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Summary of changes:

- In chapter 3.4.1 added: In the case of an organization, where independence could be threatened due to a connection with the founders of SIQ, it is necessary to investigate the connections beforehand and confirm the independence before proceeding with the process.
- In chapters 3.3.2 and 3.4.5 the precheck of technical documentation is added.
- In chapter 3.4.9 the repeat of certification audit was added.

1 Introduction

This document is intended for manufacturers of medical devices who want to obtain an EU Certificate of Conformity according to Regulation (EU) 2017/745 on medical devices (hereinafter 'the MDR'), as well as for distributors and importers carrying out activities referred to in Article 16(2) a) and/or b) of the MDR and wishing to obtain a certificate for the quality management system in accordance with Article 16(4) of the MDR. This information document explains the conditions for certification and presents the entire procedure, from submitting the application for certification to the issuance of an EU Certificate of Conformity. The document also contains information on certificate maintenance and certificate suspension or withdrawal , as well as on confidentiality and the handling of complaints.

SIQ performs medical device certification as a “third party”, i.e., an institution independent of influences from manufacturers and suppliers, on the one hand, and customers and users, on the other. 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, commercial and industry associations, as well as the interests of customers using SIQ’s services.

The aim of the certification procedure is to examine and assess the compliance of a medical device with the relevant requirements, and to issue an EU Certificate of Conformity in the case of compliance. In the case of a certification procedure related to a quality management system with distributors and importers, the aim is to issue a quality management system certificate according to Article 16(4) of the MDR. The decision on the issuance of a certificate falls within the remit of the Notified Body Commission.

2 Basic principles of operation

2.1 Policy of the Notified Body for Medical Devices

The Policy of the Notified Body for Medical Devices presents and summarises all relevant parts of SIQ Ljubljana policies relating to the policy of the notified body for medical devices under Regulation (EU) 2017/745, i.e., Policy on governance and organisation, Certification policy, and the principles of independence, impartiality and integrity:

SIQ provides its services as a Notified Body to any interested party.

SIQ – i.e., its bodies and personnel – provides and will continue to provide equal treatment of all clients ordering its services, irrespective of their location, size, turnover, type of business, etc., without discriminating against anyone in any way.

SIQ maintains its international image and reputation in the field of certification. SIQ seeks to ensure recognition of its certificates of conformity in Slovenia and abroad.

SIQ ensures independence, impartiality and an organisational structure that guarantees that, in their everyday activities, its personnel are not influenced by anyone having a direct commercial interest in the certification and that no conflict of interest will arise. SIQ has established mechanisms to resolve potential conflicts of interest.

Conformity assessment activities are performed in accordance with the requirements of Regulation (EU) 2017/745 (MDR), including applicable relevant valid legislation and MDCG, MEDDEV and NBOG (in the parts where they do not contradict the MDR) guidance and instructions.

SIQ conducts operational activities according to the documented procedures outlined in the quality management system documents for individual areas of certification and in accordance with other quality management system documentation.

SIQ's fees for services are based on the SIQ Council's pricing principles.
The fees for services are formulated so as to enable SIQ to cover its operating costs and its investments in the technical and professional development of its activities.

SIQ has established and maintains an administrative structure and organisation, as well as processes and procedures, that ensure that no organisational unit engages in activities that could undermine confidence in the integrity of the abilities, impartiality, decision-making and operation of SIQ. SIQ also ensures its impartiality in providing its services by:

- not carrying out any activities relating to medical device development, not being a manufacturer, supplier, purchaser, installer, owner or maintainer of medical devices, and/or not participating in such activities, not being an authorised representative of any of the above and not representing any party engaged in these activities,
- refraining from providing consultation services with regard to the establishment and/or maintenance of the conformity of quality management systems and medical devices with reference documents for any manufacturer, its authorised representative, supplier or commercial competitor, and not being linked to any organisation that itself provides consultancy services.

2.2 Rules for certification personnel

Certification personnel, auditors and experts of the Notified Body follow the relevant Slovenian, European and/or international standards, the requirements of international schemes and directives, regulations and rules, and the requirements of applicable legislation, as well as SIQ's rules, procedures and instructions regulating work in this area.

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 organisation involved in assessment and certification activities performed themselves or by the staff for whom they are responsible;
- to inform SIQ of any connection with the organisation in which they are about to perform an assessment and certification, and/or of any other risks that could compromise their independent judgement or integrity, before taking on any function related to the assessment and certification of the organisation;
- to inform SIQ of involvement in the design of particular medical device, as the nomination for technical documentation assessment of this particular medical device of particular manufacturer is not allowed in the future;
- to declare not to have performed any consultancy activities for the organisation, its authorised representative or commercial competitor with regard to the design, construction, marketing or maintenance of the devices or procedures that are to be assessed, and not to have provided any other services that could jeopardise their independence, impartiality or objectivity in the three consecutive years prior to the assessment and certification;
- not to accept from the organisation in which they are about to perform an assessment and certification any order for work in the field of quality management systems or related to medical devices for a period of two years after the conclusion of the assessment and certification;
- not to advertise their cooperation with SIQ while providing any consultancy services or to give rise to expectations in organisations that they will be treated differently or favourably during the audit due to their cooperation with SIQ;

- not to accept from any organisation 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, nor 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 have participated 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 authorised 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 cooperate 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 regard all information and data on the applicant as confidential and to use such information and data exclusively for the performance of the procedure.

Information on the certification procedure and related activities is regarded as a business secret of the applicant and SIQ, with the exception of information on the awarding or temporary suspension, restriction or withdrawal of a certificate, information included in a report to the Board of the Certification Body in cases of any doubts related to the certification, and information made available to accreditation/notification bodies during audits.

The applicant recognises that SIQ has exclusive rights in relation to all documents that SIQ submits to the applicant and binds itself not to copy or multiply such documents in any way, or make them available to any other third party.

3 Certification procedure in general

3.1 Basic conditions for device certification

- The applicant for certification can only be a natural or legal person registered in accordance with current regulations.
- The medical device or a group of medical devices for which an application for an EU Certificate is submitted shall be clearly and unambiguously identified.
- An agreement shall be reached with the applicant with regard to the conformity assessment procedure as well as the standards, regulations and specifications that shall form the basis for the review and assessment of conformity.
- The application and the entire documentation of the applicant relevant to the certification procedure may be either in the Slovenian, English or Croatian language. In addition, the technical documentation may be submitted in either the Slovenian, English or Croatian language. In the case that the Notified Body has a competent German-speaking auditor at its disposal, parts of the technical documentation may be submitted in the German language, with the exception of the *Device description and specification, including variants and accessories*, the *Information to be supplied by the manufacturer, the Benefit-risk analysis and risk management, Product verification and validation plans and reports* (MDR, Annex II, points 1, 2, 5 and partially 6), which may be submitted in either the Slovenian, English or Croatian language.

3.2 Basic conditions for quality management system certification according to Article 16(4) of the MDR

- The applicant for certification may only be a natural or legal person officially registered in accordance with the applicable rules and regulations.

- SIQ for the devices which are in the scope of its designation for the MDR carries out the certification procedure under Article 16(4) of the MDR for distributors and importers of medical devices which do not assume the obligations incumbent on medical device manufacturers as referred to in Article 16(1) of the MDR. This means that such distributors/importers do not:

  (a) make the device available on the market under its name, registered trade name or registered trade mark, except in cases where the distributor or importer enters into an agreement with the manufacturer under which the manufacturer is listed as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;

  (b) change the intended purpose of the device already on the market or put into service;

  (c) modify a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

  The applicants for a certification procedure under Article 16(4) of the MDR are distributors/importers that carry out the activities referred to in Article 16(2) of the MDR:

  a) provide and translate the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device;

  b) make changes to the outer packaging of a device already placed on the market, including a change of pack size, and this is carried out in such conditions that the original condition of the device cannot be affected by it.

  The MDR gives the following definitions:

  - ‘importer’ means any natural or legal person established within the Union that places a device from a third country on the Union market.
  - ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service. The activities of distributors should be deemed to include acquisition, holding and supplying of devices.

- The distributor’s/importer's quality management system shall be established in such a way as to enable the meeting of requirements and the demonstration of conformity with the requirements of Article 16(3) of the MDR.
- The medical device or group of medical devices for which the applicant is a distributor/importer carrying out the activities referred to in Article 16(2) a) and/or b) shall be clearly and unambiguously identified.
- Agreement shall be reached with the applicant on the conformity assessment procedure and the standards, regulations or specifications underlying the review and conformity assessment.

  The application and all documentation of the applicant related to the certification procedure is, as a rule, in Slovenian, English, and/or Croatian.

3.3 Activities

3.3.1 Certification procedure in the case of a conformity assessment procedure according to Annex IX and Annex XI, Part A for quality management systems

a) Inquiry and/or preliminary interview with the applicant

b) Quotation
c) Application
d) Organisation of the certification procedure
e) Submission of technical documentation for the medical device (Annex II or III), technical documentation assessment
f) Certification audit
g) If applicable, specific additional procedures
h) Assessment of the adequacy of reports, documentation and, where relevant, samples
i) Decision on granting an EU Certificate
j) Informing competent authorities via the EU electronic system
k) Surveillance and recertification audits (Annex IX; Annex XI, Part A)
l) Unannounced audits
m) Procedure for review of vigilance information
n) Decision on the maintenance, suspension, restriction and withdrawal of a certificate
o) Settling financial obligations

3.3.2 Certification procedure in the case of a conformity assessment procedure according to Annex X and Annex XI, Part B for active medical devices

a) Inquiry and/or preliminary interview with the applicant
b) Quotation
c) Application
d) Organisation of the certification procedure
e) Submission of technical documentation for the medical device (Annex II and III), precheck of the submitted documentation
f) Selection of the conformity assessment procedure:
   - In the case of the selection of a conformity assessment procedure according to **Annex XI,** P**art B** (class IIa)
   - In the case of the selection of a conformity assessment procedure according to **Annex X and Annex XI, Part B** (class IIb and III)

Product testing/certification – EU type examination (Annex X)
Conformity assessment of device technical documentation – EU type-examination (Annex X)
Product verification (Annex XI, Part B)
g) If applicable, specific additional procedures
h) Assessment of the adequacy of reports, documentation and, where relevant, samples
i) Decision on granting an EU Certificate
j) Informing competent authorities via the EU electronic system
k) Procedure for review of vigilance information
l) Decision on the maintenance, suspension, restriction and withdrawal of a certificate
m) Settling financial obligations

Certification procedures may vary depending on the class of the medical device. However, some activities, in particular in the marketing and sales phases, are common to all procedures.

3.3.3 Certification procedure under Article 16(4) of the MDR (for distributors and importers)

a) Inquiry and/or preliminary interview with the applicant
b) Quotation
c) Application

d) Organisation of the certification procedure
e) Certification audit (Part 1)
f) Where necessary, carrying out required actions and reporting by the applicant
g) Certification audit (Part 2)
h) Where necessary, carrying out required actions and reporting by the applicant
i) Assessment of the adequacy of reports and documentation
j) Decision on granting a quality management system certificate according to Article 16(4)
k) Surveillance and recertification audits (Article 16(4))
l) Decision on the maintenance, suspension, restriction and withdrawal of a certificate
m) Settling financial obligations

– The certification procedure shall also take into account the MDCG 2021-23 and MDCG 2021-26 guidance.

3.4 Details of certification procedure activities

3.4.1 Inquiry/Preliminary interview

The purpose of the preliminary interview is to inform the organisation at the beginning of the certification procedure 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 for medical devices themselves (https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en) and/or specificities in the certification procedure of distributors/importers. The interested party provides SIQ with the data needed to draw up a quotation by completing the Questionnaire: *Questionnaire on the organisation, devices and conformity assessment procedure with regard to Regulation (EU) 2017/745* on medical devices (MDR_DN036*).

In the case of an organization where independence could be threatened due to a connection with the founders of SIQ, it is necessary to investigate the connections beforehand and confirm the independence before proceeding with the process.

3.4.2 Quotation

On the basis of the completed Questionnaire, SIQ verifies whether the product meets the definition of a medical device, allocates the appropriate MD codes, checks the MD scope of designation and the class of the medical device, determines the conformity assessment procedure and the scope of service, and draws up a quotation covering the costs of obtaining and maintaining a certificate, including certification fees. The quotation, along with information on the certification procedure and requirements for the awarding and maintenance of the certificate, is sent to the interested party. The quotation is not binding.

3.4.3 Application

On the basis of the quotation, the interested party applies for certification by completing the form *Application for certification in accordance with Regulation (EU) 2017/745* on medical devices (MDR DN010)* (hereinafter: the Application), thus becoming the applicant. The Application has the validity of a contract. Upon the request of the applicant, a separate contract may be signed. By signing the Application or contract, the applicant confirms that it is familiar with the procedure as well as the terms and conditions for the awarding and maintenance of a certificate.

An applicant that is changing the notified body shall, when submitting an Application for the same devices or upon concluding a contract with SIQ, also submit the Agreement on changing the

notified body that was concluded with the outgoing notified body, as provided in Article 58 of the MDR. At the request of the manufacturer or the outgoing notified body, SIQ may help to draft a common agreement with the manufacturer and the outgoing notified body.

After signing an Application or contract, applicants may withdraw from the certification procedure at any time. In this case, they shall cover all expenses that have arisen since the beginning of the procedure. In the case that, after the review, the Application is rejected or the manufacturer itself withdraws the Application, the electronic system referred to in Article 57 of the MDR shall be formally notified. Before the Application has been signed, no pre-certification activities may be performed according to the MDR (preliminary assessment), such as assessment of the status, pre-audit, gap analysis of the technical documentation, clinical evaluation or quality management system. Any such activity carried out following the receipt of the Application already constitutes part of the certification procedure.

3.4.4 Organisation of the certification procedure

SIQ appoints an audit team to carry out the certification procedure with regard to the selected conformity assessment procedure and the type of medical device (MD code and required specific area of expertise) and informs the applicant of the appointed team and audit date. In the case that the applicant objects to the appointment of an auditor or auditors due to a potential conflict of interest, it shall inform SIQ of its objection and justify its decision. If its objection is justified, SIQ shall appoint a new auditor/auditors. Conformity assessment procedures are carried out in line with relevant annex(es) to the MDR depending on the class of the particular medical device and in line with Article 16(4) of the MDR applying to distributors and/or importers of medical devices. The applicant informs SIQ about the date of submission of technical documentation.

3.4.5 Submission of technical documentation for a medical device (Annexes II and III), assessment of technical documentation

The organisation/applicant submits the technical documentation for the medical device in electronic form. After submitting the Application, the applicant receives the instructions for submitting the technical documentation. Precheck is assessed by auditor to assure that technical file is presented in a clear, organised, readily searchable and unambiguous manner.

The technical documentation assessment/audit is conducted by the audit team. The assessment/audit can be conducted off-site – usually at the auditor's premises. At the organisation's express request, the technical documentation assessment/audit can be performed at the applicant's premises.

During an audit according to the MDCG 2019-13 document (*Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation*), a representative sample of device technical files shall be assessed. In the five years prior to the recertification audit, every technical file shall be assessed in line with the sampling plan. Before issuing the certificate, the organisation/applicant shall submit all device technical files.

SIQ submits a written report on the findings of the assessment/audit to the applicant, who shall then eliminate any detected non-compliances/non-conformities (major and minor) before the next step of the procedure can be carried out. Implemented actions are reviewed during the post-audit and the relevant report is submitted.

During the review of the technical file assessment report, competent personnel who review the report may add new findings (recommendations, minor and major non-conformities) if deviations from the audit procedure have been identified. Such findings are included in the audit report.

The deadline for reporting is no more than six months. In the case that the identified non-conformities are not eliminated within 18 months, the certification procedure is, as a rule, closed. In order for the certification procedure to continue, the organisation shall commence the procedure again from the beginning.

After the assessment/audit, the applicant is obliged to submit a written report on any other issues/findings specified in the audit report, within the time limit as specified in the conclusion to the report.

3.4.6 Product testing/certification – EU type-examination (Annex X)

Upon the request of certification personnel, type-testing is performed on a representative sample in accordance with the relevant standards and the *Rules on product certification* (CR201) in SIQ testing laboratories. The testing may also be carried out by an external competent organisation, but the test report shall be reviewed and validated by the personnel of the SIQ testing laboratories. The applicant is informed of the results of the type test and is given an opportunity to eliminate any identified non-conformities/non-compliances. If all of the requirements are met, SIQ shall issue a test report/certificate of conformity in accordance with the *Rules on product/process/service certification* (CR201).

3.4.7 Conformity assessment of device technical documentation – EU type-examination (Annex X)

The conformity of device technical documentation is assessed in line with the requirements of Annex X of the MDR. The assessment supplements the type-examination of a sample in line with Annex X. If all of the requirements are met, SIQ issues a Report/Certificate on EU-type-examination.

3.4.8 EU product verification (Annex XI, Part B)

Upon the request of certification personnel, EU product verification of each device from a certain series is performed in the SIQ testing laboratories, in line with the requirements of Annex XI, Part B. EU product verification includes an assessment of device technical documentation. If all of the requirements are met, SIQ issues a report on product verification.

3.4.9 Certification audit (Annex IX and Annex XI, Part A)

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 MDR. The audit is conducted according to the audit plan, as prepared by the lead auditor after the technical documentation assessment/audit. In the case that the certification audit is carried out in parallel to the ISO 13485 audit, the certification audit is performed along with the certification audit according to ISO 13485, Part 2.

Upon completion of the audit, the auditors verbally inform the applicant’s representatives of the audit findings that will be included in the written report.

If non-conformities are not identified during the audit, the report, including any other necessary documentation and information, is submitted to the certification personnel for review. The competent certification personnel may present new findings (recommendations, minor and major non-conformities) to the final audit report if deviations from the auditing process are identified. If recommendations are given, or if there are any other requirements relating to the audited quality management systems, the certificate holder shall take appropriate action and submit to SIQ a report on the taking into account of these recommendations and requirements no more than six months after the audit.

If non-conformities (either minor or major) with the requirements of the selected standard or some other reference document are identified during the audit, the conclusion of the report presents the requirements for actions to be implemented by the applicant prior to the final review and the issuance of the certificate. The deadline for implementing these actions is no more than six months. The implemented actions are reviewed during a post-audit. A post-audit report is drawn up and submitted to the certification personnel for review along with other necessary documentation and information.

In case the nonconformities of technical documentation report are still opened or the technical documentation has not yet reviewed/submitted within 12 months after the certification audit is performed, the certification audit has to be repeated.

In the event that the organization operates virtually and in case of emergency, when the circumstances do not allow the on-site audit, or with the aim of more efficient use of resources, SIQ can carry out part of the audit by reviewing the documentation and/or remotely using information and communication technologies. In doing so, the provisions of the IAF document (e.g. IAF ID 3) and/or in case of extraordinary circumstances the guidance or instructions of EU commission has to be taken into account.

3.4.10 Certification audit (Article 16(4), distributors/importers)

SIQ shall verify and assess whether the distributor/importer has a quality management system in place that includes the management of the structure, responsibilities, procedures, processes and resources necessary to ensure compliance with the provisions of Article 16(3) of the MDR. The quality management system shall cover and address at least the following:

- documentation of the quality management system, including management responsibilities and the development of policies and procedures;
- management of resources, including the premises and equipment necessary to carry out the activities referred to in points a) and b) of Article 16(2), as well as the selection and supervision of suppliers and subcontractors;
- policies for the allocation of activities and responsibilities to personnel, ensuring the availability of the resources and information necessary to support the operation and monitoring of these activities;
- procedures to ensure that the distributor/importer is informed of any corrective action taken by the manufacturer in relation to the device concerned in order to address safety issues or to ensure that the device is in conformity with the MDR, including a contract with the manufacturer showing the responsibilities regarding notification;
- procedures to ensure that there is no effect on the conformity of the device with the applicable requirements, inter alia, that:
  - the translation of information is accurate and regularly updated,
  - the activities from points a) and b) of Article 16(2) MDR are carried out in a manner and under conditions that preserve the original condition of the device,
  - the packaging of the repackaged device is not defective, of poor quality or untidy;
- management of corrective actions, including procedures for handling non-compliant devices and recalls from the market as a result of activities carried out in accordance with points a) and b) of Article 16(2), and, where appropriate, field safety corrective actions and determination of their effectiveness;

- procedures to ensure the traceability of devices and labels and instructions for use, and of the outer packaging indicating the modification of the device;
- document management;
- records management;
- supervision of the implementation and management of the quality management system, including internal audits and management review.

3.4.10.1 Certification audit – Part 1

The certification audit – Part 1 shall include documentation assessment, assessment of the establishment of the quality management system, and preparation for the next step in the certification audit. The audit shall normally be carried out by a lead auditor as an off-site audit.

Documentation assessment is conducted on the basis of the requirements of Article 16 of the MDR. Its completeness, internal coherence and suitability for the audited quality management system shall be assessed. As a general rule, a Quality Manual or other umbrella document of the quality management system is sufficient. If the description in the Quality Manual or other umbrella document is too short, the lead auditor may also request additional documents.

The assessment of the establishment of the quality management system depends on the audited quality management system. As a rule, the performance of the management review and internal audit shall be checked, along with their adequacy, as well as the understanding, establishment and implementation of the quality management system.

Preparation for the next step of the assessment includes identification of the sites and processes to be subject to the certification audit – Part 2, and agreement on the audit plan and schedule.

Upon completion of the audit, the auditors verbally inform the applicant's representatives of the audit findings that will be included in the written report, including identification of any areas or activities of concern that could be classified as nonconformity during the next step of the certification procedure.

Report on the actions required
Before continuing the certification procedure, the applicant shall implement actions to address the areas of concern described in the report on the certification audit – Part 1. The applicant shall draw up a written report on the implemented actions and send it to SIQ within six months. The lead auditor shall assess the appropriateness of the actions and determine the date on which it is reasonable to continue the certification procedure. This date shall be no more than six months from the last day of the certification audit – Part 1. If this deadline is exceeded, the certification audit – Part 1 shall be repeated.

3.4.10.2 Certification audit – Part 2

SIQ conducts the certification audit – Part 2 on-site at the distributor's/importer's premises or, where necessary, at its subcontractor's premises.

During the certification audit – Part 2, it shall be assessed whether procedures are documented, established and implemented in line with the requirements of Article 16(3) of the MDR (see also 3.4.10). The audit shall be carried out according to the audit plan drawn up by the lead auditor together with the applicant's representative at the time of the certification audit – Part 1.

After the audit has been conducted, the auditors shall inform the applicant's representatives verbally of the findings of the audit that will be included in the written report.

If non-conformities are not identified during the audit, the audit report, together with the other documentation and information required, shall be submitted to the certification personnel for review. If non- conformities with the requirements of Article 16(3) of the MDR are found during the assessment, the conclusion of the audit report shall specify the requirements on actions to be taken by the applicant prior to the final review. The deadline for implementing these actions is no more than six months. The implemented actions are checked during a post-audit. A post-audit report is drawn up and submitted to the certification personnel for review along with other necessary documentation and information.

3.4.11 Specific additional procedures

Consultation with the European Commission, competent authorities or the European Medicines Agency (EMA) should also be carried out for the following devices:

- Class III implantable devices, active devices class IIb, intended to administer and/or remove a medicinal product as referred to in Rule 12 of Annex VIII
- Devices incorporating a medicinal substance
- Devices composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

a) Class III implantable devices, active devices class IIb, intended to administer and/or remove a medicinal product as referred to in Rule 12 of Annex VIII

SIQ shall submit the clinical evaluation assessment report with the manufacturer's clinical evaluation documentation, referred to in points (c) and (d) of Section 6.1. of Annex II of the MDR to the European Commission.

The Commission should submit these documents to the relevant expert panel, which may do one of the following:

- decide, in 21 days, not to provide a scientific opinion, or
- provide a scientific opinion within 60 days, or
- not provide a scientific opinion within 60 days.

No consultation is required for the renewal of a certificate when the device is designed as the new generation of an already certified device of the same manufacturer with the same intended use, in the case that the manufacturer has already demonstrated that the benefit-risk ratio has not been reduced, as confirmed by SIQ, and when the clinical evaluation of the manufacturer complies with Common specifications.

Upon receipt of the decision of the expert panel, SIQ takes the standpoints expressed in the scientific opinion into account in an appropriate way. When the expert panel finds that the level of clinical evidence is insufficient or that it in any other way raises serious concerns regarding benefit-risk determination and the consistency of that evidence with the intended use including medical indication(s) and the PMCF plan, SIQ requires the manufacturer to take appropriate corrective actions. After appropriate actions have been implemented, SIQ continues with the certification procedure in accordance with the certification programme.

b) Devices incorporating a medicinal substance

In addition to technical documentation, the applicant shall submit documentation in compliance with the MDR, Annex IX, point 5.2, in order to verify the quality, safety and usefulness of the substance by analogy with the methods laid down in Annex I to Directive 2001/83/EC.

In agreement with the applicant, SIQ selects the competent authority or EMA through which it will conduct the consultation procedure. SIQ sends a technical documentation audit report with the appropriate actions taken by the manufacturer and the manufacturer's documentation (MDR, Annex IX, point 5.2) to the selected competent authority or EMA. The competent authority or EMA provides its opinion to the notified body within 210 days of the receipt of all of the necessary documentation. In accordance with the opinion of the competent authority or EMA, SIQ may require the manufacturer to take appropriate corrective actions, refuse the certification of the device with adequate justification, or approve the technical documentation of the device. After adequate actions have been implemented, SIQ continues with the certification procedure in accordance with the certification programme.

c) Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

SIQ shall verify whether, in addition to meeting the requirements in the MDR, the technical documentation of the applicant also meets the requirements of Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances, and the potential for adverse reactions.

In agreement with the applicant, SIQ selects the competent authority or EMA through which it will conduct the consultation procedure – obtain a scientific opinion. SIQ sends the technical documentation audit report with appropriate actions taken by the manufacturer and the manufacturer's documentation. The competent authority or EMA provides its opinion to the notified body within 150 days of the receipt of all of the necessary documentation. In accordance with their opinion, SIQ may require the manufacturer to take appropriate corrective actions. After adequate actions have been implemented, SIQ continues with the certification procedure in accordance with the certification programme.

3.4.12 Assessment of the adequacy of reports, documentation and, where relevant, samples – final review

Certification personnel review the following documentation:

- Audit reports, where non-conformities have already been resolved (Annex IX and Annex XI, Part A of the MDR, and Article 16(4) of the MDR)
- Test reports/Certificates of Conformity and Conformity reports concerning documentation (Annex X) and reports on EU type-examination;
- Inspection reports on product verification (Annex XI, Part B);
- Other documentation (e.g., Quality Manual, technical documentation for devices).

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

3.4.13 Decision on granting a certificate

3.4.13.1 EU certificate

If the Notified Body Commission concludes that all of the requirements have been met, it adopts a decision on the awarding of an EU Certificate. Based on the Notified Bodies Commission's decision, SIQ issues a certificate and adds the certificate holder to the List of EU Certificate holders published on SIQ's website (www.siq.si). The EU certificate and the *Detailed list on device names, models and types* that forms part of the EU certificate is issued in English. At the customer's specific/express request, a *Detailed list of device names, model and types* can also be issued in the Slovenian language.

Types of EU certificates:

- EU Certificate – Quality Management System
- EU Certificate – Production Quality Assurance
- EU Certificate – Product verification
- EU Certificate – Technical documentation assessment for devices class II and implantable devices, classified as class IIb, except for sutures, medical staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.
- EU Certificate – Type-Examination if the type is compliant with the MDR

Once the EU Certificate is issued, the EU Certificate holder affixes the CE marking to the deivce along with the number of the Notified Body (SIQ's number is **1304**).

3.4.13.2 Quality management system certificate under Article 16(4) of the MDR

If the Notified Body Commission finds that all of the requirements have been met, it shall adopt a Decision on granting a certificate for the quality management system under Article 16(4) of the MDR. On the basis of the Commission's Decision, SIQ shall issue a quality management system certificate under Article 16(4) of the MDR and put the certificate holder on the *List of Holders of Valid Certificates*, which is published on SIQ's website (www.siq.si). The certificate is issued in the English language.

3.4.14 Informing the Competent Authority

SIQ enters the results of the conformity assessment and the consequent decision into the electronic system referred to in Article 57 of the MDR and notifies thereof the Competent Authority, i.e., the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), the European Commission and other relevant authorities. The following decisions are entered in the electronic system:

- information on all issued EU certificates, including changes or additions to the certificates, and information on the re-issuance of suspended certificates,
- information on rejected, suspended, restricted or withdrawn EU certificates,
- information to other notified bodies on a manufacturer that has withdrawn an Application for certification before being granted an EU certificate by SIQ, or on SIQ's rejection of an Application for certification,
- in the case that it was necessary to carry out a consultation procedure for implantable medical devices class III or active medical devices class IIb intended to administer and/or remove a medicinal product (Article 55(1)) regarding the granted certificate.

In addition, SIQ reports to the JAZMP in the following cases:

- when it determines that the CE marking has been affixed to a device incorrectly, i.e., the CE marking has been affixed to a device that either does not comply with the legal requirements (MDR) or is not covered by these legal requirements.

SIQ also carries out other activities of informing and complementing the European electronic database:

- uploading the summary of safety and clinical performance for implantable medical devices class III,

- uploading the assessment (audit reports with details of any actions taken) of a safety report for implantable medical devices or medical devices class III (in accordance with its competences),
- notifying – for implantable medical devices Class III and active medical devices IIb intended to administer and/or remove a medicinal product (Article 54(3)) – whether or not it is necessary to carry out a consultation procedure; a report on clinical evaluation assessment should be added to the notice,
- in handling procedures for devices that present an unacceptable risk for health or safety, the competent body for market surveillance informs SIQ of the action taken; SIQ initiates the procedure of vigilance data review.

3.4.15 Surveillance and recertification audits

3.4.15.1 Annex IX and Annex XI, Part A

With surveillance audits, SIQ verifies whether the EU certificate holder meets the requirements of the MDR. Such audits are carried out once a year, with the first audit taking place twelve months after the certification audit and the subsequent audits occurring at the same time interval. According to the sampling plan, the technical documentation assessment(s) shall also be planned and carried out in the same timeframe, but planned and documented separately (a separate audit report is issued). Three months before the planned assessment, the manufacturer is called upon to submit the technical documentation. The organisation shall submit the technical documentation within 30 days of the receipt of the request for the submission of the technical documentation from SIQ.

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

If non-conformities (either minor or major) have been identified during the surveillance audit, the certificate holder shall resolve them and submit a written report thereof, along with the relevant evidence, to SIQ within one month (for major non-conformities) or three months (for minor non-conformities) at the latest. After the submission of the evidence by the certificate holder within the specified period, an additional audit is performed. As a rule, SIQ performs a post-audit of the quality management system audit findings within eight weeks of the receipt of the evidence.

Every fifth year after the certification audit, a recertification audit is performed to provide a comprehensive evaluation of the five-year performance of the quality management system and its effectiveness, a plan for technical documentation sampling is drawn up for the new certification cycle, the technical documentation is reassessed in line with the sampling plan, and the adequacy of the scope of the audits conducted in the five-year period is evaluated. The technical documentation shall be assessed nine months before the planned date of the recertification audit, which shall be planned and documented separately in order to enable the documentation to be assessed in a timely manner prior to the recertification audit. The organisation shall submit the technical documentation within 30 days of the receipt of the request for the submission of the technical documentation from SIQ. Prior to the recertification audit, SIQ shall check the audit scope and, where appropriate (in the case of major changes in the organisation), define a new scope of audit activities and a new fee. The audit scope of the technical documentation is assessed taking into account the changes to the device and the sampling plan of the technical documentation. When performing the recertification procedure, the same prescribed forms are used when it is reasonable to do so, and no re-application for certification is required.

If no non-conformities are found during the recertification audit, a new issuance of the EU certificate is granted to the certificate holder. If non-conformities are found during the recertification audit, the certificate holder shall first meet the requirements stipulated in the conclusion of the audit report before a new issuance of the certificate can be granted. Compliance with these requirements is assessed during the post-audit, after which a post-audit report is issued.

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

3.4.15.2 Article 16(4) of the MDR

Surveillance audits verify that the certificate holder meets the requirements of Article 16(3) of the MDR. Surveillance audits shall be carried out once a year, with the first audit taking place twelve months after the certification audit - Part 2, and subsequent audits occurring at the same time interval. Surveillance audits may be conducted with documentation assessment only, on the basis of a risk assessment and experience with the organisation.

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

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

Every fifth year after the certification audit, a recertification audit is performed to provide a comprehensive evaluation of the five-year performance of the quality management system and its effectiveness, and the adequacy of the scope of the audits conducted within that period is evaluated. Prior to the recertification audit, SIQ shall check the audit scope and, where appropriate (in the case of major changes in the organisation), define a new scope of audit activities and, as a result, a new fee. When performing the recertification procedure, the same prescribed forms are used when it is reasonable to do so, and no re-application for certification is required.

If no non-conformities are found during the recertification audit, a new issuance of a certificate for the quality management system under Article 16(4) of the MDR shall be granted to the certificate holder. If non-conformities are found during the recertification audit, the certificate holder shall meet the requirements given in the conclusion of the audit report before a new issuance of the certificate can be granted. Compliance with these requirements is assessed during a post-audit, after which a post-audit report is issued.

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

3.4.16 Unannounced audits

SIQ performs unannounced audits to verify that the certificate holder is maintaining and updating the quality management system even when the audit is not announced in advance. Unannounced audits shall be carried out at any time at least once every five years, except for MD class III, where an unannounced audit shall be carried out at least once every two years.

Unannounced audits are carried out more often than noted above 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 MDR.

An unannounced audit can be conducted on-site at the certificate holder's premises, or at the premises of its subcontractor or critical supplier. The auditor's identification is confirmed with a letter – a notice of the Notified Body regarding the unannounced audit – which the auditor shall bring to the audit. During the unannounced audit, a sample of the device from production or already manufactured devices is also taken and a test is carried out at the manufacturer's site. The sampling criteria and test procedure shall be determined by competent personnel in cooperation with the lead auditor prior to the unannounced audit.

SIQ issues an audit report following the unannounced audit. In the case of identified non-conformities, deadlines for their resolution are set. The adequacy of the implemented corrective actions are verified with a post-audit conducted by the lead auditor. An appropriate written report is issued. All expenses arising from the activities following a detected non-conformity shall be covered by the certificate holder according to SIQ's current *Schedule of fees*.

3.4.17 Information on changes and modifications

By signing the contract/application MDR DN010, the organisation declares that, as the manufacturer of the medical device, it will inform SIQ in advance of any essential changes that could affect the performance and operation in terms of the safety and efficiency of the medical device, as well as the conditions laid down for the use of the device, which shall be approved by SIQ before placing the modified device on the market. Any such change or modification of the medical device or the approved quality management system shall be communicated to SIQ on the MDR DN015 form.

The manufacturer shall inform SIQ of changes regarding:

- the system or quality management system or devices included,
- the design of the device,
- the intended use of the device and its references,
- the type of medical device, and any substance that is incorporated or used for the manufacture of the device and for which specific procedures apply in accordance with Section 5 of Annex IX, and Section 6 of Annex V, of the MDR (including changes related to the production process).

In the procedure for approving the change, it is verified whether the device still meets the requirements of the MDR. Meeting these requirements may be verified by assessing the technical documentation and, where appropriate, by an additional audit at the location of the organisation, for which SIQ issues a report. If no non-compliances are found during the assessment/audit, the holder shall, where appropriate, be granted a new issuance of the EU certificate. If non-compliances are found, the certificate holder shall comply with the requirements given in the conclusion of the audit report before the new issuance of the EU certificate. The meeting of these requirements shall be verified by a post-audit, for which SIQ issues a report. In the event that no additional activities are required or no new issuance of an EU certificate is required, and the manufacturer may place the device on the market, SIQ shall inform the certificate holder thereof.

By signing the contract/application MDR DN010, the distributor/importer also declares that it will inform SIQ in advance of any plan for changes that might affect the validity of the certificate, in particular those related to the activities and devices falling within the certification scope. Any such modification or addition to a medical device or approved quality management system shall be reported by the organisation to SIQ on form MDR DN015.

By signing the contract/application MDR DN010, the organisation also declares that it will notify SIQ in the case of the termination of the contract and the conclusion of a contract with another notified body. In such case, SIQ draws up an agreement on the change of the notified body, as provided in Article 58 of the MDR, which specifies:

- the date on which the certificates issued by SIQ become invalid,
- the date until which SIQ's identification number may be indicated in the information supplied by the manufacturer (labels, instructions for use, promotional material, etc.),
- the last serial number or lot number manufactured under SIQ's identification number,
- the date after which SIQ no longer performs the conformity assessment tasks for the manufacturer.

The agreement is binding to the organisation. The Notified Body Commission withdraws the certificate with the validity date of the certificate specified in the agreement.

3.4.18 Procedure of review of vigilance information

SIQ shall verify the information from the post-production phase and take action in the case of suspicion that the manufacturer has failed to assure conformity with the requirements of the MDR.

Reporting by the manufacturer:

- in the case of serious incidents, when the manufacturer has established a causal relationship between the incident and its device. The manufacturer shall report such an incident immediately, and no later than 15 days after becoming aware of the incident;
- in the case of all safety corrective actions;
- in the event of a serious public health threat, the report shall be provided immediately and not later than two days after the incident;
- in the event of death or unforeseen serious deterioration in a person's state of health, the report shall be submitted immediately, and no later than two days after the incident;
- reporting on a vigilance case is submitted via the electronic system in accordance with Article 92 of the MDR;
- the manufacturer shall immediately inform the users of the device in question about the adequate safety corrective actions to be taken.

The manufacturer shall take corrective actions and report thereof to SIQ. In the case that the manufacturer believes that the incident is not a serious incident or side effect, it shall provide an explanation. In the case that SIQ disagrees with the manufacturer's finding, the manufacturer shall take further actions in accordance with Article 89 of the MDR.

SIQ may conduct post-audits or an unannounced audit or order a review of selected devices, processes or quality management system elements for the next audit. SIQ may conduct another review of the certificate issuance process and, if necessary, initiate cancellation/withdrawal, suspension or restriction of the certificate.

In the event of a serious vigilance case, the competent staff may order the taking of samples of devices from the market in order to verify that the device complies with the technical documentation. The sampling criteria and the test procedure are determined by SIQ on a case-by-case basis.

These activities shall also be carried out by SIQ at the request of JAZMP or other national institution or the European Commission, and the results shall be reported via the electronic system on vigilance in accordance with Article 92 of the MDR.

3.4.19 Sample test of devices produced or from the market

If a divergence is found between the sample taken from the devices produced, from the manufacturing process or from the market and the specifications laid down in the technical documentation or the approved design, the manufacturer shall take corrective actions and report to SIQ on such actions. SIQ may review the procedure leading to the issuance of the certificate and, if necessary, withdraw or suspend the relevant certificate, or impose restrictions on it.

3.5 Settlement of financial obligations

The applicant/certificate holder shall cover all costs related to the certification procedure and maintenance of certification, as defined in the quotation/contract, as well as any additional expenses of post-audits. In the case of organisational changes (number of employees, additional activities and devices, number of locations, new subcontractors, etc.), SIQ has the right to determine a new fee for the changed scope of activities in line with the SIQ's current *Schedule of fees*. Any breach of financial contractual obligations may result in the termination of the contract.

3.6 Monitoring of changes to standards and regulations

In the case of changes to the MDR, related regulations and guidelines, or when a medical device no longer meets the relevant requirements, SIQ shall set a time limit within which the holder of the certificate or license shall bring its device into compliance with the new requirements.

4 Misuse of an EU Certificate or CE Marking

SIQ shall supervise the use of EU certificates, the CE marking, and the certificate for a quality management system according to Article 16(4) of the MDR. If SIQ determines that an EU certificate holder is using a CE marking incorrectly or that it is using an EU certificate, CE marking and quality management system certificate issued according to Article 16(4) of the MDR in relation to medical devices that have not been certified, it shall take corrective actions or, if necessary, even legal measures. Misuse of a certificate or a certification mark may result in the withdrawal or cancellation of the certificate.

5 Suspension, restriction or withdrawal of a certificate

As a rule, the validity of an EU Certificate for medical devices and the quality management system certificate under Article 16(4) of the MDR is five years.

In specific cases, the withdrawal of an EU Certificate is required by the relevant legislation (e.g., high risk for public health). The Notified Body Commission may withdraw a certificate issued for a specific medical device and/or a certificate granted to a distributor/importer for the quality management system under Article 16(4), if, during surveillance, SIQ determines that there has been a misuse of the certification mark or any other breach of the rules set out in this document or other documents that define certification procedures in detail.

The certificate is also withdrawn in the following cases:

- withdrawal of a device from production;

- bankruptcy or termination of operations of the certificate holder;
- incomplete or false information given during or in relation to audits (Annexes II,III,IX, X, XI, and Article 16(3));
- concealment of significant changes in the quality management system or the company status, or significant changes to the device, e.g., the design of the device, the intended use of the device or its reference, changes to the type or a substance that is incorporated or used for the manufacture of the device and for which specific procedure are applicable in accordance with Section 5 of Annex IX and Section 6 of Annex X (Annexes II, III, IX, X, XI, Article 16(3));
- failure to comply with the requirements given in an audit report and during the review of vigilance information (Annexes II, III, IX, X, XI, Article16(3));
- failure to comply with the requirements given in an audit report or, where there is a high risk to public health, in the event that the examination of a sample of devices from production, produced devices or devices taken from the market establishes a deviation between the sample taken and the specifications in the technical documentation or the approved design;
- failure to fulfil financial obligations toward SIQ;
- a written request by 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 of the date of the last conducted audit (Annex IX and Annex XI, Part A, and Article 16(4));
- in the case that the producer does not allow the audit team to conduct an unannounced audit.

The withdrawal procedure of the certificate is triggered when the organisation fails to send a written report with appropriate evidence of the elimination of the non-conformities given in an audit report within one month (in case of a major non-conformity) or three months (in case of a minor non-conformity), or if any other violations and irregularities stated in the previous paragraphs are detected.

In the case that the organisation fails to comply with the requirements stated in the conclusion of an audit report within one month (for a major non-conformity) or three months (for a minor non-conformity), or in the case of the misuse (misleading use) of the CE marking, or incorrect (misleading) references to the certificate, the Notified Body Commission may initiate the procedure for temporary suspension or restriction of the certificate. When there is no high risk to public health, the product manager shall, prior to submitting a proposal for the temporary suspension of the certificate, inform the certificate holder thereof and invite it to provide an explanation/defence within eight working days. Since such an act on the part of the organisation gives rise to suspicion of non-compliance with the quality management system requirements, the product manager may decide to initiate the procedure to carry out an unannounced audit.

The duration of such a suspension shall be no more than nine months, and the suspension is terminated when a post-audit has been successfully conducted. The post-audit shall be conducted prior to the expiry of the suspension or restriction. After the termination of the suspension, audits are conducted according to the audit programme, as established prior to the suspension of the certificate. If the post-audit is not conducted during the period of suspension, the withdrawal of the certificate is permanent.

In the case of suspension, restriction, withdrawal or expiry of documents issued by the Notified Body, the holder of an EU certificate shall no longer place on the market devices labelled with the CE marking, and shall remove the CE marking from the deivce and other places/documents in which it has been used.

In the case of suspension, restriction, withdrawal or expiry of documents issued by the Notified Body, the holder of a certificate under Article 16(4) shall no longer place the devices falling within the scope of the certificate on the market.

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

6 Obligations of applicants and/or certificate Holders

6.1 Availability of information

The applicant/certificate holder shall immediately inform SIQ of any changes that 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, changes in the status of the company (e.g., bankruptcy, insolvency), and/or changes in the organisation of the company (number of employees, additional activities, new or additional locations, etc.). Point Information on changes and modifications gives more details in this regard. Prior to surveillance or a recertification audit, the certificate holder shall inform SIQ of any changes in the quality management system and relevant documentation. Based on the changes, SIQ shall determine a new scope of activities and a new fee.

The applicant/certificate holder shall inform SIQ on the termination of the contract and the conclusion of a contract with another notified body and shall sign an agreement with SIQ on the change of the notified body, which shall include agreement on the date on which the certificate issued by the notified body becomes invalid, the date until which SIQ's identification number is used, including the last lot, and the date after which SIQ shall no longer perform the conformity assessment tasks, as well as maintenance of confidentiality and ownership rights in the case of any transfer of documents belonging to SIQ and the manufacturer to the new notified body.

Prior to the audit (Annex IX, Part A of Annex XI, and Article 16(4)), the applicant/certificate holder shall inform the auditors of any issue that may be relevant to the audit. The applicant/certificate holder shall facilitate the audit by ensuring that the responsible personnel are available to the auditors during the audit and by providing such personnel with the necessary information. The applicant/certificate holder shall prepare the required documentation and any other evidence in order to ensure unimpeded auditing.

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

The applicant/certificate holder shall keep records of complaints, visits by the authorities and feedback from the post-production phase, as well as records of corrective actions taken. The auditors shall have access to these records when conducting the audit. The applicant/certificate holder shall also keep previous versions of the quality management system documentation and technical documentation, as well as responses to audit findings previously submitted to SIQ to prove that findings have been taken into consideration and non-conformities have been resolved.

The applicant/certificate holder shall enable the auditors to conduct the audit in organisations providing any outsourced process that affects the device's compliance with the relevant requirements and/or the effectiveness of the audited quality management system.

7 Handling of complaints and appeals, and the responsibility of SIQ

7.1 Handling of complaints and appeals

The applicant/certificate holder may file a complaint regarding the work of SIQ or an appeal against the decisions of the Notified Body Commission for medical devices (NBC MDR).

Complaints regarding the work of SIQ are examined at the first instance by the MSA Director and referred to the MDR Product Manager. In the case that the MDR Product Manager is involved in the conformity assessment procedure, the complaint is dealt with by the MDR Product Manager's deputy. The complainant is informed of the decision in writing. The complainant can file an appeal against the MSA Director's decision to the Commission for Complaints, which is the body of second instance. Decisions of the Commission for Complaints are final.

Complaints against the certificate holder's quality 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 ongoing procedure and its outcome.

An appeal against a decision taken by NBC MDR shall be filed by the appellant in writing within 15 days of the receipt of the decision. The appellant shall document the appeal appropriately. The appeal is examined by the Board of Appeal. Decisions of the Board of Appeal are final.

If a complaint or an appeal is well founded, 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 device/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, restriction or withdrawal 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

In addition to the quotation for the provision of certification services, any interested party shall also receive this document for information about the procedures related to the certification of medical device and/or quality management system pursuant to Article 16(4).

SIQ reserves the right to modify the *Info for Applicants* due to changes in the MDR, or in guidance and guidelines applicable to notified bodies for medical devices, as well as upon requests by bodies supervising the work of SIQ (the notifying authority), and due to changes in the organisation or operation of SIQ. The applicant/certificate holder is instructed to inform itself about any changes in the certification procedures of medical devices, as published on SIQ's website (www.siq.si), prior to each subsequent step in the process. If the applicant/certificate holder raises no objections against the changes, it shall be deemed that it agrees with them.

Any other disputes shall be resolved by the competent court with subject-matter jurisdiction in Ljubljana, unless the contract provides otherwise. All relationships are subject to the applicable legislation of the Republic of Slovenia.