

Product Certification

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1 Introduction

This publication is intended for applicants seeking a product certificate of conformity in accordance with normative documents within the certification schemes established by SIQ Ljubljana (hereinafter referred to as SIQ) and implemented as part of the certification system for products, processes and services and the certification system of a notified body. It outlines the conditions for certification and describes the entire process, from application submission to certificate issuance and surveillance of issued certificates.

A certificate is a document by which SIQ certifies that the object of certification (product) meets specific requirements of normative documents. This assurance is based on the conformity assessment procedures outlined by the certification scheme. Depending on the certification scheme, the document may also have a different designation, such as a license for the use of a certification mark instead of a certificate.

This publication provides information on the certificate's validity, maintenance, suspension, or withdrawal as well as procedures for handling complaints and appeals against decisions of the SIQ certification or notified body.

The publication also includes provisions regarding data confidentiality.

SIQ conducts product certification as an independent "third party" separate from manufacturers, suppliers, buyers, and users. Its independence is guaranteed by its legal status as an institute and by the appropriate management and certification structure. The certification activities are supervised by the Board of Certification Body, which represents the interests of public, economic, and industrial associations, as well as the interests of the customers of the institute's services.

2 Basic principles of operation

2.1 Certification policy and principles

SIQ offers certification and notified body services to all interested applicants.

SIQ, including its governing bodies and personnel, treats all applicants equally, regardless of their geographical location, size, revenue, type of business or other circumstances, without discrimination.

SIQ ensures internationally recognized and valid certification and strives to continuously strengthen the reputation of its certificates both domestically and abroad.

SIQ guarantees independence, impartiality, and an organizational structure that prevents personnel from being influenced by anyone with a direct commercial interest in certification, ensuring that no conflicts of interest arise in its operations.

SIQ conducts product certification as a third party according to the general competence requirements outlined in the relevant SIST EN ISO/IEC 17000 series of standards, the additional competence requirements, the additional requirements of EU directives/regulations, and the additional requirements of certification schemes.

SIQ conducts operational activities according to the documented procedures outlined in the quality management system documents for each certification area, and according to the other relevant quality management system documentation.

SIQ charges for its services according to the pricing policy set by the SIQ Council. The generated revenue covers operating costs and investments in technical and professional development.

SIQ holds exclusive rights over the certificates granted to its clients.



2.2 Independence, impartiality and integrity

SIQ firmly adheres to the fundamental principles of independence, impartiality, and integrity in all its activities, including its activities as the certification body.

2.3 Confidentiality

SIQ ensures that all information and data obtained during the certification process remain confidential, except for information related to the issuance or withdrawal and cancellation of a certificate.

SIQ undertakes to respect the principles of business confidentiality regarding any data obtained during the service provision procedures.

All data obtained or generated in the course of the service, except for data made available to the public by the applicant itself or where otherwise agreed with the applicant (where disclosure is essential for achieving compliance), shall be considered confidential unless otherwise required by law.

If the disclosure of confidential data is required by law, SIQ Ljubljana shall be obliged to disclose the data to official supervisory institutions within the scope of the powers granted to these institutions by law.

SIQ may also use this data, without the prior written consent of the applicant, during audits or verifications of the authorisations and accreditations acquired, carried out by competent bodies.

2.4 Competence

SIQ ensures a sufficient number of professionally qualified personnel to carry out certification activities. Its competence is demonstrated through obtained accreditations and authorised designations.

2.5 Professional liability insurance

SIQ maintains professional liability insurance in the amount specified in the risk assessment or the amount required by the relevant certification scheme.

2.6 Collaboration

SIQ actively collaborates with other certification bodies within international schemes, the coordination of notified bodies, and other technical and professional organizations.

3 Legal status, funding, and organization of a certification body

3.1 Legal Status

SIQ is registered with the District Court in Ljubljana as the insitute "Slovenski institut za kakovost in meroslovje, Ljubljana", translated as "Slovenian Institute of Quality and Metrology, Ljubljana", with its headquarters at Mašera-Spasićeva ulica 10, Ljubljana, and with the abbreviated name SIQ Ljubljana.

3.2 Funding

SIQ is financed by charging clients for its services based on the applicable price list. The pricing bases are approved by the SIQ Council and other governing bodies responsible for overseeing its operations.

SIQ operates as a not-for-profit institution, allocating its revenue to cover ongoing expenses and continuously investing in the development of its activities.

3.3 Rules for applicants

By confirming the offer, application, or contract, the applicant for certification undertakes to:



- comply with the requirements of the certification scheme and normative documents under which the certification procedure was conducted;
- ensure the continuous conformity of certified products;
- facilitate the execution of certification procedures, regular surveillance, and access to the required documentation and records, factory production sites, equipment, personnel, subcontractors, and other relevant data according to the applicable certification procedures;
- cease using the certificate, referring to it, and using the certification mark in the event of noncompliance with certification requirements or the withdrawal of the certificate, and take appropriate measures;
- adhere to the rules regarding the use of certification marks;
- maintain records of complaints related to certified products and provide them to SIQ if necessary;
- promptly notify SIQ of any changes affecting the certified product and its production (e.g., changes in legal or organizational status, ownership, key management and technical personnel, product modifications, changes in the production process of the certified product, or significant changes in the quality management system);
- settle all financial obligations before the certificate is issued;
- agree to the GN007 General terms and conditions for provision of services.

4 General information on certification procedures

4.1 Basic conditions for issuing certificates of conformity

- The applicant for certification shall be registered according to applicable regulations.
- The product for which the applicant wishes to obtain a certificate shall be clearly and unambiguously identified.
- Normative documents (standards, directives, regulations, rules) according to which the certification process is conducted can be national (SIST standards), regional (CEN, CENELEC, ETSI standards, EU directives/regulations), or international (ISO, IEC standards, UN regulations).

The subject matter of certification shall be in accordance with the scope of the normative document under which the certification procedure is carried out. Agreement shall be reached with the applicant regarding the choice of the normative document.

4.2 Activities in the certification process

- Application for a service;
- Review and confirmation of the order;
- Evaluation (testing, inspection, management system audit);
- Certification review;
- Certification decision;
- Surveillance of issued certificates.



4.3 Application for a service

During an introductory meeting, SIQ informs the applicant about the certification procedures and the estimated costs.

The applicant initiates the certification procedure by submitting an application, which can be completed using the designated form or by confirming the provided offer or contract. By doing so, the applicant undertakes that they are aware of the certification rules and procedures and agree to comply with them. The applicant assumes full responsibility for payment of all costs associated with the certification procedure.

4.4 Review and confirmation of the order

SIQ reviews the order and received information to ensure that the details about the client and the product are sufficient for conducting the certification process, that the scope of certification, including the product type, normative document, and certification scheme, is clearly defined, and that it can carry out the certification procedure.

4.5 Evaluation (testing, inspection, management system audit)

Evaluation is carried out according to the certification scheme, based on a certification plan for testing, production control, and management system audit. During evaluation, the client is allowed to rectify any identified non-conformities. If evaluation is performed by subcontractors, SIQ shall obtain the applicant's agreement.

4.6 Certification review

SIQ conducts an independent review of the evaluation activities, including all information and reports on testing, control, and management system assessment. Based on a positive assessment of the conformity of all information and results related to the evaluation of the product, it is proposed that a certificate be issued for the product. If nonconformities were identified during the certification procedure, SIQ informs the client of the reasons for the refusal to issue a certificate.

4.7 Certification decision

The final independent decision to issue the certificate is made by the certification committee for products, processes and services, or in the case of issuing documents within the framework of a notified body, by the commission of the notified body for the relevant EU directive/regulation.

4.8 Surveillance of issued certificates

This activity is carried out during certification with regular annual surveillance of the product and production process. SIQ verifies the compliance of certified products, their production, and the quality management system through regular annual factory inspections. The surveillance includes regular factory inspection of production locations and, if required by the certification rules, surveillance testing of sampled products.

5 Certification within a regulated area

As a Notified Body, SIQ carries out certification (conformity assessment) within the regulated scope of EU Directives and Regulations, according to the modules for which SIQ is designated and notified.

Certification is carried out according to the requirements of the relevant EU directive/regulation and corresponding national legislation for products.

Certification (conformity assessment) within the EU regulated area can only be performed for the manufacturer.



Certification procedure activities for each EU directive/regulation include the design and production phase. They consist of one or two modules. SIQ, as a notified body, conducts conformity assessment procedures for the relevant module for which it is designated.

The detailed scope of SIQ's designation as a notified body with number 1304, including the products and procedures for which SIQ is designated, can be found in the <u>NANDO</u> database of notified bodies for specific EU directive/regulation.

The validity of certificates issued by SIQ as a notified body can be verified with the SIQ notified body on request. If a public database of certified products exists, the validity of the certificate can also be checked in the database. Information about the database, if available, is provided below for each specific EU directive/regulation.

5.1 Electromagnetic compatibility

Products subject to certification are defined by the Regulation on electromagnetic compatibility (Official Gazette of the Republic of Slovenia No. 39/16, 9/20) and the Directive relating to Electromagnetic Compatibility (EMC) <u>2014/30/EU</u> (Official Journal of the European Union L 96/2014).

SIQ is a notified body for conformity assessment, for carrying out the procedures defined in the Annex to the EMC Directive:

Annex III – Module B: EU-type examination.

5.2 Radio equipment

Products subject to certification are defined by the Regulation on radio equipment (Official Gazette of the Republic of Slovenia No. 03/16, 9/20, 124/23) and the Directive regarding the availability of radio equipment on the market (RED) <u>2014/53/EU</u> (Official Journal of the European Union L 153/2014).

SIQ is a notified body for conformity assessment of the essential requirements under Article 3 of the Radio Equipment Directive (RED), for carrying out the procedures defined in the Annex to the directive:

Annex III – Module B: EU-type examination.

5.3 Medical devices

The certification procedures for medical devices are defined by the Medical devices act (Official Gazette of the Republic of Slovenia No. 98/09) and the related implementing regulations, and the Directive on medical devices (MDD) 93/42/EEC (Official Journal of the European Union L 169/1993), now replaced by the Regulation on medical devices (MDR) No. 2017/745 (Official Journal of the European Union L 117/2017), relevant legal guidelines, taking into account the Code of conduct for notified bodies, and the applicable Slovenian legislation.

The specifics of the certification procedures for medical devices are described in detail in the information for clients (MDD DP006) for medical devices according to 93/42/EEC Directive (MDD) and (MDR DP006) according to Regulation (EU) 2017/745 (MDR).

A list of issued certificates is available in the European medical device database EUDAMED.

5.4 Equipment for use in potentially explosive atmospheres

Products subject to certification intended for use in explosion hazardous areas (Ex-equipment), are defined by the Regulation on explosion protection (Official Gazette of the Republic of Slovenia No. 41/16) and the Directive regarding equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)) 2014/34/EU (Official Journal of the European Union L 96/2014).



SIQ is a notified body for conformity assessment of equipment in Group I (mining electrical and non-electrical equipment) and Group II (industrial electrical equipment – for gases and dust, and non-electrical equipment – for gases and dust), for carrying out the procedures defined in the Annexes to the directive:

- Annex III Module B: EU-type examination;
- Annex IV Module D: Conformity to type based on quality assurance of the production process;
- Annex V Module F: Conformity to type based on product verification;
- Annex VI Module C1: Conformity to type based on internal production control plus supervised product testing;
- Annex VII Module E: Conformity to type based on product quality assurance;
- Annex IX Module G: Conformity based on unit verification; retention of documentation Article 13, (1) b (ii).

The specifics of the certification procedures for Ex-equipment are detailed in the EU guidelines on Type Examination, Conformity to Type and Unit Verification (TPEx07), Document Storage (TPEx08), Production Quality System Assessment (TPEx09), and Certification of Electrical Ex-Equipment Category 3 or with EPL Gc or Dc and Non-Electrical Ex-Equipment Categories 2 and 3 (TPEx10).

5.5 Machinery

Products subject to certification are defined by the Regulation on machinery safety (Official Gazette of the Republic of Slovenia No. 75/08, 66/10) and the Machinery directive (MD) <u>2006/42/EC</u> (Official Journal of the European Union L 157/2006).

SIQ is a notified body for conformity assessment of products listed in Annex IV to the Machinery Directive, for carrying out the procedures defined in the Annexes to the directive:

- Annex IX Module B: EC type-examination;
- Annex X Module H: Full quality assurance.

The manufacturer of a machine or a safety component listed in Annex IV may apply for the initiation of a regulatory procedure after an informative interview showing the nature of the product:

- procedure for EC-Type Examination from Annex IX and internal factory inspection for machines, as outlined in point 3 of Annex VIII (EC-Type Examination certificate);
- procedure for Full Quality Assurance from Annex X.

5.6 Noise emission from machines used outdoors

Products subject to certification are defined by the Regulation on noise emission from machines used outdoors (Official Gazette of the Republic of Slovenia No. 106/02, 50/05, 49/06) and the Directive concerning the emission of noise to the environment caused by equipment used outdoors (NOISE) <u>2000/14/EC</u> (Official Journal of the European Union L 162/2000).

SIQ is a notified body for conformity assessment, for carrying out the procedures defined in the Annexes to the directive:

- Annex V Mudule A1: Internal control of production with assessment of technical documentation and periodic checking;
- Annex VII Module G: Verification and attestation of a product;
- Annex VIII Module H: Full quality assurance.



5.7 Measuring instruments

Products subject to the design review of electricity meters are defined by the Regulation on measuring instruments (Official Gazette of the Republic of Slovenia No. 19/16, 98/23) and the Directive regarding the availability of measuring instruments on the market (MID) <u>2014/32/EU</u> (Official Journal of the European Union L 57/2014).

SIQ is a notified body for conformity assessment of active electrical energy meters (MI-003) as defined in Annex V, for carrying out the procedures defined in the Annexes to the Measuring Instruments Directive (MID):

- Annex II Module B: EU-type examination;
- Annex II Module D: Conformity to type based on production quality assurance;
- Annex II Module H: Conformity based on full quality assurance.

A list of issued certificates is available in the <u>database of approved types of measuring</u> <u>instruments</u> of the Office for Metrology of the Republic of Slovenia.

5.8 Construction products

The certification procedures for construction products are defined by the Construction products act (Official Gazette of the Republic of Slovenia No. 82/13) and the Regulation on the determination of harmonized conditions for marketing of construction products (CPR) No. <u>305/2011</u> (Official Journal of the European Union L 88/2011).

SIQ is a notified body for carrying out the assessment and verification of constancy of performance of traffic signs with variable messages according to EN 12966 and equipment for traffic control equipment – signal heads according to EN 12368, for carrying out procedures defined for System 1 in Annex I to the regulation.

Annex V to the CPR Regulation defines the activities for issuing a certificate of conformity by the Notified Body for the durability of the product characteristics under System 1, based on:

- determination of the product type based on the assessment of the construction product's characteristics (ITT), carried out through testing (including sampling), calculations, tabulated values, or descriptive documentation of the product;
- initial inspection of the manufacturing plant and factory production control (FPC);
- ongoing surveillance, assessment, and evaluation of factory production control (FPC).

The manufacturer performs:

- factory production control;
- further testing of samples taken by the manufacturer in the manufacturing plant according to the prescribed testing program.

SIQ performs certification procedures under system 1 for variable message traffic signs according to the EN 12966 standard and equipment for road traffic control and management – signal heads according to the EN 12368 standard.

5.9 Railway interoperability

The certification procedures for components and subsystems in railway transport are defined by the Railway safety act (Official Gazette of the Republic of Slovenia No. 30/18, 54/21) and related implementing regulations, and the Directive on railway interoperability in the European Union 2016/797.

SIQ is a notified body for conformity assessment of subsystems and components ENE, ROLLING STOCK, WAG, LOC&PAS and CCS (CCO, CCT), and for carrying out the conformity assessment



procedures defined in Modules CA1, CA2, CB, CD, CF, CH, CH1, CV, SB, SD, SF, SG, SH1, SH2.

A list of issued certificates is available in the European Railway Agency's interoperability and safety database <u>ERADIS</u>.

6 Certification based on type testing

SIQ carries out product certification based on type testing, evaluating all available information and test results against the requirements of the relevant standards without further inspection and surveillance.

Certificates are generally issued with a validity period of 3 years.

6.1 Issuance of CB certificate of conformity

SIQ is a national certification body and testing laboratory in the <u>IECEE CB scheme</u>, which is established within the testing and certification system for safety, electromagnetic compatibility, and energy efficiency of products under the International Electrotechnical Commission (IEC).

With a CB certificate and the associated test report, the supplier or manufacturer can easily, quickly, and cost-effectively obtain foreign certifications from the members of the IECEE CB scheme.

The scope of standards covered by SIQ in the IECEE CB scheme by categories is available on the <u>IECEE CB scheme</u> website.

Product testing is carried out according to international IEC standards within the scope of the scheme.

A list of certificates issued by IECEE members is available online in the <u>IECEE CB Test</u> <u>Certificates</u> database.

6.2 Issuance of SIQ certificate of conformity

The certification process can be carried out based on national SIST standards, European EN standards, international IEC or ISO standards or other normative documents (e.g., UN regulations) for technical areas which SIQ is proven to be qualified (safety, technical characteristics, electromagnetic compatibility, radio spectrum, equipment intended for use in potentially explosive atmospheres).

The basis for certification review may also be test reports obtained by the client from:

• A testing laboratory and certification body operating within the IECEE CB scheme, the IECEx scheme, or the ETICS agreement for CCA, CCA-EMC, ENEC, and ENEC+ schemes;

• A testing laboratory and certification body with which SIQ has a mutual cooperation agreement;

• A testing laboratory that meets specific conditions and is under the supervision of SIQ.

Additionally, a factory inspection report from a certification body operating within the ETICS agreement for the CIG scheme may also be used for certification review.

SIQ certificates of conformity are valid for products subject to certification, typically for three years or until the expiration date of the specified standards, whichever occurs first.

The validity of SIQ certificates of conformity can be verified upon request by the SIQ certification body for products, processes, and services.

7 Certification with regular surveillance of a product and a production process



The certification of products with regular surveillance of a product and a production process is carried out to obtain the following:

- licenses for use of the SIQ certification marks »SIQ«, »SIQ Type Approved«, and »SIQ Medical Approved«;
- licenses for use of the common European certification marks »<u>ENEC</u>«, »<u>ENEC+</u>«, and »<u>CCA</u>
 <u>EMC</u>« within the ETICS association;
- CCA NTR certificate within the ECS agreement, including the license for use of the »SIQ« certification mark;
- certificate within the IECEx scheme.

Detailed instructions for surveillance testing can be found in the document OD ENEC 324.

7.1 Issuance of licenses for use of the SIQ certification marks »SIQ«, »SIQ Type Approved«, and »SIQ Medical Approved«

The purpose of this certification is to provide a comprehensive system for determining conformity with applicable valid European safety and other European standards and to enable continuous monitoring of the stability of the production process while ensuring consistent compliance with requirements.

The SIQ certification marks on the product confirm the products' conformity while emphasizing the manufacturer's responsibility for user safety, protection of human health, and environmental preservation. Manufacturers and suppliers can use this as a competitive advantage.

The »SIQ« mark can be obtained by manufacturers or suppliers for products based on valid European EN safety standards for which SIQ is duly qualified.

The »SIQ Type Approved« mark can be obtained by manufacturers or suppliers for components that cannot be used independently but are intended for installation based on valid European EN safety standards for which SIQ is duly qualified.

The »SIQ Medical Approved« conformity mark can be obtained by manufacturers for products that cannot be used independently but are intended for installation in medical electrical equipment or are part of electrical medical systems, based on valid European EN standards for basic safety and essential characteristics of electrical medical products, for which SIQ is duly qualified.

The license holder can be a legal entity, either the manufacturer or supplier, who assumes full responsibility for the products marketed under their name.

By signing the license agreement, the license holder agrees to comply with all conditions for obtaining and maintaining the license.

Certification procedures, which include regular factory inspection, are designed according to international guidelines applicable under international agreements on mutual recognition among certification bodies. To obtain the license, a pre license factory inspection must be performed at all factory locations, according to the requirements specified in the CIG scheme document (e.g., CIG 021). To maintain the certificate, regular factory inspections must be carried out, and if required by the certification rules, surveillance testing of sampled products as part of the annual surveillance.

The basis for certification review may also be test reports obtained by the client from:

• A testing laboratory and certification body operating within the IECEE CB scheme, the IECEx scheme, or the ETICS agreement for CCA, CCA-EMC, ENEC, and ENEC+ schemes;

• A testing laboratory and certification body with which SIQ has a mutual cooperation agreement;



• A testing laboratory that meets specific conditions and is under the supervision of SIQ.

Additionally, a factory inspection report from a certification body operating within the ETICS agreement for the CIG scheme may also be used for a certification review.

For the maintenance of licenses for use of »SIQ« certification mark, SIQ charges an annual license fee, which also covers the costs of control testing. SIQ annually verifies the validity of issued licenses and informs license holders of any changes to the validity of the standards upon which the licenses were issued, as well as changes to the rules governing certification procedures.

In case of changes in the validity of standards or certification procedure requirements, the SIQ certification body for products, processes, and services sets a deadline by which the certificate or license holder must align the product with the requirements of the new applicable standard.

The basic rules for the operation of the SIQ schemes are the same as for the issuance of the NTR certificate under the CCA agreement.

The validity of licenses for the use of SIQ certification marks »SIQ«, »SIQ Type Approved« and »SIQ Medical Approved« can be verified upon request by the SIQ certification body for products, processes and services.

7.2 Issuance of licence for use of »ENEC« certification mark

SIQ is a signatory to mutual recognition agreements for common European marks of conformity to standards (ENEC, ENEC+, CCA EMC) of the ETICS association.

SIQ's participation in the ENEC agreement covers the following product categories:

- batteries (BATT),
- switches and automatic electrical controls (CONT),
- household and similar equipment (HOUS),
- installation accessories and connection devices (INST),
- information technology audio-video (ITAV),
- lighting (LITE),
- measurement, control, and laboratory equipment (MEAS),
- safety transformers (SAFE),
- portable tools (TOOL).

The certification process is carried out according to applicable European EN standards for product safety. The basic operating rules of the scheme are described in documents PD ENEC 301, PD ENEC 303, PD ENEC 304, PD ENEC 308, OD ENEC 324, OD ENEC 312, AD ENEC 327, AD ENEC 331, OD-CIG 023, OD ECS 080.

A list of issued ENEC licenses by ETICS members is available in the online database of issued <u>ENEC</u> licenses.

7.3 Issuance of licence for use of »ENEC+« certification mark

SIQ's participation in the ENEC+ agreement includes the verification of performance characteristics of luminaires according to the following ENEC+ specifications:

- EPRS 001: LED modules for general lighting Performance requirements;
- EPRS 002: Luminaires performance Part 1: General requirements;
- EPRS 003: Luminaire performance Part 2: Specific requirements for LED luminaires.



A valid ENEC certificate is a prerequisite for the issuance of the ENEC+ license.

A list of issued ENEC+ licenses, granted by ETICS association members, is available in the online database of ENEC+ licenses.

7.4 Issuance of the license for use of "CCA EMC" certification mark

SIQ's participation in the CCA-EMC agreement includes verifying the conformity of electromagnetic compatibility of products according to applicable European EN standards.

The basic operational rules of the scheme are described in documents OD CCA-EMC 501, OD CCA-EMC 505 and OD CCA-EMC 506.

The validity of licenses to use the certification mark "SIQ CCA EMC" can be verified upon request at SIQ certification body for products, processes and services.

7.5 Issuance of an NTR document under the CCA Agreement

When issuing the CCA NTR certificate, SIQ follows the rules defined in the documents of the agreement (e.g., PD CCA 210, OD CCA 207, PD CCA 223-7, PD CCA 228-1, PD CCA 223-2, OD CCA 226, OD CCA 237, and OD ECS 080).

The certification process is conducted according to the applicable European EN standards for product safety.

In addition to the NTR certificate, a license for use of the "SIQ" certification mark is also issued. The conditions for granting the certificate are in line with the requirements for obtaining and maintaining the certification mark license.

The validity of NTR certificates can be verified upon request by the SIQ certification body for products, processes, and services.

7.6 Scope of application and fees for individual certification marks

7.6.1 »SIQ« mark



The »SIQ« mark can be obtained by manufacturers or suppliers for products based on valid European EN safety standards for which SIQ is duly qualified.

Frequency of visits at the manufacturer: once a year.

7.6.2 »SIQ Type Approved« mark

| SIQ |
|----------------|
| Type Approved |
| Bauart Geprüft |

The »SIQ Type Approved« mark can be obtained by manufacturers or suppliers for components that cannot be used independently but are intended for installation based on valid European EN safety standards for which SIQ is duly qualified.

Frequency of visits at the manufacturer: once a year.

7.6.3 »SIQ Medical Approved« mark

| 6 | | Approved Medical Device |
|---|-----|-----------------------------------|
| | SIQ | IEC/EN 60601-X IEC/EN 60601-XX |

The »SIQ Medical Approved« conformity mark can be obtained by manufacturers for products that cannot be used independently but are intended for installation in medical electrical equipment or are part of electrical medical systems, based on valid European EN standards for basic safety and essential characteristics of electrical medical products, for which SIQ is duly qualified.

Frequency of visits to the manufacturer: once a year.

Remark: Citing standards on the certification mark is not mandatory.



7.6.4 »ENEC« mark



The »ENEC« mark with number 22, issued by SIQ, is a high-quality European mark for electrical products, demonstrating compliance with European EN safety standards.

Frequency of visits at the manufacturer: once a year for manufacturers who have production organized according to ISO 9001 standards (this requirement is mandatory for manufacturers of luminaires and luminaire components), and twice a year for all other manufacturers. Details regarding frequency are specified in the documents PD ENEC 301 Annex B and PD ENEC 308.

7.6.5 »ENEC+« mark



The »ENEC+« mark with number 22, issued by SIQ, is a conformity mark for the performance characteristics of luminaires, demonstrating compliance with ENEC+ specifications.

Frequency of visits to the manufacturer: once a year for manufacturers who have production organized according to ISO 9001 standards (this requirement is mandatory for manufacturers of luminaires and luminaire components), and twice a year for all other manufacturers. Details regarding frequency are specified in the documents PD ENEC 301 Annex B and PD ENEC 308.

7.6.6 »CCA EMC« mark



The "CCA EMC" conformity mark with the SIQ designation is a highquality European mark for electrical products, demonstrating compliance with European EN standards for electromagnetic compatibility.

Frequency of visits at the manufacturer: once a year.

7.7 Issuance of certificates within the IECEx scheme

SIQ is the national certification body and testing laboratory within the international <u>IECEx scheme</u> for testing and certifying equipment intended for use in potentially explosive atmospheres, as well as for assessing the competence of workshops for the repair of equipment used in such environments.

Certificates of conformity ExCoC, Test Reports ExTR, and Quality Assessment Reports QAR are issued in compliance with the rules defined in IECEx operational documents. Product testing and certification and assessments at manufacturers are conducted according to international standards (IEC and ISO). A test report ExTR is issued after completed product testing. A certificate of conformity ExCoC is issued in consideration of an ExTR and a quality assessment report QAR with an adequate scope, type of protection, and manufacturing location. Assessments at manufacturers for issuing QARs are conducted periodically every 12 months or 18 months in the case of the certified quality system according to ISO 9001, which is required for maintaining the validity of ExCoC and ExTR.

Within IECEx, SIQ also conducts assessments of service facilities for repairing Ex-equipment. The purpose of the assessment is to see if a service facility performs repair of Ex-equipment with an IECEx certificate in compliance with international standards (IEC and ISO). This assures the validity of IECEx certificates for Ex-equipment also after repair. Assessments of service facilities are conducted annually.

A list of issued certificates provided by IECEx members is available in the <u>IECEx Certificates</u> online database.

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8 Misuse of a certificate or a conformity mark

When publishing information related to certificates and when using certification marks, clarity must be ensured to prevent any potential misleading. The applicant must not use the certificate in a way that could be misleading or harmful to the reputation of SIQ.

SIQ monitors the use of certificates and certification marks. If SIQ finds that the applicant is incorrectly using the mark on a product or in advertising, or if the certificate or mark is used for uncertified products, it shall notify the client. If necessary, SIQ may initiate legal actions against the applicant. Abuse of a certificate or certification mark may also lead to the withdrawal and cancellation of the certificate.

The certificate may be withdrawn and cancelled if misuse of the certificate, certification mark, or other violation of the certification procedures is detected. In such cases, SIQ shall notify the applicant of the intended revocation, usually within 30 days, unless the reasons for the revocation are addressed. During this period, the certificate holder may correct the irregularities and provide evidence of the correction.

The following are considered abuses of a certification mark on a product or in advertising:

- if the mark deviates from the standard logo in shape or dimensions;
- if the mark is used for products for which no certification has been issued, or if changes have been made to the certified product without the knowledge and approval of SIQ;
- if the mark is used for purposes not covered by the certification (e.g., advertising or promoting product features that were not subject to certification);
- if the mark is used before signing or after the expiration of the licence agreement.

9 Withdrawal and cancellation of a certificate

A certificate may be withdrawn and cancelled if misuse of the certificate, certification mark, or other violations of certification procedures are identified.

SIQ may also cancel the certificate in the following cases:

- if the products no longer meet the requirements of applicable regulatory documents and the certificate holder fails to ensure compliance with new requirements;
- if the certification mark is incorrectly used to demonstrate compliance with other regulatory documents that were not the basis for certification or for products not included in the certification process;
- if the certificate holder does not wish to maintain the certificate or terminates the licence agreement;
- if the product is no longer being manufactured;
- if incomplete, false, or concealed information about the product or management system has been provided;
- if the certificate holder does not meet the requirements related to production site control or control testing;
- in the case of bankruptcy or cessation of business operations of the applicant;
- if the applicant does not settle the agreed financial obligations.

The request for certificate cancellation must be submitted using form CN231 Request for cancellation of license certificate.



10 Handling of complaints and appeals

The applicant may file a complaint against the work of SIQ or submit an appeal against a decision made by the SIQ certification body for products, processes, and services or notified body.

Complaints against the work of a certification body or a notified body are accepted by the certification manager. The complainant shall be notified in writing about the receipt of the complaint and the decision made. Complaints and irregularities are addressed following the SN029 procedure.

An appeal against a decision made by the SIQ certification body for products, processes and services shall be submitted in writing within 15 days from the decision, as specified in the <u>Appeals</u> <u>Regulation CR105S E</u>.

In the event of an appeal against a decision related to services within the IECEx scheme, the applicant may appeal to the IECEx scheme, as described in Annex A to the <u>IECEx01</u> document.

All other disputes fall within the competence of the Court of proper jurisdiction over the subject matter in Ljubljana. The currently valid legislation of the Republic of Slovenia is used for ruling all relations.

| | Contact person | Telephone No. |
|--|-------------------------|-----------------|
| | | |
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| Factory inspection | Simon Malovrh | 352 |
| Safety and Electromagnetics, testing | Andrej Škof | 854 |
| Notified body | - | |
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| RED | Marjan Mak | 878 |
| MDD in MDR | Ana Pribaković Borštnik | 153 |
| ATEX | Matej Debenc | 227 |
| MD | dr. Miha Otrin | 256 |
| NOISE | dr. Miha Otrin | 256 |
| MID | Matjaž Lindič | 310 |
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11 Contact persons



Product Certification

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