- Not to accept from any organization in which they perform an assessment and certification, or from its representatives, or from any other person who could benefit in any way, any hints, presents, orders, discount, or any other advantage, as well as not to allow any of the personnel for whom they are responsible to do so;
- Not to disclose, partially or entirely, any findings of the audit team in which they took part or for which they are responsible, or any information acquired in the course of an assessment and certification procedure to a third party, unless they are authorized to do so in writing by the auditee and by SIQ;
- Not to adversely affect the reputation or interests of SIQ or of the auditee;
- To co-operate in any investigation in the case of an infringement of the above principles;
- To act in conformance with the Code of Ethics of SIQ.

2.3 Confidentiality

SIQ binds itself to observe all information and data on the applicant as confidential and to use them exclusively for performance of the procedure.

The information on the certification procedure and related activities are regarded as business secret of the applicant and SIQ, with the exception of the information on the award or cancellation of a certificate, information included in a report to the Board of Certification in cases of doubt related to the certification, as well as information given at the disposal to accreditation/authority bodies during audits.

The applicant recognizes that SIQ has exclusive rights in relation to all documents SIQ has submitted to the applicant and binds him/herself not to copy or multiply these documents in any way, or give them at disposal to any other third party.

3 Certification Procedure in General

3.1 Basic conditions for product certification

- The applicant for certification can only be a company/institution registered in accordance with current regulations.
- A medical device or a group of medical devices for which an application for an EC Certificate is submitted shall be clearly and unambiguously identified.
- An agreement shall be reached with the applicant in regard to the conformity assessment procedure as well as standards, regulations and specifications that shall provide basis for the review and assessment of conformity.
- The Application and the entire documentation of the applicant relevant for the certification procedure may be in Slovenian, English, Serbian or Croatian language. The technical documentation also has to be submitted in Slovenian, English, Serbian or Croatian language. In case the Notified Body disposes with a competent auditor, parts of the technical documentation can be submitted in German or Russian language (see part B of technical documentation from NB-MED/2.5.1./Rec5).

3.2 Activities

3.2.1 Certification procedure in case of conformity assessment procedure according to Annex II, Annex V, Annex VI

a) Preliminary interview with the applicant
b) Quotation
c) Application
d) Organization of the certification procedure
e) Submission of technical documentation for medical device (Annex VII), technical documentation assessment
f) Certification audit (Annexes II, V, VI)
g) Conformity assessment of reports, documentation and, where relevant, samples
h) Decision on granting an EC Certificate
i) Informing of JAZMP (Agency for Medicinal Products and Medical Devices of the Republic of Slovenia)
j) Surveillance and recertification audits (Annexes II, V, VI)
k) Unannounced audits
l) Procedure for review of vigilance information
m) Decision on cancellation, withdrawal, suspension of Certificates
n) Settlement of financial obligations

3.2.2 Conformity assessment procedure according to Annex III and Annex IV for active medical devices

a) Preliminary interview with the applicant
b) Quotation
c) Application
d) Organization of the certification procedure
e) Submission of technical documentation for medical device (Annex VII)
f) Selection of conformity assessment procedure:
   - In case of the selection of conformity assessment procedure according to Annex IV (except for class IIb and class III)

EC Verification (Annex IV)

- In case of the selection of conformity assessment procedure according to **Annex III + Annex IV**

Product testing/certification – *EC type examination* (*Annex III)*
Conformity assessment of product technical documentation – EC type examination (Annex III)
EC Verification (Annex IV)

- In case of the selection of conformity assessment procedure according to **Annex III + Annex V** or **Annex VI** (IIb class only)

Product testing/certification – *EC type examination* (*Annex III)*
Conformity assessment of product technical documentation – EC type examination (Annex III)
Certification audit (Annexes V or VI - except for class III of medical devices)

g) Assessment of adequacy of reports, documentation and, where relevant, samples
h) Decision on granting an EC Certificate
i) Reporting to JAZMP (Agency for Medicinal Products and Medical Devices of the Republic Slovenia)
j) Surveillance and recertification audits (Annexes II, V, VI)
k) Unannounced audits
l) Procedure for review of vigilance information
m) Decision on cancellation, withdrawal, suspension of Certificates
n) Settlements of financial obligations

Certification procedures may differ with regard to the class of a medical device. However, some activities, in particular in the marketing and sales phases, are common to all procedures.

3.3 Details of certification procedure activities

3.3.1 Preliminary interview

The purpose of the preliminary interview is to inform the organization at the beginning of the certification process about all certification aspects concerning the CE marking of a medical device and about specific procedures, in particular about legal requirements for manufacturers of medical devices and medical devices itself (https://ec.europa.eu/growth/sectors/medical-devices/guidance_en). The interested party provides SIQ with data needed to draw up a quotation by completing the Questionnaires: *Questionnaire on manufacturer, products and assessment route in accordance with the medical device directive 93/42/EEC – MDD* about medical devices *(AN036E_MDD)* and *Questionnaire on legal entity (AN036E)* (in continuation the Questionnaires).

3.3.2 Quotation

On the basis of a completed Questionnaires, SIQ checks a MD Code, MD scope expressions and classification of a medical device, a conformity assessment procedure and the scope of service, and draws up a quotation covering the costs of the obtaining and maintenance of a certificate, including certification fees. The quotation, including the information on the certification procedure and requirements for the award and maintenance of the certificate, is sent to the interested party. The quotation is not binding.

3.3.3 Application

On the basis of the quotation, the interested party applies for certification by completing the form Application for certification of medical devices according to the 93/42/EEC MDD* Directive concerning medical devices (in continuation the Application), thus becoming the applicant. The Application has the validity of a contract. Upon request by the applicant, a separate contract may be signed. By signing the Application or a contract, the applicants confirm that they are

familiar with the procedure and the terms and conditions for the award and maintenance of a certificate.

After signing the Application or a contract, applicants can withdraw from the certification procedure. In this case, they shall cover all expenses that have arisen from the beginning of procedure.

3.3.4 Organization of the certification procedure

SIQ appoints an audit team to carry out a certification procedure with regard to the selected conformity assessment procedure and the type of medical device (MD Code and required specific knowledge) and informs the applicant of the appointed team and audit date. In the case the applicant disagrees with the appointed auditor(s), they shall inform SIQ of their disagreement and justify their decision. If their disagreement is justified, SIQ appoints a new auditor/s. Conformity assessment procedures are carried out in line with relevant annex(es) to the MDD 93/42/EEC Directive, depending on the class of a particular medical device. These procedures are illustrated in chapter Flow charts.

The audit team leader makes arrangements with the applicant about the first visit, as a rule, to the applicant's location, in line with the agreed in the quotation (e.g. a Certification audit – stage 1)

3.3.5 Submission of technical documentation for a medical device

The organization submits technical documentation for a medical device by post, in printed or electronic form (CD, USB key). The technical documentation audit is conducted by the audit team.

The audit can be conducted off-site – usually at the auditor's site. At the organization's special request, the technical documentation audit can be performed on the applicant's site.

During an audit according to the NBOG BPG 2009-4 document (Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis), only a representative sample of product technical files is assessed. Within 3 years up to a recertification audit, every technical file shall be assessed. Afterwards, the sampling starts anew.

SIQ submits a written report on audit findings to the applicant, who has to eliminate detected noncompliance / nonconformities (major and minor) prior the next step of the procedure. Implemented actions are reviewed during the post-audit and relevant report is submitted.

During the review of technical file audit report, competent personnel/auditor, which review audit report, has the authority to define new findings (recommendations, minor and major nonconformities) if deviations from the audit procedure have been discovered. Findings are written in the audit report.

The deadline for reporting is maximum 6 months. In case the nonconformities are not eliminated within 18 months, the certification procedure is, as a general rule, ended. For eventual continuation, the organization shall start the certification procedure from scratch.

After the audit, the certificate holder is obliged to submit a written report on other matters, specified in the audit report, within the time frame specified in the audit report.

3.3.6 Product testing/certification – EC type examination (annex III)

Upon request by certification personnel, a type testing is performed on a representative sample against relevant standards and Rules on product certification (CR201) in SIQ testing

laboratories. The applicant is informed of the results of the type test and is given the possibility to eliminate possible nonconformities/noncompliance.

3.3.7 Conformity assessment of product technical documentation – EC type examination (annex III)

The conformity of product technical documentation is assessed in line with the requirements of Annex III. The assessment supplements a type examination of a sample in line with Annex III. If all the requirements are met, SIQ issues a verification report.

3.3.8 EC Verification (Annex IV)

Upon request by certification personnel, EC verification of each device or of their statistically selected number from a series is performed in SIQ testing laboratories, in line with the requirements of Annex IV. The evaluation includes a review of product technical documentation. If all requirements are met, SIQ issues a verification report.

3.3.9 Certification audit (Annexes II, V, VI)

The purpose of the certification audit is to evaluate whether the procedures are documented, established, implemented and effective, in line with the requirements of the Medical device directive 93/42/EEC. The audit is conducted according to the audit plan prepared by a lead auditor after the technical documentation audit.

Upon completion of the audit the auditors orally inform the representatives of the applicant of their audit findings that will be included in a written report.

If non-conformities are not detected during the audit, the report, including any other necessary documentation and information, is handed over to certification personnel for review. Certification personnel have the authority to define new findings (recommendations, minor and major nonconformities) if deviations from the auditing process are identified. If recommendations are given or there are any other requirements relating to the audited management systems, the certificate holder shall act accordingly and submit to SIQ a report on the taking into account of those recommendations and requirements within six months after the audit at the latest.

If non-conformities (either minor or major) with the requirements of the selected standard or some other reference document were identified during the audit, the requirements for actions to be implemented by the applicant prior to the conformity assessment of reports are given in the conclusion of the audit report. The deadline is six months maximum. Implemented actions are reviewed during a post-audit. A post-audit report is drawn up and submitted to certification personnel for review along with other necessary documentation and information.

3.3.10 Conformity assessment of reports, documentation and, where relevant, samples

Certification personnel review the following documentation:

- Audit reports, where non-conformities have already been resolved (Annexes II, V and VI of the MDD 93/42/EEC);
- Test reports / Certificates of conformity and Conformity reports concerning documentation (Annex III);
- Inspection reports – EC verification (Annex IV);
- Other documentation (e.g. quality manual, technical documentation for products).

If these documents are found compliant, a proposal for issuing a certificate is submitted to a Notified Body Commission.

3.3.11 Decision on granting an EC certificate

If the Notified Body Commission concludes that all requirements have been met, it adopts a decision on the award of an EC Certificate. Based on the Notified Bodies Commission's decision SIQ issues a certificate and adds the certificate holder to the List of EC Certificate holders published on www.siq.si.

Once the EC Certificate is issued, the EC Certificate holder affixes the CE mark along with the number of the Notified Body (SIQ's No. is **1304**) to its product in line with the provisions of the MDD93/42/EEC Directive.

3.3.12 Informing of JAZMP

SIQ notifies the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) of the issuing of an EC Certificate.

Besides that, SIQ reports to the JAZMP in the following cases:

- When it finds out that the CE mark has been affixed to a product incorrectly, i.e. the CE mark has been affixed to a product that either does not comply with legal requirements (Directive concerning medical devices) or is not covered by these legal requirements;
- Change, withdrawal, suspension or reduction of EC Certificates;
- When a manufacturer did not ensure or no longer ensures compliance with relevant requirements of the MD Directive.
- When during the audit (Annexes II, V and VI) we identify the nonconformity related to vigilance procedure, e.g. when producer has not submitted the report to JAZMP, in case when producer does not agree with the nonconformity.

3.3.13 Surveillance and recertification audits (Annexes II, V, VI)

At surveillance audits, SIQ checks whether a CE certificate holder meets the requirements of the Medical Device Directive 93/42/EEC. They are carried out once annually, the first one twelve months after the certification audit and the others at the same time intervals. The assessment of technical documentation is planned and performed in accordance with the sampling plan and can be carried out together with the surveillance audit or separately. The organization shall submit the technical documentation within 30 days from the receipt of the request for submitting of documentation from SIQ.

After the audit, the auditors orally inform the representatives of the certificate holder about the audit findings that will be included in a written report. In the conclusion of the report, the auditors may state requirements to be met by the certificate holder.

If non-conformities (either minor or major) are identified during a surveillance audit, the certificate holder shall resolve them and shall submit a relevant written report, along with relevant evidence, to SIQ within one month (for major nonconformities) or three months (for minor nonconformities) at the latest. After the submission of evidence by the certificate holder within a specified period, an additional audit is performed. SIQ performs post audit within 6 weeks from receipt of the evidence.

In the event of any changes that might affect the performance or functioning of the medical device, SIQ defines the necessary further activities, in order to verify if the device still complies with the requirements of directive 93/42/EEC. The compliance with the mentioned requirements can be checked by the assessment of technical documentation and, if necessary, by a post audit at the location of the organization, for which SIQ issues a report. If no nonconformities are detected during the audits, a new version of EC Certificate is issued to the holder, where

necessary. If nonconformities are detected, the certificate holder shall first comply with the requirements listed in the conclusion of the audit report before a new version of EC Certificate is issued. The compliance with these requirements is determined during a post audit, for which SIQ issues an audit report. By receiving a new issue of a certificate, the holder may place its device on the market. In case no additional activities are required and a new issue of an EC Certificate is not required, SIQ informs the certificate holder that the device can be placed on the market.

Every fifth year after the certification audit, a recertification audit is performed to provide comprehensive evaluation of a five-year performance of the management system and its effectiveness, to reassess technical documentation and to assess the adequacy of the audits conducted in that period. The organization shall submit the technical documentation for assessment 3 months before the planned term of a recertification audit, in order to be able to assess the documentation in due time up to the recertification audit. Prior to a recertification audit, SIQ checks the audit scope and, where appropriate (in the case of major changes in the organization), defines a new scope of audit activities and a new fee. The audit scope of the technical documentation is assessed in regard to changes of the product.

If non-conformities are not found during a recertification audit, a new issue of a CE certificate is granted to the certificate holder. If non-conformities are found during a recertification audit, the certificate holder shall meet the requirements given in the conclusion of the audit report before a new issue of the certificate can be granted. The compliance with these requirements is assessed during a post-audit for which a post-audit report is issued.

After each audit, the certificate holder shall submit to SIQ a written report on other issues identified in the audit report within the timeframe defined in the conclusion of the audit report.

3.3.14 Unannounced audits

SIQ performs unannounced audits to verify that the certificate holder maintains and renews the quality Management System when the audit is not pre-announced. Unannounced audit is carried out at any time at least once every five years, except for MD Class III, where the assessment is carried out at least once every two years.

Unannounced audits are carried out more often than previously noted in the case of:

- medical devices of higher risk classes,

- medical devices that are often inconsistent,

- suspicion that the manufacturer or its medical device no longer meets the requirements of the MDD Directive 93/42 / EEC.

Unannounced audit can be conducted at the site of the certificate holder, its subcontractor or critical supplier. Auditor's identification is confirmed with the letter – a notice of the notified body for the unannounced audit, which the auditor has to bring to the audit.

SIQ issues an audit report regarding the unannounced audit. In case of identified nonconformities, deadlines for their resolving are set. The adequacy of the implemented corrective actions is verified with the post-audit, conducted by the lead auditor. A pertinent written report is issued. All the expenses arising from the activities following the detected non-compliance are covered by the certificate holder, according to the valid SIQ schedule of fees.

3.3.15 Procedure of review of vigilance information

SIQ must verify the information from the post-production phase and to take action in case of suspicion that the manufacturer doesn't assure adequacy to the requirements of 93/42/EGS directive on medical devices. The manufacturer must take corrective actions and report to SIQ.

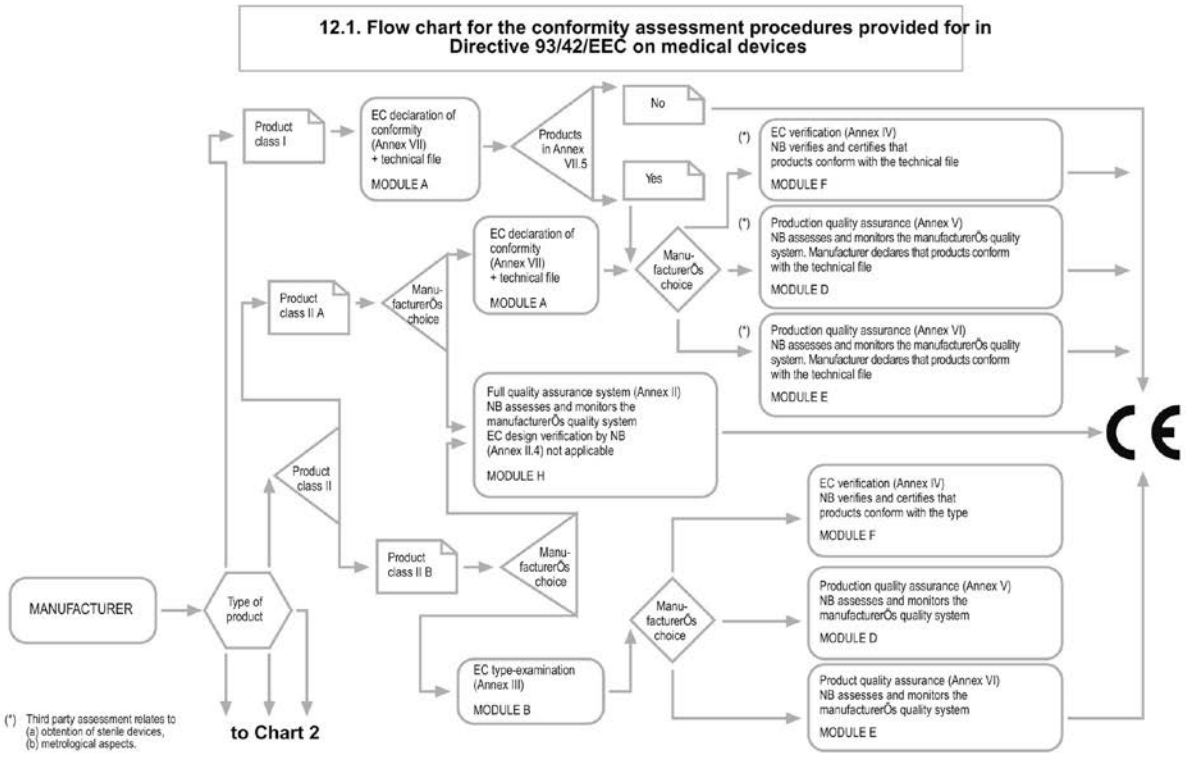
SIQ can conduct post- or unannounced audit or order the review of selected products, processes or quality management system elements on the next audit. SIQ can conduct another review of the certificate issuance process and if necessary, initiate cancellation, suspension or the reduction of the certificate.

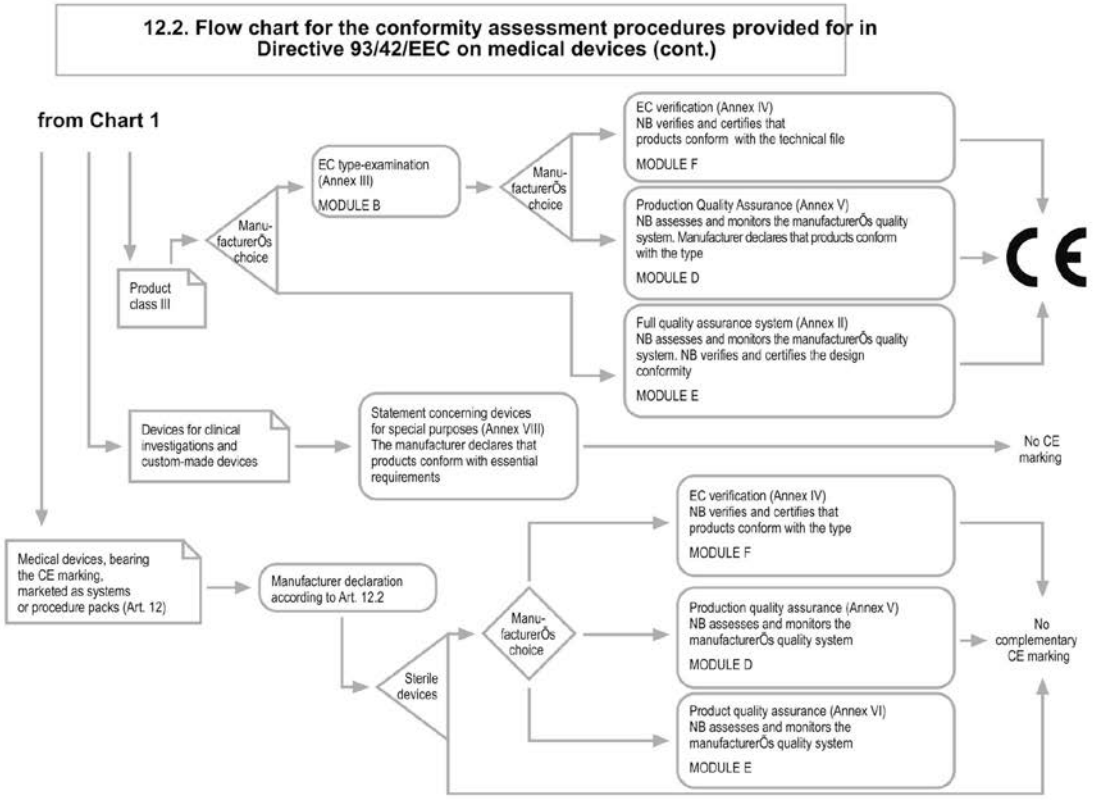
Stated activities have to be carried out by SIQ also at the request of JAZMP or other national institution, to which results have to be reported.

3.4 Flow charts

The following flow charts illustrate certification procedures with regard to a class of a medical device.

According to the current directive 2007/47/EC:
- A procedure according to Annex II also may be selected for medical devices of class I defined in item VII.5 of annex VII; and
- Only a procedure according to annexes II and V may be selected for medical devices representing a set or system and which are sterilized.





consequence.

3.6 Monitoring of changes to standards and regulations

In cases of changes to the Medical Devices Directive, related regulations and guidelines, or when a medical device no longer meets relevant requirements, SIQ sets a time frame within which a holder of a certificate or a license shall bring its product in compliance with the new requirements.

4 Misuse of an EC Certificate or CE Mark

SIQ supervises the use of certificates and of the CE marking. If SIQ finds out that a certificate holder uses the CE marking incorrectly or that he/she uses a certificate or CE marking in relation to medical devices that have not been certified, it takes corrective actions or, if necessary, even legal measures. Misuse of a certificate or a certification mark may have a withdrawal or cancellation of a certificate as a consequence.

5 Withdrawal/Cancellation and suspension of EC Certificates or Licenses

As a rule, the validity of an EC Certificate for medical devices is five years.

In specific cases a cancellation of an EC Certificate is required by the relevant legislation. The Notified Body Commission may withdraw or cancel a certificate issued for a specific medical device if during the surveillance SIQ finds out that there has been a misuse of the certification mark or any other breach of the rules set in this document or other documents which define certification procedures in detail.

In such cases the Certification Commission informs a holder of a certificate and a license that after a certain period of time (usually from 30 to 60 days) it will cancel a certificate or a license. During this time a holder of a certificate and a license shall eliminate detected non-conformities and provide the Certification Commission with relevant evidence, or shall file an appeal/complaint, which may be accepted or rejected by the Appeals Commission.

A certificate is cancelled also in the following cases:

- If a product has been removed from production;
- Due to the certificate holder's bankruptcy or termination of operations;
- Incomplete or false information given during or in relation to audits (Annexes II, III, IV, V, VI, VII);
- Concealment of significant changes in the management system or the company status (Annexes II, V, VI);
- Failure to comply with the requirements given in an audit report and during the review of vigilance information (Annexes II, III, IV, V, VI, VII);
- Failure to fulfil financial obligations toward SIQ;
- A written requirement of a certificate holder;
- Failure to conduct a recertification audit before the expiry date of the certificate or failure to conduct a surveillance audit within 15 months from the date of the last conducted audit (Annexes II, V, VI),
- In case that producer does not allow to the audit team to conduct non-announced audit.

The cancellation procedure of the document is triggered, when the organization does not send a written report with appropriate evidence of the elimination of the non-conformities given in the audit report, within one month (in case of major nonconformity) or three months (in case of minor nonconformity), or if any other violations and irregularities, stated in previous paragraphs, are detected. Since an organization with such act gives rise to a suspicion of non-compliance with the management system requirements, the product manager may decide to initiate the procedure for carrying out an unannounced audit.

In the event, the organization doesn't comply with the requirements stated in the conclusion of the audit report within one month (for major nonconformity) or three months (for minor nonconformity) or in case of the misuse (misleading use) of EC labelling or incorrect (misleading) references to EC certificate, the notified body commission may initiate the procedure for temporary withdrawal/ suspension of the certificate. When there is no high risk of public health, the product manager shall, prior to submitting a proposal for the temporary withdrawal of the certificate, inform the holder of the certificate and invite him/her to give an explanation/defence within eight working days.

The duration of the temporary withdrawal is not more than 9 months and it is cancelled when the post-audit is successfully conducted. After the cancellation of temporary withdrawal, audits are conducted according to the audit program, as it was set prior the temporary withdrawal of the certificate. If the post-audit is not conducted during the period of temporary withdrawal, the cancellation of the certificate is permanent.

In the case of suspension, limitation, cancellation or expiry of documents issued by a notified body, the holder of a certificate must no longer place on the market products labelled with the CE mark, he/she should remove the mark from the product and other places/documents from which it was used.

A certificate holder has the right to file an appeal against the decision of the Notified Body Commission with the Appeals Commission of the Board of Certification Body.

6 Obligations of Applicants and/or Certificate Holders

6.1 Availability of information

The applicant/ holder of a certificate shall immediately inform SIQ of any changes which are in any way related to the certified medical device, e.g. changes to the medical device, changes in ownership, name or address of the company, the status of the company (e.g. bankruptcy, insolvency), and/or changes in the organization of the company (number of employees, additional activities, additional locations etc.). The applicant/holder of the certificate shall inform SIQ of any significant changes that might affect the characteristics and performance of a medical device, before placing it on the market. On the basis of the notification, SIQ determines the necessary further activities / audits in order to verify continued compliance of the device with the requirements of directive 93/42/EEC and informs the applicant/holder of the results. The applicant/holder can place the device on the market after the new issue of the certificate has been granted, or when SIQ notifies the certificate holder that the device can be placed on the market.

Prior to a surveillance or recertification audit, the certificate holder shall inform SIQ of the changes in the management system and relevant documentation. Based on the changes, SIQ determines a new scope of activities and a new fee.

Prior to the audit (Annexes II, V, VI), the applicant/certificate holder shall inform the auditors of any issue that can be of importance to the audit. They shall facilitate the audit by ensuring that the responsible personnel are available to the auditors during the audit and to provide them with the necessary information. They shall prepare the required documentation and any other evidence to ensure unimpeded auditing.

The applicant/holder of a certificate shall provide the management system documentation required for the performance of the certification process activities upon each request by SIQ.

The applicant/certificate holder shall keep records of complaints, visits by the authorities and feed-back information from a post-production phase, as well as records of corrective actions.

The auditors shall have access to these records when conducting the audit. The applicant/certificate holder shall also keep previous versions of the manual as well as responses to audit findings that were submitted to SIQ to prove that the findings had been taken into consideration or nonconformities had been resolved.

The applicant/certificate holder shall enable the auditors to conduct the audit in the organizations providing any outsourced process that has impact on the product's compliance with the relevant requirements or on the effectiveness of the audited management system.

7 Handling of Complaints and Appeals and the Responsibility of SIQ

7.1 Handling of complaints and appeals

The applicant/certificate holder can file a complaint against the work of SIQ or an appeal against the decisions of the MDD Notified Body Commission.

Complaints against the work of SIQ are examined at first instance by the MSA director who informs the complainant of the decision in writing. The complainant can file an appeal against the MSA director's decision to the Appeals Commission which is a body of second instance. Its decisions are final.

Complaints against the certificate holder's management system can be filed in writing by anybody and are subject to the same procedure as complaints against the work of SIQ. The complainant and the certificate holder are kept informed of the on-going procedure and its outcome.

An appeal against the MDD Notified Body Commission's decision shall be filed by the appellant in writing within 15 days after the receipt of the decision. The appellant shall document the appeal appropriately. The appeal is examined by the Appeals Commission. Its decisions are final.

If a complaint or an appeal is justified, the MSA director shall ensure that the causes of the complaint/appeal are eliminated.

7.2 Responsibility of SIQ

SIQ shall not assume a certificate holder's liability for the product/service or property damage.

SIQ is not liable and does not assume liability for damages due to activities and actions not carried out by the certificate holder and leading to the suspension, limitation or cancellation of the certificate.

SIQ holds a professional liability insurance policy, covering any damage that may occur as the consequence of faults, omissions or breaches while performing the registered activity either by its employees or its subcontractors. The insurance amount is 1.400.000 EUR.

8 Final Provisions

A valid issue of this publication for informing about the procedures related to certification of medical device is sent to the organization which is interested, together with a quotation for the provision of certification services.

SIQ reserves the right to modify Info for Applicants due to changes in the Medical Device Directive or guides and guidelines applicable to notified bodies for medical devices, as well as upon request by bodies supervising the work of SIQ (notification bodies), and due to changes in the organization or operation of SIQ. The applicant/certificate holder is requested to check for changes in the procedures for certification of medical devices, published on www.siq.si, prior to next step in the process. If the applicant/certificate holder raises no objections against the changes, it shall be deemed that he/she agrees with them.

For settling other disputes, the District Court of Ljubljana is competent, unless agreed otherwise by a contract. The valid legislation of the Republic of Slovenia is applicable in all relations.