1 Introduction

This publication is intended for manufacturers and suppliers of medical devices who want to get an EU Certificate of Conformity according to the regulation concerning medical devices (MDR 2017/745). The publication explains the conditions for certification and illustrates the entire procedure, from the application for certification to the issue of an EU 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 EU 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 endeavors 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 SIST EN ISO/IEC 17021-X, SIST EN ISO/IEC 17065, as well as Regulation MDR 2017/745, including related valid legislation and MEDDEV and NBOG (in parts, where they do not contradict with MDR) 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 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 counselling activities in the organization, its authorized representative or commercial competitor 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 favorably 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 temporary suspension, restriction or withdrawal 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 EU 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 or Croatian language. The technical documentation also has to be submitted in Slovenian, English 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, except the Device description and specification, including variants and accessories, and the Information, to be supplied by the manufacturer (MDR, Annex II, item 1 and 2), which must be submitted in Slovenian, English and Croatian language.

3.2 Activities

3.2.1 Certification procedure in case of conformity assessment procedure according to Annex IX and Annex XI part A-with quality system

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

3.2.2 Conformity assessment in case of 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) Organization of the certification procedure
e) Submission of technical documentation for medical device (Annex II and III)
f) Selection of conformity assessment procedure:
   - In case of the selection of conformity assessment procedure according to **Annex XI part B** (class IIa)

- In case of the selection of conformity assessment procedure according to **Annex X + Annex XI part B** (class IIb and III)

Product testing/certification – EU type examination (Annex X)
Conformity assessment of product technical documentation – EU type examination (Annex X)
Product verification (Annex XI part B)

g) If applicable, specific additional procedures
h) Assessment of adequacy of reports, documentation and, where relevant, samples
i) Decision on granting an EU Certificate
j) Informing competent authorities via EU electornic system
k) Procedure for review of vigilance information
l) Decision on maintenance, suspension, restriction and withdrawal of Certificates
m) 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 Inquiry / 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 Questionnaire: *Questionnaire on manufacturer, products and assessment route in accordance with the medical device regulation MDR 2017/745* on medical device (MDR_DN036*).

3.3.2 Quotation

On the basis of a completed Questionnaire, SIQ checks, if the product meets the definition of medical device, checks the MD Codes, 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 MDR 2017/745* regulation on medical devices (MDR DN010) (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.

When submitting the Application or at concluding the contract, the Applicant, who changes the notified body, must also submit the Agreement on changing the notified body concluded with outgoing notified body as provided in Article 58 of the MDR regulation. At the request of the manufacturer or the outgoing notified body, SIQ may participate at preparation of a common agreement with the manufacturer and the outgoing notified body.

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. In case, that after the review, the application is rejected or the manufacturer withdraws it himself, the electronic system from Article 57 of Regulation MDR 2017/745 should be formally notified.

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), due to possible conflict of interest, 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 MDR 2017/745 regulation depending on the class of a particular medical device. The Applicant informs SIQ about the date of submission of technical documentation.

3.3.5 Submission of technical documentation for the medical device (Annex II, III), assessment of technical documentation

The organization submits technical documentation for 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), a representative sample of product technical files is assessed. Representative sample is drawn up every 3 year. Within 5 years up to a recertification audit, every technical file shall be assessed.

SIQ submits a written report on audit findings to the applicant, who has to eliminate detected noncompliances / 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 technical documentation audit has to be re-conducted within the scope, defined by SIQ.

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 – EU type-examination (annex X)

Upon request by certification personnel, a type testing is performed on a representative sample in accordance wtih 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/noncompliences.

3.3.7 Conformity assessment of product technical documentation – EU type examination (annex X)

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

3.3.8 EU Product Verification (Annex XI part B)

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

3.3.9 Certification audit (Annexes IX, 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 Medical device regulation 2017/745. The audit is conducted according to the audit plan prepared by a lead auditor after the technical documentation audit. In case the audit is conducted together with ISO 13485 audit, a certification audit is conducted together with certification audit ISO 13485 stage 2.

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. Competent 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 Specific additional procedures

Consultation with the Commission, Competent authorities or Europeam Meidicnes 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, that are composed of subtances or of combinations of bustances 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 has to 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 MDR regulation to the European commission.

The commission should transmit those documents to the relevant expert panel, which decides on the basis of the following possibilities:

- Decides, not to provide a scientific opinion within 21 days
- Provides a scientific opinion within 60 days
- Decides not to provide a scientific opinion within 60 days

The consultation is not required at the renewal of certificate, when the device is designed as the new generation of already certified device of the same manufacturer with the same intended use, where the manufacturer already demonstrated, that the benefit/risk ratio wasn't reduced and it was confirmed by SIQ and when the clinical evaluation of manufacturer complies with Common specifications.

Upon receipt of decision of the expert panel, SIQ adequately takes the standpoints, expressed in the scientific opinion into account. When the expert panel finds, that the level of clinical evidence is insufficient or in any other way provokes serious concerns regarding benefit-risk determination, the consistency of that evidence with the medical indication or indications and the PMCF plan, SIQ requires that manufacturer takes appropriate corrective actions. After the implementation of adequate actions, 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 must submit the documentation in compliance with MDR, Annex IX item 5.2, to verify the quality, safety and usefulness of the substance by analogy with the methods specific in Annex I to Directive 2001/83/EC.

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

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

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

In agreement with the Applicant, SIQ selects the competent authority or EMA, by through it will conduct the consultation procedure – gain the scientific opinion. SIQ sends a technical documentation audit report with appropriate actions taken by manufacturer and the manufacturer's documentation. The competent authority or EMA provides its opinion to notified body within 150 days of the receipt of all necessary documentation. In compliance with the

opinion, SIQ may require the manufacturer to take appropriate corrective actions. After the implementation of adequate actions SIQ continues with the certification procedure in accordance with the certification programme.

3.3.11 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 IX and Annex XI part A of the MDR 2017/745
- Test reports / Certificates of conformity and Conformity reports concerning documentation (Annex X);
- Inspection reports – EU verification (Annex XI part B);
- 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.

3.3.12 Decision on granting an EU certificate

If the Notified Body Commission concludes that all requirements have been met, it adopts a decision on the award 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 www.siq.si. EU certificate and Detailed list on product names, models and types, which is a part of the EU certificate, is issued in English. At the custome'rs special request, a Detailed list of product names, model and types can also be issued in Slovenian language.

Types of EU certificate:

- 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 MDR

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**). .

3.3.13 Informing the Competent Authority

SIQ enteres the results of the conformity assessment and consequently the decision into electronic system referred to in Article 57 of the MDR 2017/745 and notifies the competent authority the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), 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 temporarily suspended certificates.

- Information on rejected EU certificates, temporarily suspended, restricted or withdrawn EU certificates
- Information to other notified bodies on the manufacturer, who withdrawn the Application for certification before SIQ granted EU certificate or if SIQ rejected the application for certification
- In case, that it was necessary to carry out 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 item 1) regarding the granted 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 (Regulation concerning medical devices) or is not covered by these legal requirements

Other acitivies of informing and complementing the European electronic database, performed by SIQ:

- uploads the summary of safety and clinical performance for implantable medical devices class III
- Uploads the assessment (audit reports with details of any actions taken) of safety report for implantable medical devices or medical devices class III (in accordance with their competences)
- Notices for implantable medical devices Class III and active medical devices IIb intended to administer and/or remove a medicinal product (Article 54 item 3) whether it is /not necessary to carry out a consultation procedure; a report on clinical evaluation assessment should be added to the notice
- In the process of dealing with devices, which present unacceptable risk for health or safety, the competent body for market surveillance informs SIQ of the action taken; SIQ launches a Procedure of review of vigilance data

3.3.14 Surveillance and recertification audits (Annexes IX and Annex XI part A)

At surveillance audits SIQ checks whether a EU certificate holder meets the requirements of the Medical Device Regulation 2017/745. They are carried out once annually, the first one twelve months after the certification audit and the others at the same time intervals.

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.

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. 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 and sampling plan of technical documentation.

If non-conformities are not found during a recertification audit, a new issue of a EU 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.

3.3.15 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 Regulation MDR 2017/745.

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. During the unannounced audit, also a sample of product from production or already manufactured devices is taken and a test is carried out at the manufacturer's site. The sampling criteria and test procedure shall be determined by competent technical assistant in cooperation with lead auditor prior the unannounced 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 are 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.

3.3.16 Information on changes and modifications

By signing the contract / application MDR DN010 the organization declares, that, as a manufacturer of medical device, they will inform SIQ in advance of any essential changes, which could affect the performance and operation in terms of safety and efficiency of medical devices. Any such change or modification of medical device or approved quality management system should be communicated to SIQ on the MDR DN015 form.

The manufacturer is obliged to inform SIQ on the changes regarding:

- The system or quality management system or devices included
- Design of the device
- Intented use of the devices and its references

- Type of medical device and
- Any substance, which is incorporated or used for manufacture of device and for which specific procedures are valid in accordance with Section 5, Annex IX and section 6 Annex V, regulation MDR 2017/745 (also changes, relating to the production process)

By signing the contract / application MDR DN010 the organization also declares, that it will notify SIQ at the termination of the contract and conclusion of the contract with another notified body. SIQ prepares an agreement on the change of the notified body, as provided in Regulation MDR Article 58, in which it specifies:

- Validity date of the certiticate
- The date, until which the SIQ's identification number may be indicated in the information supplied by the manufacturer (labels, instructions for use, promotional material,..)
- The last serial number or lot number manufactured under the SIQ's identification number
- The date, after which SIQ no longer performs the conformity assessment tasks for tha manufacturer

The agreement is binding to the organization. The Notified body commission withdraws the certificate with the validity date of certificate specified in the agreement.

3.3.17 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 2017/745 regulation on medical devices.

Reporting by the manufacturer:

- In case of serious incidents, when the manufacturer have established the causal relationship between the incident and their device. Manufacturer shall report immediately and not later than 15 days after they become aware of the incident
- At all safety corrective actions;
- In the event of a serious public health threat the report shall be provided immediately, and not later than in 2 days;
- In the event of death or unanticipted serious deterioration in a person's state of health, the report shall be provided immediately, and not later than in 2 days;
- Reporting on vigilance case is submitted via electronic system in accordance with Article 92 of Regulation (EU) MDR 2017/745;
- The users of relevant product must be immediately informed by the manufacturers about the adequate safety corrective actions.

The manufacturer must take corrective actions and report to SIQ. In case that the manufacturer believes, that the incident is not a serious incident or side effect, it must provide an explanation. In case SIQ disagrees with the manufacturer's finding, the manufacturer must take further actions in accordance with Article 89 of Regulation (EU) 2017/745.

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 restriction of the certificate.

In case of a serious vigilance case, MDR product manager may, at the proposal of a competent technical assistant, order the taking of samples of devices from the market to verify, that the device complies with the technical documentation. The sampling criteria and the test procedure is determined by SIQ on a case-by-case basis.

Stated activities have to be carried out by SIQ also at the request of JAZMP or other national institution or European commission and the results should be reported via electronic system on vigilance in accordance with Article 92 or Regulation (EU) 2017/745.

3.4 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 additional expenses of post-audits. In the case of organizational changes (number of employees, additional activities and products, number of locations, etc.), , SIQ has a right to determine new fee for the changed scope of activities in line with the valid SIQ list of fees. Breach of financial contractual obligations may have a termination of a contract as a consequence.

3.5 Monitoring of changes to standards and regulations

In cases of changes to the Medical Devices Regulation, 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 Temporary suspension, restriction or withdrawal of EU Certificate

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

In specific cases a cancellation of an EU Certificate is required by the relevant legislation (e.g. high risk for public health). 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.

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,IX, X and XI);
- Concealment of significant changes in the management system or the company status , significant changes of the device, e.g. design of the device, intended use of the device or

its reference, changes on type, substance, which is incorporated or used for the manufacture of device and for which specific procedure are valid in accordance with Section 5, Annex IX and section 6 Annex X (Annexes II, III, IX, X, XI).
- Failure to comply with the requirements given in an audit report and during the review of vigilance information (Annexes II, III, IX, X, XI);
- 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 IX and XI part A)),
- 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.

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 EU labelling or incorrect (misleading) references to EU certificate, the notified body commission may initiate the procedure for temporary suspension or restriction of the certificate. When there is no high risk of public health, the product manager shall, prior to submitting a proposal for the temporary suspension of the certificate, inform the holder of the certificate and invite him/her to give an explanation/defense within eight working days. 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.

The duration of the temporary suspension is not more than 9 months and it is cancelled when the post-audit is successfully conducted. The post-audit has to be conducted prior the expiry of the temporary suspension or restriction. 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 temporary suspension, restriction, withdrawal or expiry of documents issued by a notified body, the holder of a certificate must no longer place on the market products labeled 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.). More is written in the clause Information on changes and modifications. 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.

The applicant/holder of a certificate must inform SIQ on the termination of the contract and conclusion of the contract with another notified body and sign an agreement with SIQ on the change of the notified body, in which also the expiry date on validity of certificate is agreed, the date until which the SIQ's identification number is used including last lot, the date after which SIQ will no longer perform the conformity assessment tasks as well as maintenance of confidentiality and ownership rights in case of possible transfer of SIQ documents and manufacturer to a new notified body.

Prior to the audit (Annexes IX, XI part A), the applicant/certificate holder shall obliged to 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 MDR Notified Body Commission.

Complaints against the work of SIQ are examined at first instance by the MSA director and handed over in procedure to MDR product manager of product manager deputy. In case of involvement in the conformity assessment procedure, the complaint is dealt with by MDR product manager deputy. The complainant is informed 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 MDR 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 temporary suspension, restriction or cancellation/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

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 Regulation 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.