

SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY, LJUBLJANA

Introduction to SIQ

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May 2024



SIQ Ljubljana is an independent, impartial, and not-for-profit institution operating in the fields of conformity assessment of products and processes, in the field of metrology and in the field of training. SIQ Ljubljana has been founded according to the Institutes Act (Official Gazette of RS No. 12/92-1) as a private institute and not-for-profit institution. Its legal status is evident from the Agreement on the founding of an institute and registration documents.

Name

Full name: Slovenski institut za kakovost in meroslovje, Ljubljana

Short name: SIQ Ljubljana

English translation: Slovenian Institute of Quality and Metrology, Ljubljana.

Registration of the institute

Registration body: District Court of Law, Ljubljana.

Numbers and dates of registrations:

first registration: 199210779 / 1993-01-29;

transfer of registration into the central register: 199308050 / 1996-11-15;

registration number: 5700108000.

Registration of research organisation

Registration body: Ministry of Science and Technology

(now: Ministry of Education, Science and Sport)

Number and date of registration: 26 / 1993-07-07.

Mission

We assess, but also pass on knowledge and experience. By doing so, we contribute to the sustainable development of the society that, based on knowledge, high-quality services and products, is providing the conditions for a higher quality of life.

Vision

Being on the world market-oriented institution that reaches top positions in key areas of our operations and of which the advantages on a worldwide scale are knowledge and partner relations.

Motto

This vision is mirrored in the motto: Our knowledge, partner relations and complete solutions – the keys to business success.

Values

The values that guide us in fulfilling our mission and achieving the set objectives are the following:

In respect of the society:

- endeavours for the sustainable development of the society;
- transparency;
- honesty, independence and impartiality;

In respect of our partners:

- exceeding the expectations of our partners;
- competence and confidentiality;
- endeavours for long-term stability and good reputation of our institute;

In respect of our employees:

- professional and personal growth;
- team spirit;
- innovativeness.



FIELDS OF ACTIVITY

Conformity assessment of products, processes and services

- Testing and certification of various types of products listed in the Scope of Activities section; issuing of reports, certificates and other documents of conformity and granting of licences for the use of certification marks.
- Verification of information security.
- Inspection services, i.e.: factory inspection for certified products; conformity assessment of measures in the field of explosion protection (explosion protection documents, installation and maintenance of equipment for potentially explosive atmospheres) and assessment of competence of contractors; verification and inspection of measuring instruments; inspection in the field of railways.
- Assessment and certification of management systems and issuing of certificates and other documents of conformity.
- Acting as a validation and verification body for verification of reports on greenhouse gas emissions.
- Acting as a notified body under different directives and regulations.

Conformity assessments are performed according to national, international and other standards, as well as to national and foreign regulations.

Metrology

- Holder of two national measurement standards
- Calibration of measuring instruments
- Verification and inspection of measuring instruments
- Manufacture of measuring instruments
- Maintenance of measuring equipment
- Training

Training services

Organization of open and closed-group seminars, workshops, courses, conferences and panel discussions for our customers and the public at large with the aim to share knowledge and experience in the field of management systems, human resources management, applicable national and European technical legislation, technical issues and normative aspects related to product testing, calibration, assessment, certification and inspection.

Research and development

The area of conformity assessment and the area of metrology cover, in addition to their principal tasks, also research and development within the scope of quality, metrology, and standardization. This is the basis for registration of SIQ as a research organization.



ADMINISTRATIVE STRUCTURE

SIQ Ljubljana has been founded according to the Law on Institutions and is governed by SIQ Council. SIQ certification system is administered and supervised by the Board of Certification Body.

The members of both governing bodies of SIQ are the representatives of the interested public, economic, industrial and other associations representing the customers of SIQ's services.

HISTORY

1960 The grounds for the development of the activities of current SIQ are laid out in 1960 when the Institute for Automation is founded to ensure promotion of Slovenian electric and machine industry.

1961 Design units of individual factories of Iskra company are incorporated into the Institute for Automation to form a common research & development organization for entire Iskra.

1964 Progressive and systematic development of product testing, measuring techniques, and of activities related to the maintenance of measuring instruments takes place in the then established Sector for Measurements and Quality that operates as a central testing and metrological laboratory of Iskra. That is why the year 1964 is considered as the year of the establishment of the activities of current SIQ. Independence and impartiality are the underlying principles of that Sector from its very beginnings.

Establishment of the activities of product testing and maintenance and calibration of measuring instruments.

1974 The Sector for Measurements and Quality becomes an independent organization, i.e. ISKRA - Institute of Quality and Metrology (ISKRA - IKM).

1979 Acquisition of the first Yugoslavian authorization within the system of obligatory attestation – for measurements of radiofrequency disturbances of electrical apparatus.

1987 IKM is separated from Iskra and thus also formally becomes an independent organization.

1990 Start of the Management Systems Assessment activity

1992 The Slovenian Institute of Quality and Metrology is founded as a successor to IKM to realize the idea of an institution which will assure harmonization and compatibility with similar testing laboratories and certification bodies in Europe and throughout the world. In this way, new foundations are laid for participation of Slovenia in existing and developing international agreements for mutual recognition of test results.

Start of the Training activity.

1993 SIQ is accepted as a national certification body into the IECEE certification Scheme and start of the Explosion Protection activity.

1996 SIQ receives the first internationally valid accreditation in Slovenia as a calibration laboratory and is accepted into the IQNET – the international certification network for management systems assessment.



1998 SIQ becomes a holder of two national measurement standards, i.e., for electric quantities and for time and frequency.

2002 Start of the Gaming Technologies activity.

2004 Commencement of operations of the very first daughter company located in Croatia – SIQ Croatia d.o.o. – and the setup of the first testing laboratory abroad in the second daughter company – SIQ Italia S.r.l.

2011 SIQ opens a testing laboratory and a daughter company in Germany – SIQ Testing and Certification GmbH.

2012 SIQ opens a testing laboratory and a daughter company in South Africa – SIQ Conformity Assessment Africa (Pty) Ltd.

2013 SIQ opens a testing laboratory and a daughter company in Serbia – SIQ d.o.o. Beograd.

2017 New SIQ headquarters.

2022 End of Gaming Technologies activity and closure of the subsidiaries SIQ Croatia, SIQ Italia, SIQ Conformity Assessment Africa (Pty) Ltd and the branch offices in the USA and Spain.

2023 Launch of the verification and inspection of railway infrastructure through the SIQ subsidiary DIS RAIL.



SCOPE OF ACTIVITIES

The status of a Notified Body – SIQ Ljubljana

Notified Body No. 1304 under:

- Electromagnetic Compatibility Directive (2014/30/EU–EMC)
- Machinery Directive (2006/42/EC–MD)
- Medical Devices Directive (93/42/EEC–MDD)*
- Regulation on medical devices ((EU) 2017/745–MDR)
- Directive on equipment and protective systems intended for use in potentially explosive atmospheres (2014/34/EU–ATEX)
- Radio Equipment Directive (2014/53/EU–RED)
- Noise Emission by Outdoor Machinery Directive (2000/14/EC–Noise)
- Construction Products Regulation (Regulation (EU) No. 305/2011–CPR)
- Measuring Instruments Directive (2014/32/EU–MID)
- Interoperability of Rail System within the Community Directive (2016/797)

The scope of operation under individual directive is published in the NANDO EU database at the following address: <https://ec.europa.eu/growth/tools-databases/nando/>.

**From 26 May 2021, the Notified Bodies designated in accordance with Directive 93/42/EEC can no longer issue new certificates in accordance with the said directive but are only allowed to perform surveillance activities for the certificates issued in accordance with the said directive in the transition period, as specified in Article 130 of Regulation (EU) 2017/745.*

The status of a Notified Body – DIS RAIL

Notified Body No. 1304 under:

- Interoperability of Rail System within the Community Directive (2016/797)

Product testing

household and similar appliances, information technologies, audio and video, power electronics, entertainment electronic equipment, electrical medical equipment, measuring, inspection and laboratory equipment, electrical motor-operated and hand-held tools, portable tools, lighting and accessories, switches and automated electrical control devices, installation accessories and connecting devices, transformers and power transducers, batteries, power supply systems for electric vehicles, machinery

Safety

- Testing of electrical, mechanical, thermal, ergonomic, emission, and chemical hazards
- Testing of functional safety
- Exposure to electromagnetic fields
- Measuring of noise emission and vibration from machinery
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Environmental impacts

- Testing of mechanical exposures: vibration, impact and free-fall tests
- Testing of climatic exposures: temperature exposure, exposure to humidity, dust resistance and salt atmosphere testing



- Testing of degrees of protection provided by enclosures against ingress of solid foreign objects, ingress of water and against mechanical impacts.

Electromagnetic compatibility and radio spectrum

- Testing of electromagnetic compatibility of products (emission, resistance)
- Electromagnetic compatibility and environmental conditions testing for automotive equipment

Radio spectrum

- Measuring of radio spectrum

Information security

- Cyber security testing

Explosion protection

- Testing of equipment intended for use in potentially explosive atmospheres

Energy efficiency

- Measuring of energy and power consumption in a stand-by mode.

Visible and physical properties of equipment

Testing of road traffic command and control equipment

Testing of technical characteristics and presenting photometric data for lamps and luminaires

Interoperability of rail transport

- Interoperability of rail transport subsystems: energy, control-command, signalling, and rolling stock.

Certification of products, processes and services

Product certification

- Conformity certification in the regulatory sphere. The certification rules are defined in technical regulations issued by corresponding national authorities.
- Conformity certification based on type testing. Certification documents issued within this procedure are as follows:
 - SIQ certificate of conformity and/or
 - CB test certificate, i.e., an internationally valid certification document issued by SIQ Ljubljana as a member of the IECEE/CB Scheme.
- Conformity certification based on a type test of a product and regular inspection of a manufacturing process, and regular inspection of a product where so required by a certification scheme. Within this procedure, the following documents are issued:
 - licence to use the SIQ certification mark;
 - licence to use the SIQ BG certification mark;
 - licence to use the SIQ Medical Approved certification mark
 - licence to use the common European certification marks (ENEC, ENEC+, CCA EMC);
 - Notification of Test Results (NTR), i.e., an internationally valid certification document issued by SIQ Ljubljana as a member of the CENELEC Certification Agreement (CCA);



- IECEx certificate of conformity, i.e., an internationally valid certification document issued by SIQ Ljubljana as a member of the IECEx Scheme.

Service certification

- Service certification according to Regulation (EU) No. 910/2014 on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation).

Inspection services

- Factory inspection for certified products
- Inspection of explosion protection measures
- Inspection and verification of measuring equipment
- Inspection in the field of railways

Metrological activities

- Maintenance of national measurement standards for electrical quantities, time and frequency
- Maintenance of measurement standards for basic and derived units of electrical and other physical and chemical quantities
- Calibration and verification of measuring instruments
- Manufacture of measuring instruments
- Repair and adjustment of measuring instruments and equipment
- Training

Management systems certification

SIQ Ljubljana performs certification of various management systems. Our auditors and experts master a wide range of industry branches, e. g. electrical, machine, chemical, and paper industries, and also service organizations, such as hotels, banks, health institutions, schools and public administration. More and more organisations are establishing an integrated management system of which the main feature is compliance with the requirements of more than one management system: quality management system in combination with environmental, occupational health and safety, food safety or information security management systems, or corporate responsibility. Audits of such integrated management systems are usually jointly performed.

Our services include:

- management systems assessment and certification according to ISO 9001 standard (quality management system)
- ISO 14001 standard (environmental management system)
- EMAS scheme (eco-management and audit scheme – Regulation (EU) 1221/2009 and Regulation (EU) 2017/1505)
- ISO 50001 standard (energy management system)
- BS OHSAS 18001 standard (occupational health and safety management system)
- ISO 45001 standard (occupational health and safety management system)
- SA 8000 standard and IQNET SR 10 specification (social responsibility)
- ISO 9001 standard including HACCP, HACCP system and the following standards: ISO 22000 (food safety management system), IFS (International Food Standard), IFS Logistic, BRC Global Standard for Food Safety
- ISO 55001 standard (asset management – management systems)



ISO/IEC 27001 (information security management system), ISO/IEC 20000 (IT service management system), ISO 22301 (societal security – business continuity management systems), and ISO/IEC 27018 (Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors), ISO/IEC 27017:2015 (information technology – security techniques – code of practice for information security controls based on ISO/IEC 27002 for cloud services) and ISO/IEC 27701:2019 (security techniques – extension to ISO/IEC 27001 and ISO/IEC 27002 for privacy information management – requirements and guidelines) standards
IATF 16949 standard (quality system in automotive industry)
ISO 13485 standard (quality management system in production of medical devices)
ISO 15378 standard (Primary packaging materials for medicinal products -- Particular requirements for the application of ISO 9001:2015, with reference to Good Manufacturing Practice (GMP))
Quality in Education model (quality for the future of education and schooling)
ISO 22716 standard (Cosmetics – Good Manufacturing Practices (GMP))
NGO model (quality standard for non-governmental organizations)
FSC CoC standard (FSC chain of custody)
EU Council Regulations no. 333/2011, 715/2013 and 1179/2012 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council of the EU
EN 15224 standard (health care services – quality management systems)
ISO 28000:2017 standard (specification for security management systems for the supply chain)
NATO standard AQAP-2110 NATO quality assurance requirements for design, development and production, Edition D, Version 1, June 2016
Food Supplements Europe Guide to Good Manufacturing Practice (GMP) for Manufacturers of Food Supplements
ISO 37001 (Anti-bribery management systems);
ISO/IEC 33061 (Information technology — Process assessment — Process assessment model for software life cycle processes);

Validation and verification

verification of reports on greenhouse gas emissions according to the Commission implementing Regulation (EU) 2018/2067 with amendments, Commission implementing Regulation (EU) 2018/2066 with amendments and Commission delegated Regulation (EU) 2019/331 with amendments.;

verification of accuracy of documentation and declaration of conformity for fluorinated greenhouse gases according to Regulation (EU) No 517/2014

verification of sustainability reports according to GRI standards (Global Reporting Initiative)

carbon footprint verification (ISO 14064-3) or carbon footprint calculation (ISO 140641, ISO 14064-2 and ISO 14067 standards, GHG protocol and PAS 2020).

SIQ Ljubljana co-operates with peer foreign institutions on the basis of bilateral agreements and within the IQNET – the International Certification Network.

Training programmes

Management systems – quality, sustainable development, environment, energy, occupational safety and health, medical devices, trade in pharmaceutical products, information security, business continuity, food safety: presentation of the requirements and various aspects of ISO 9001, ISO 14001, ISO 50001, BS OHSAS 18001, ISO/IEC 27001, ISO/IEC 27002, ISO 22301, ISO 22000, IFS FOOD standards; establishment of a management system and efficient maintenance and integration of a management system with other management systems and



models; legislation; courses for lead and internal auditors; training for management systems managers; School of Quality; School of food safety.

Production, automotive industry and technical: presentation of the requirements and specific aspects of IATF 16949, AIAG & VDA standards; establishment of a management system and efficient maintenance and integration of a management system with other management systems and models; legislation; courses for internal auditors, product conformity and CE mark; directives and technical requirements for machinery; School for lean project improvement managers, School for working group managers in production.

Laboratories, inspection and certification bodies: presentation of the requirements of ISO/IEC 17025, ISO/IEC 17020, ISO/IEC 17065, EN ISO 15189 standards; accreditation of a laboratory, control of measuring equipment, measuring uncertainty; validation of methods of analysis, courses for internal auditors; School of quality for analytical laboratories.

Management and human resources: a set of training events and drills in employee management business and sales skills: satisfaction, motivation, annual employee performance evaluation interviews, selection interviews, onboarding, communication, competence, work performance an efficiency, negotiations, sales, management of working groups; School of modern leadership.

Explosion protection.



SIQ LJUBLJANA IN FIGURES

Employees	
permanently employed in SIQ Ljubljana	169
permanently employed abroad (SIQ Testing and Certification GmbH, SIQ d.o.o. Beograd)	15
permanently employed in DIS RAIL, d.o.o.	4
Freelance auditors and experts	231

INTERNATIONAL CO-OPERATION

SIQ Ljubljana participates as a national certification body (NCB) in three multilateral recognition arrangements:

- in **IECEE/CB** Scheme set up within the system for testing and certification of safety and electromagnetic compatibility of electrical equipment (IECEE) and under the International Electrotechnical Commission
- in **IECEX** Scheme for testing and certification of electrical equipment for use in potentially explosive atmospheres, and also for assessment of competence of service facilities of equipment for potentially explosive atmospheres
- in **ETICS** (European Testing Inspection Certification System)

Signatory to mutual recognition arrangements on the use of commonly agreed European marks of conformity to standards:

- **ENEC** – a mark of conformity covering safety luminaires and accessories, electrical switching and control devices, transformers, electrical household appliances, electric hand-held and portable tools, information technology equipment, alarm systems, measuring and laboratory equipment and batteries.
- **ENEC+** – a mark of conformity covering technical characteristics of products within ENEC for LED modules and LED based luminaires.
- **CCA EMC** – a mark of conformity covering conformity to European standards for electromagnetic compatibility

Member of **IQNET** – The International Certification Network

- International partnership of organizations providing management systems assessment and certification services

Member of **IQNET** Academy

- The academy created within IQNet Association, focused on the international recognition of the training courses provided by its members

Designated body by the Metrology Institute of the Republic of Slovenia (MIRS)

- Member of the EURAMET (European Association of National Metrology Institutes)
- Member of BIPM (Bureau International des Poids et Mesures)



RECOGNITIONS FOR TECHNICAL COMPETENCE AND SCOPE OF ACCREDITATIONS, AUTHORISATIONS AND RECOGNITIONS

SIQ Ljubljana has been granted accreditations and recognitions by the following institutions:

SA: Slovenian Accreditation

ATS: Accreditation Body of Serbia

JAZMP: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

MIRS: Metrology Institute of the Republic of Slovenia

Notified Body (No. 1304)

<p><i>Machinery Directive 2006/42/EC</i></p>	<p><i>Notified Body for the types of machinery listed in Annex IV to Directive 2006/42/EC</i></p> <p>Annex IX – Article 12 (3)(b) and (4)(a): EC type-examination</p> <p>Annex X – Article 12 (3)(c) and (4)(b): Full quality assurance</p> <p><i>except for:</i></p> <ul style="list-style-type: none"> - machinery for underground working (section A12) - machines for the manufacture of pyrotechnics (section A17) - roll-over protection structures - ROPS (section B4) - falling-object protective structures - FOPS (section B5)
<p><i>ATEX Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres</i></p>	<p><i>Notified Body for the equipment referred to in Directive 2014/34/EU</i></p> <p>Annex III – Module B: EU type-examination</p> <p>Annex IV – Module D: Conformity to type based on quality assurance of the production process</p> <p>Annex V – Module F: Conformity to type based on product verification</p> <p>Annex VI – Module C1: Conformity to type based on internal production control plus supervised product testing</p> <p>Annex VII – Module E: Conformity to type based on product quality assurance</p> <p>Annex VIII – Module A: Internal production control</p> <p>Annex IX – Module G: conformity based on unit verification</p> <p>Equipment-group I, electrical</p> <p>Equipment-group I, non-electrical</p> <p>Equipment-group II, dust, electrical</p> <p>Equipment-group II, dust, non-electrical</p> <p>Equipment-group II, gas, electrical</p> <p>Equipment-group II, gas, non-electrical</p>
<p><i>EMC Directive 2014/30/EU</i></p>	<p>Notified Body under Directive 2014/30/EU for electrical and electronic devices (Annex III).</p> <p>Module B: EU type-examination</p>
<p><i>RE Directive 2014/53/EU</i></p>	<p><i>Notified Body for entire equipment covered by Directive 2014/53/EU</i></p> <p>Module B: EU type-examination</p>



<p>Directive 2000/14/EC on noise emissions from machinery</p>	<p><i>Notified Body for the entire equipment from Article 10 of Directive 2000/14/EC</i></p> <p>Annex VI: Internal control of production with assessment of technical documentation and periodical checking</p> <p>Annex VII: Unit verification</p> <p>Annex VIII: Full quality assurance</p>
<p>Construction Products Regulation (EU No. 305/2011)</p>	<p><i>Notified Body for the following categories of construction products covered by Regulation (EU) No. 305/2011</i></p> <p>System 1:</p> <ul style="list-style-type: none"> - Variable message traffic signs (EN 12966-1) - Signal heads (EN 12368)
<p>MI Directive 2014/32/EU</p>	<p><i>Notified body for active electrical energy meters</i></p> <p>Module B: EU type-examination</p> <p>Module D: Conformity to type based on quality assurance of the production process</p> <p>Module H1: Conformity based on full quality assurance plus design examination</p>
<p>Directive 2016/797 on the interoperability of the rail system within the Community</p>	<p><i>Notified body under Directive 2016/797 on the interoperability of the rail system within the Community for the following conventional subsystems:</i></p> <ul style="list-style-type: none"> - Energy (Article 9 (2), Annex IV) <ul style="list-style-type: none"> ENE CR Dec 2011/274 ENE Reg 1301/2014 SRT Dec 2008/163 SRT Reg 1303/2014 - Control-command and signalling (Article 9 (2), Annex IV) <ul style="list-style-type: none"> CCS Dec 2012/88 SRT Dec 2008/163 CCS CR Dec 2006/679 - Rolling stock (Article 9 (2), Annex IV) <ul style="list-style-type: none"> LOC&PAS CR Dec 2011/291 NOI CR Dec 2006/66 PRM Dec 2008/164 WAG CR Dec 2006/861 NOI Reg 2019/774 SRT Dec 2008/163 PRM Reg 1300/2014 SRT Reg 1303/2014 LOC&PAS Reg 1302/2014 NOI CR Dec 2011/229 WAG Reg 321/2013 PRM Reg 2019/772

Notified Body (No. 1304)

<p>Regulation (EU) 2017/745 on medical devices</p>	<p><i>Notified Body for the following categories of medical devices and the following procedures covered by Regulation (EU) 2017/745:</i></p>
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I. CODES THAT REFLECT DESIGN AND INTENDED PURPOSE OF THE DEVICE

A. Active devices

MDA CODE	Active non-implantable devices for imaging, monitoring and/or diagnosis	ANNEXES					CONDIT IONS
		IX (I)	IX (II)	X	XI (A)	XI (B)	
MDA 0202	Active non-implantable imaging devices utilising non-ionizing radiation	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
MDA 0203	Active non-implantable devices for monitoring of vital physiological parameters	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
MDA 0204	Other active non-implantable devices for monitoring and / or diagnosis	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	

MDA CODE	Active non-implantable therapeutic devices and general active non-implantable devices	ANNEXES					CONDIT IONS
		IX (I)	IX (II)	X	XI (A)	XI (B)	
MDA 0302	Active non-implantable devices utilising non-ionizing radiation	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDA 0305	Active non-implantable devices for stimulation or inhibition	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
MDA 0307	Active non-implantable respiratory devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDA 0308	Active non-implantable devices for wound and skin care	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
MDA 0309	Active non-implantable ophthalmologic devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Annexes X and XI(B) for lasers only. Other annexes without limitations
MDA 0310	Active non-implantable devices for ear, nose and throat	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
MDA 0311	Active non-implantable dental devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Annexes X and XI(B) for lasers only. Other annexes without limitations
MDA 0312	Other active non-implantable surgical devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDA 0313	Active non-implantable prostheses, devices for	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	



	rehabilitation and devices for patient positioning and transport						
MDA 0315	Software	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDA 0317	Active non-implantable devices for cleaning, disinfection and sterilisation	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDA 0318	Other active non-implantable devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

B Non-active devices

MDN CODE	Non-active implants and long term surgically invasive devices	ANNEXES					CONDITIONS
		IX (I)	IX (II)	X	XI (A)	XI (B)	
MDN 1102	Non-active osteo- and orthopaedic implants	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1103	Non-active dental implants and dental materials	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1104	Non-active soft tissue and other implants	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Nonabsorbable stitches only

MDN CODE	Non-active non-implantable devices	ANNEXES					CONDITIONS
		IX (I)	IX (II)	X	XI (A)	XI (B)	
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Devices for dialysis excluded
MDN 1203	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1204	Non-active non-implantable devices for wound and skin care	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1205	Non-active non-implantable orthopaedic and rehabilitation devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1206	Non-active non-implantable ophthalmologic devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1207	Non-active non-implantable diagnostic devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1208	Non-active non-implantable instruments	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1209	Non-active non-implantable dental materials	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MDN 1213	Non-active non-implantable devices composed of substances	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	



	to be introduced into the human body via a body orifice or the dermal route						
MDN 1214	General non-active non-implantable devices used in health care and other nonactive non-implantable devices	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

II. HORIZONTAL CODES

MDS CODE	Devices with specific characteristics		CONDITIONS
MDS 1001	Devices incorporating medicinal substances	<input checked="" type="checkbox"/>	
MDS 1004	Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council	<input checked="" type="checkbox"/>	
MDS 1005	Devices in sterile condition	<input checked="" type="checkbox"/>	Aseptic processing, filtration, steam sterilisation, ethylene oxide gas sterilisation, sterilisation with non-ionising radiation
MDS 1006	Reusable surgical instruments	<input checked="" type="checkbox"/>	
MDS 1007	Devices incorporating or consisting of nanomaterial	<input checked="" type="checkbox"/>	
MDS 1008	Devices utilising biologically active coatings and / or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body	<input checked="" type="checkbox"/>	Biologically active coatings and / or materials excluded.
MDS 1009	Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices	<input checked="" type="checkbox"/>	
MDS 1010	Devices with a measuring function	<input checked="" type="checkbox"/>	
MDS 1011	Devices in systems or procedure packs	<input checked="" type="checkbox"/>	
MDS 1012	Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	<input checked="" type="checkbox"/>	
MDS 1013	Class III custom-made implantable devices	<input checked="" type="checkbox"/>	Orthopaedic implantable devices only.

MDT CODE	Devices for which specific technologies or processes are used		CONDITIONS
MDT 2001	Devices manufactured using metal processing	<input checked="" type="checkbox"/>	
MDT 2002	Devices manufactured using plastic processing	<input checked="" type="checkbox"/>	
MDT 2003	Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	<input checked="" type="checkbox"/>	



MDT 2004	Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	<input checked="" type="checkbox"/>	
MDT 2006	Devices manufactured using chemical processing	<input checked="" type="checkbox"/>	
MDT 2007	Devices which require knowledge regarding the production of pharmaceuticals	<input checked="" type="checkbox"/>	
MDT 2008	Devices manufactured in clean rooms and associated controlled environments	<input checked="" type="checkbox"/>	
MDT 2010	Devices manufactured using electronic components including communication devices	<input checked="" type="checkbox"/>	
MDT 2011	Devices which require packaging, including labelling	<input checked="" type="checkbox"/>	
MDT 2012	Devices which require installation, refurbishment	<input checked="" type="checkbox"/>	
MDT 2013	Devices which have undergone reprocessing	<input checked="" type="checkbox"/>	



Notified Body (No. 1304) (continued)

Medical Devices Directive (93/42/EEC)

From 26 May 2021, the Notified Bodies designated in accordance with Directive 93/42/EEC can no longer issue new certificates in accordance with the said directive but are only allowed to perform surveillance activities for the certificates issued in accordance with the said directive in the transition period, as specified in Article 130 of Regulation (EU) 2017/745.

The surveillance activities for the certificates validly issued in accordance with Directive 93/42/EEC are performed for the following categories of medical devices:

A: General non-active medical devices

- Non-active devices for anaesthesia, emergency and intensive care (Annex II, V, VI)
- Non-active devices for injection, infusion and transfusion (Annex II, V, VI)
- Non-active devices for orthopaedics and rehabilitation (Annex II, V, VI)
- Non-active medical devices with measuring function (Annex II, V, VI)
- Non-active ophthalmologic devices (Annex II, V, VI)
- Non-active instruments (Annex II, V, VI)
- Accessories in pregnancy (Annex II, V)
- Non-active devices for disinfecting, cleaning, rinsing (Annex II, V)
- Non-active medical devices for ingestion (Annex II, V)
- Non-active orthopaedic implants (Annex II, V)
- Bandages and wound dressings (Annex II, V, VI)
- Suture material and clamps (Annex II, V, VI)
- Other medical devices for wound care (Annex II, V, VI)
- Non-active dental devices and instruments (Annex II, V, VI)

B: General active medical devices:

- Devices for extra-corporal circulation, infusion and haemopheresis – only infant incubators included (Annex II, V, VI)
- Respiratory devices (Annex II, V, VI)
- Devices for stimulation or inhibition (Annex II, III, IV, V, VI)
- Active surgical devices (Annex II, V, VI)
- Active ophthalmologic devices (Annex II, III, IV, V, VI)
- Active dental devices (Annex II, III, IV; V, VI)
- Active devices for disinfection and sterilisation (Annex II, V, VI)
- Active devices for positioning and transport of patients (Annex II, V, VI)
- Software (Appendix II, V, VI)
- Accessories for diagnostic imaging and therapy with ionizing radiation (Appendix II, V, VI)
- Accessories for diagnostic imaging and radiation therapy with non-ionizing radiation (Appendix II, III, IV, V, VI)
- Monitoring devices of non-vital physiological parameters (Annex II, III, IV, V, VI)
- Monitoring devices of vital physiological parameters (Annex II, III, IV, V, VI)
- Devices that use non-ionizing radiation (Annex II, V; VI)
- Medical devices incorporating medicals, subject of Directive 2001/83/EC
- Medical devices, subject of Directive 2006/42/EC on machinery
- Medical devices in sterile condition – without sterilisation with formaldehyde
- Medical devices which contain software / use software / are controlled by software



Conformity assessment of products: testing

<p><i>SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number LP-009 in the field of testing (SIST EN ISO/IEC 17025)</i></p> <p><i>certificate: LP-009</i> <i>standard: SIST EN ISO/IEC 17025</i> http://www.slo-akreditacija.si/</p>	<p><i>Testing of safety of products</i></p> <ul style="list-style-type: none">- household and similar appliances- portable tools- luminaires- safety transformers- switches and automatic electrical control devices- batteries- power supply systems for electric vehicles- information technology, audio/video, power electronics- entertainment electronics- laboratory, measuring and inspection equipment- electrical medical equipment- machinery <p><i>Testing of electromagnetic compatibility</i></p> <ul style="list-style-type: none">- emissions- resistance <p><i>Testing of radio spectrum</i></p> <p><i>Testing of human exposure to electromagnetic fields</i></p> <p><i>Testing of visible and physical properties</i></p> <ul style="list-style-type: none">- traffic road equipment- lighting <p><i>Testing of low energy consumption</i></p> <p><i>Testing of environmental impacts</i></p> <p><i>Testing of equipment for use in potentially explosive atmospheres</i></p> <ul style="list-style-type: none">- in electrical and non-electrical equipment- in devices and components <p><i>Testing of product safety in SIQ Testing and Certification GmbH in a partial scope:</i></p> <ul style="list-style-type: none">- information technology and audio-video, power electronics- electrical medical equipment- laboratory, measuring and inspection equipment
<p>ATS <i>certificate: 01-439</i> <i>standard: ISO/IEC 17025</i> http://www.ats.rs/</p>	<p><i>Testing of electromagnetic compatibility and testing of product safety in SIQ d.o.o. Beograd</i></p> <p><i>Product categories:</i></p> <ul style="list-style-type: none">- household and similar electrical appliances- audio/video, IT and communication technology equipment- electrical machinery equipment



Conformity assessment of products: certification

SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CP-001 in the field of certification of products, processes and services (SIST EN ISO/IEC 17065)

certificate: CP-001
standard: SIST EN ISO/IEC 17065
<http://www.slo-akreditacija.si/>

Certification of safety of products

- with regular inspection of the product and the manufacturing process
- based on type testing
- according to Slovenian regulation

Product categories:

- electrical household appliances
- IT equipment
- laboratory, measuring and inspection equipment
- audio/video, IT and communication technology equipment
- electrical lamps and accessories
- electrical transformers
- electrical switches
- electrical control devices
- installation accessories and connection devices
- sockets and socket outlets
- hand-held and motor-operated electric tools
- medical electrical equipment
- electrical traffic signs
- machinery
- medical electrical devices
- radio equipment
- batteries

Certification of electromagnetic compatibility and electromagnetic radiation

Certification of radio spectrum

Certification of visible and physical properties

- with regular inspection of the product and manufacturing process
- based on type testing

Product categories:

- traffic road equipment
- lighting

Certification of equipment for use in potentially explosive atmospheres

Design examination of active electrical energy meters

Conformity assessment of services: certification

SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CP-001 in the field of certification of products, processes and services (SIST EN ISO/IEC 17065)

certificate: CP-001
standard: ISO/IEC 17065
<http://www.slo-akreditacija.si/>

Certification of services:

- according to (EU) Regulation 910/2014, on electronic identification and trust services for electronic transactions in the internal market (EIDAS).



Conformity assessment of products: inspection

<p><i>SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number K-002 inspection (SIST EN ISO/IEC 17020, Type A)</i></p> <p><i>certificate: K-002</i> <i>standard: SIST EN ISO/IEC 17020</i> <i>type of inspection body: A</i> http://www.slo-akreditacija.si/</p>	<p><i>Conformity assessment of measures in the field of explosion protection</i></p> <ul style="list-style-type: none">- inspection of explosion protection documents- inspection of installation and maintenance of equipment for potentially explosive atmospheres- inspection of competence of contractors for installation, maintenance and repair of equipment for potentially explosive atmospheres- inspection of Ex-equipment in use- assessment of causes of explosion and assessment of Ex-equipment after explosion <p><i>Inspection and verification of measuring instruments</i></p> <ul style="list-style-type: none">- tire pressure measuring instruments- exhaust gas analyzers- exhaust gas analyzers for motor vehicles (compression-ignition)- blood pressure measuring devices <p><i>Inspection in the field of railways</i></p> <ul style="list-style-type: none">- Risk management procedure and the results of its application
<p>ATS <i>certificate 06-190</i> <i>standard: ISO/IEC 17020</i> <i>type of inspection body: A</i> http://www.ats.rs/</p>	<p><i>Inspection of safety parameters</i> <i>SIQ d.o.o. Beograd</i></p>



Metrology

SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number LK-001 in the field of calibration (SIST EN ISO/IEC 17025)

certificate: LK-001

standard: SIST EN ISO/IEC 17025

<http://www.slo-akreditacija.si/>

Calibration of measuring instruments and measurement standards for:

- Electrical quantities
 - o DC and low-frequency (LF) quantities:
 - voltage: DC and AC voltage, power quality parameters, high voltage (DC, AC), pulse amplitude
 - current: DC and AC current, power quality parameters
 - voltage ratio
 - AC/DC voltage transfer
 - AC/DC current transfer
 - power and energy: apparent, active, reactive
 - resistance: AC and DC resistance, impedance
 - capacitance: LF and HF capacitance
 - dissipation factor
 - o High-frequency (HF) quantities:
 - HF voltage: CW flatness, matched output voltage of generator, voltmeters indicating incident voltage, voltmeters indicating voltage at input terminal
 - Impedance: voltage reflection coefficient (VRC; Scalar), directivity (D; Scalar), S-parameters; reflection and transmission (S_{ii} and S_{ij}; real and imaginary)
 - HF power: absolute, relative
 - Attenuation
 - EMC; artificial mains network
 - Longitudinal conversion loss (LCL)
 - EMC; coupling-decoupling networks
 - EMC; transients
 - EMC; electrostatic discharge
 - EMC CISPR detectors
- Time and frequency:
 - o time:
 - time scale difference: local clock vs. UTC, local clock vs. UTC(SIQ)
 - time interval
 - rise time
 - o frequency:
 - frequency
 - modulation: amplitude, frequency and phase modulation
 - distortion
 - harmonic content
- Dimensional quantities:
 - o length: diameter
 - o angle
 - o speed (speedometer)
- Mechanical quantities:
 - o force
 - o balances
 - o gauge pressure
 - o acceleration
- Acoustical quantities:



	<ul style="list-style-type: none">○ acoustical pressure○ sound exposure○ vibration: acceleration, velocity, displacement○ transducers (electrical quantities): charge sensitivity of accelerometer, charge sensitivity of charge amplifier, microphones, sound level meters, electroacoustic filters- Optical quantities:<ul style="list-style-type: none">○ optical power: absolute power, attenuation, attenuation linearity○ optical time domain reflectometers: loss scale attenuation coefficient, offset error, distance scale deviation, event and attenuation deadzone, dynamic range of OTDR○ glass fibres: optical length at known group refractive index○ opacity and light transmittance: opacity rate, opacity coefficient, light transmittance- Temperature, humidity and thermos-physical properties:<ul style="list-style-type: none">○ temperature:<ul style="list-style-type: none">▪ internal reference junction▪ resistance temperature indicators and simulators - direct measurement▪ resistance temperature indicators and simulators▪ thermocouple temperature indicators and simulators – direct measurement▪ direct voltage temperature simulators and indicator○ evaluation of climatic controlled chambers:<ul style="list-style-type: none">▪ temperature chambers○ humidity:<ul style="list-style-type: none">▪ humidity chambers
<p>MIRS decision no.: 6401-18/2008/75 http://www.mirs.si</p>	<p><i>Holder of national measurement standards for</i></p> <ul style="list-style-type: none">- electric quantities- time and frequency
<p>MIRS decision no.: 6416-2/2012/14 official stamp identification: 349 http://www.mirs.si</p>	<p><i>Appointed entity for carrying out compliance assessment and first, regular and additional verifications of:</i></p> <ul style="list-style-type: none">- Instruments for tire pressure measuring and instruments for tire pressure measuring, which can carry EEC marks and signs- Exhaust gas analysers and instruments for measuring the exhaust gas of motor vehicles (compression-ignition)- Blood pressure measuring devices



Management systems certification

SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CS-001 in the field of certification of management systems (SIST EN ISO/IEC 17021-1)

certificate: CS-001

standard: SIST EN ISO/IEC 17021-1

<http://www.slo-akreditacija.si/>

Assessment and certification of quality management systems according to ISO 9001:2015 standard, taking into account ISO/IEC 17021-3:2019

- agriculture, forestry and fishing;
- mining and quarrying
- food products, beverages and tobacco
- textiles and textile products
- leather and leather products
- wood and wood products
- pulp, paper and paper products
- publishing companies
- printing companies
- manufacture of coke and refined petroleum products (19.2 only)
- nuclear fuel
- chemicals, chemical products and fibres
- pharmaceuticals
- rubber and plastic products
- non-metallic mineral products
- concrete, cement, lime and plaster etc.
- basic metals
- machinery and equipment
- electrical and optical equipment
- shipbuilding
- aerospace (33.16 only)
- other transport equipment
- manufacturing not elsewhere classified
- recycling
- electricity supply
- gas supply
- water supply
- construction
- wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods
- hotels and restaurants
- transport, storage and communication
- financial intermediation, real estate, renting
- information technology
- engineering services
- other services
- public administration
- education
- health and social work
- other social services

SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CS-001 in the field of certification of management systems (SIST EN ISO/IEC 17021-1)

certificate: CS-001

standard: SIST EN ISO/IEC 17021-1

<http://www.slo-akreditacija.si/>

Certification of environmental management systems according to ISO 14001:2015 standard, taking into account ISO/IEC 1701-2:2019

- agriculture, forestry and fishing;
- mining and quarrying
- food products, beverages and tobacco
- textiles and textile products
- leather and leather products
- wood and wood products
- pulp, paper and paper products
- publishing companies
- printing companies
- manufacture of coke and refined petroleum products
- nuclear fuel
- chemicals, chemical products and fibres
- pharmaceuticals
- rubber and plastic products
- non-metallic mineral products
- concrete, cement, lime and plaster etc.
- basic metals
- machinery and equipment



	<ul style="list-style-type: none"> - electrical and optical equipment - shipbuilding - aerospace - other transport equipment - manufacturing not elsewhere classified - recycling - electricity supply - gas supply - water supply - construction - wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods - hotels and restaurants - transport, storage and communication - financial intermediation, real estate, renting - information technology - engineering services - other services - public administration - education - health and social work - veterinary activities - other social services
<p><i>SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CS-001 in the field of certification of management systems (SIST EN ISO/IEC 17021-1)</i></p> <p><i>certificate: CS-001</i> <i>standard: SIST EN ISO/IEC 17021-1</i> http://www.slo-akreditacija.si/</p>	<p><i>Certification of occupational health and safety management systems according to ISO 45001:2018 standard, taking into account ISO/IEC 1721-10:2018</i></p> <ul style="list-style-type: none"> - agriculture, forestry and fishing; - mining and quarrying - food products, beverages and tobacco - textiles and textile products - leather and leather products - wood and wood products - pulp, paper and paper products - publishing companies - printing companies - manufacture of coke and refined petroleum products - nuclear fuel - chemicals, chemical products and fibres /excluding radioactive substances under ISO 45001) - pharmaceuticals - rubber and plastic products - non-metallic mineral products - concrete, cement, lime and plaster etc. - basic metals - machinery and equipment - electrical and optical equipment - other transport equipment - manufacturing not elsewhere classified - recycling - electricity supply - gas supply - water supply - construction - wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods - hotels and restaurants - transport, storage and communication - financial intermediation, real estate, renting - information technology - engineering services - other services - public administration - education - health and social work - other social services



SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CS-001 in the field of certification of management systems (SIST EN ISO/IEC 17021-1)

certificate: CS-001

standard: SIST EN ISO/IEC 17021-1

<http://www.slo-akreditacija.si/>

Certification of food safety management systems according to ISO 22000:2005 standard and ISO 22000:2018 standard, taking into account ISO/TS 22003:2016.

- Processing of perishable animal products
 - Processing of perishable plant products
 - Processing of perishable animal and plant products (mixed products)
 - Processing of ambient stable products
 - Catering
 - Provision of Transport and Storage Services for Perishable Food and Feed
 - Provision of Transport and Storage Services for Ambient Stable Food and Feed
-



SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CS-001 in the field of certification of management systems (SIST EN ISO/IEC 17021-1)

certificate: CS-001

standard: SIST EN ISO/IEC 17021-1

<http://www.slo-akreditacija.si/>

Certification of quality management systems – medical devices according to ISO 13485:2016 standard

Non-active medical devices

- Non-active non-implantable medical devices, general
 - Non-active devices for anaesthesia, emergency and intensive care
 - Non-active devices for injection, infusion, transfusion
 - Non-active orthopaedic and rehabilitation devices
 - Non-active medical devices with measuring function
 - Non-active ophthalmologic devices
 - Non-active instruments
 - Contraceptive medical devices
 - Non-active devices for disinfecting, cleaning, rinsing
 - Non-active medical devices for ingestion

○ **Non-active implants**

- Non-active orthopaedic implants

○ **Devices for wound care**

- Bandages and wound dressings
- Suture materials and clamps
- Other medical devices for wound care

○ **Non-active dental devices and accessories**

Non-active dental equipment and instruments

Active non-implantable medical devices

○ **Active medical devices, general**

Devices for extracorporeal circulation, infusion and haemopheresis – only incubators for children included

Respiratory devices

Devices for stimulation and inhibition

Active surgical devices

Active ophthalmologic devices

Active dental devices

Active devices for disinfection and sterilisation

Active devices for patient positioning and transport

Software

○ **Devices for imaging**

Imaging devices utilising ionizing radiation

Imaging devices utilising non-ionizing radiation

○ **Monitoring devices**

Monitoring devices of non-vital physiological parameters

Monitoring devices of monitoring of vital physiological parameters

○ **Devices for radiation therapy and thermo therapy**

Devices utilising non-ionizing radiation

Medical devices in a sterile condition

○ **Ethylene Oxide (EtO) sterilization**

○ **Moist sterilization**

○ **Gamma Ray sterilization**

○ **Production in aseptic environment**

In vitro diagnostic medical devices

- **In vitro diagnostic medical devices - devices for performance evaluation – all medical devices from Directive IVD 98/79/ES, except for medical devices from lists A and B and medical devices for testing itself**

Medical devices subject of Directive 2006/42/EC on machinery

all relevant devices listed above

Medical devices incorporating medicals

Medical devices incorporating software / utilising software / controlled by software

Parts or services

- Raw materials
- Components
- Subassemblies
- Calibration services
- Distribution services
- Maintenance services
- Transportation services
- Other services



<p>SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CS-001 in the field of certification of management systems (SIST EN ISO/IEC 17021-1)</p> <p>certificate: CS-001 standard: SIST EN ISO/IEC 17021-1 http://www.slo-akreditacija.si/</p>	<p>Certification of quality management systems according to ISO 9001:2015 standard including HACCP</p> <ul style="list-style-type: none">- Production- Food and feed processing- Catering- Retail, transport and storage- Ancillary services- Mining- Production of biochemicals
<p>SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CS-001 in the field of certification of management systems (SIST EN ISO/IEC 17021-1)</p> <p>certificate: CS-001 standard: SIST EN ISO/IEC 17021-1 http://www.slo-akreditacija.si/</p>	<p>Certification of energy management systems according to ISO 50001:2018 standard including ISO 50003:2021:</p> <ul style="list-style-type: none">- Industry - light to medium- Heavy industry (excluding EA 10 and EA 11)- Building- Building complexes- Transport- Mining- Agriculture- Energy supply
<p>SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number CS-001 in the field of certification of management systems (SIST EN ISO/IEC 17021-1)</p> <p>certificate: CS-001 standard: SIST EN ISO/IEC 17021-1 http://www.slo-akreditacija.si/</p>	<p>Certification of quality management systems according to regulations on the status of waste:</p> <ul style="list-style-type: none">- Regulation (EU) No. 333/2011, type of waste: scrap metal, iron and scrap aluminium- Regulation (EU) No. 715/2013, type of waste: scrap copper



SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number SI-V-001 in the field of environmental verification (SIST EN ISO/IEC 17021-1)

certificate: SI-V-0001

standard: SIST EN ISO/IEC 17021-1

<http://www.slo-akreditacija.si/>

Verification and attestation in accordance with Regulation (EC) no 1221/2009

- operation of dairies and cheese making
- manufacture of ice cream
- manufacture of distilled potable alcoholic beverages
- manufacture of wines
- other printing
- manufacture of dyes and pigments
- manufacture of paints, varnishes, printing ink and mastics
- manufacture of soap and detergents, cleaning and polishing preparations
- manufacture of basic pharmaceutical products
- manufacture of pharmaceutical preparations
- manufacture of plastic packing goods
- manufacture of electronic components
- manufacture of electric motors, generators and transformers
- manufacture of electricity distribution and control apparatus
- installation of machinery and apparatus for industrial use
- manufacture of other wire and cable
- manufacture of sockets, switches, and other wiring devices
- manufacture of lighting devices and equipment
- manufacture of electrical household appliances
- repair of machinery
- repair of electrical equipment
- installation of machinery and apparatus for industrial use
- wholesale of pharmaceutical goods and medical goods
- water collection, treatment and supply
- collection of hazardous waste
- collection of non-hazardous waste
- treatment and disposal of hazardous waste
- treatment and disposal of non-hazardous waste
- dismantling of wrecks
- recovery of sorted materials
- wholesale of office machinery and equipment
- hotels and other provision of similar accommodation
- camping sites and other provision of short-stay accommodation
- sweetshops and coffee-houses
- line telecommunication activities
- wireless telecommunication activities
- maintenance of facilities
- general industrial cleaning
- road cleaning and other cleaning
- planting and maintenance of green areas
- combined office administrative service activities
- photocopying, document preparation and other specialised office support activities
- public administration
- primary education
- elementary education
- general secondary education
- technical and vocational secondary education
- tertiary education
- other education n.e.c
- funeral services



Validation and verification:

<p>SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number P-002 in the field of validation and/or verification (SIST EN ISO/IEC 17029)</p> <p>certificate: P-002 standard: SIST EN ISO/IEC 17029 http://www.slo-akreditacija.si/</p>	<p>Commission implementing Regulation (EU) 2018/2067 with amendments, Commission implementing Regulation (EU) 2018/2066 with amendments and Commission delegated Regulation (EU) 2019/331 with amendments.</p>
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Multilateral Agreements: testing and certification of products

<p>IECEE/CB Scheme Scheme of the IECEE for Mutual Recognition of Test Certificates http://www.iecee.org</p>	<p><i>National Certification Body (NCB)</i> <i>Recognized CB Testing Laboratory (CBTL)</i> for testing of electric safety and electromagnetic compatibility according to IEC standards SIQ Ljubljana can issue CB certificates of conformity for the following product categories:</p> <ul style="list-style-type: none"> - information technology and office equipment (OFF) - information technology, audio and video equipment (ITAV) - household and similar equipment HOUS) - electrical equipment for medical use (MED) - safety transformers (SAFE) - luminaires (LITE) - laboratory equipment (MEAS) - portable tools (TOOL) - switches for appliances and automatic controls (CONT) - installation accessories and connection devices (INST) - electronic, entertainment (TRON) - electric vehicles (ELVH) - industrial automatization (INDA) - energy efficiency (E3) - low voltage switching equipment (POW) - electromagnetic compatibility (EMC) - batteries (BATT)
<p>IECEX Scheme IEC Scheme for Certification to Standards for Electrical equipment for Explosive Atmospheres http://www.iecex.com</p>	<p><i>IECEX Assessment and Testing Laboratory (ExTL)</i> <i>Ex Certification Body (ExCB)</i> SIQ Ljubljana can issue IECEX certificates of conformity for the following types of protection:</p> <ul style="list-style-type: none"> - flameproof enclosure Ex d - increased safety Ex e - intrinsic safety Ex i - encapsulation Ex m - non-sparking apparatus Ex n - dust ignition protection Ex t - non-electrical Ex equipment Ex h - and certificates for Service Facilities
<p>CCA Mutual recognition Agreement within CENELEC http://www.eepca.org</p>	<p><i>National Certification Body (NCB)</i> <i>Recognized Testing Laboratory (TL)</i> SIQ Ljubljana can issue NTR certificates for the following product categories:</p> <ul style="list-style-type: none"> - information technologies and audio-video equipment (ITAV) - information technology and office equipment (OFF) - household and similar equipment HOUS) - electrical equipment for medical use (MED) - safety transformers (SAFE)



	<ul style="list-style-type: none"> - luminaires (LITE) - laboratory equipment (MEAS) - portable tools (TOOL) - switches for appliances and automatic controls (CONT) - installation accessories and connection devices (INST) - electronic, entertainment (TRON) - low-voltage switch (POW)
CCA-EMC Mutual recognition arrangement on the use of a common European mark of conformity to standards concerning electromagnetic compatibility http://www.etics.org	<i>National Certification Body (NCB)</i> <i>Recognized Testing Laboratory (TL)</i>
ENEC Mutual recognition arrangement on the use of a common European mark of conformity to standards http://www.etics.org	<i>National Certification Body (NCB)</i> <i>Recognized Testing Laboratory (TL)</i> <i>SIQ can grant licences for the ENEC mark for the following product categories:</i> <ul style="list-style-type: none"> - luminaires (LITE) - information technology, audio and video equipment (ITAV) - information technology and office equipment (OFF) - household and similar equipment HOUS) - switches for appliances and automatic controls (CONT) - safety transformers (SAFE) - portable tools (TOOL) - electronic, entertainment (TRON) - laboratory equipment (MEAS) - batteries (BATT) - installation and connecting devices (INST)
ENEC+ Mutual recognition arrangement on the use of a common European mark of conformity to standards http://www.etics.org	<i>National Certification Body (NCB)</i> <i>Recognized Testing Laboratory (TL)</i> <i>SIQ can grant licences for the ENEC+ mark for the following product categories:</i> <ul style="list-style-type: none"> - technical characteristics of products within ENEC for LED modules and LED based luminaires
FCC (Federal Communication Commission), USA Notification: SI0001 https://apps.fcc.gov/oetcf/eas/reports/TestFirmSearch.cfm	<i>Recognized testing laboratory for testing of electromagnetic radiation from electronic, electrical, industrial and medical equipment.</i>
ISED (Innovation, Science and Economic Development), Canada Notification: SI0001 https://ised-isde.canada.ca/site/mutual-recognition-agreements/en/wireless-device-testing-laboratories	<i>Recognized testing laboratory for testing of wireless devices according to Canadian requirements for radio equipment.</i>
PCI DSS (Payment Card Industries Data Security Standard) https://www.pcisecuritystandards.org 5083-01-03, 2016	<i>Accreditation as an ASV (Approved Scanning Vendor) QSA (Qualified Security Assessor) of IT solutions for card operations.</i>
Republic of Serbia, Ministry of Economy SIQ d.o.o. Beograd Number: 119-01-503/2017-07	<i>Appointment as a conformity assessment body according to the Rules on electrical equipment designed for use within certain voltage limits (Official Gazette of the Republic of Serbia 25/16)</i>
Republic of Serbia, Ministry of Economy SIQ d.o.o. Beograd	<i>Appointment as a conformity assessment body according to the Rules on electromagnetic compatibility (Official Gazette of the Republic of Serbia 25/16)</i>



Number: 119-01-504/2017-07	
Republic of Serbia, Ministry of Economy SIQ d.o.o. Beograd Number: 119-01-307/2019-07	<i>Appointment as a conformity assessment body according to the Rules on machinery safety (Official Gazette of the Republic of Serbia 58/2016)</i>

Multilateral Agreements: management systems assessment and certification

IQNET http://www.iqnet-certification.com	<i>Co-operation and mutual recognition</i> and promotion of issued certificates for management systems
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Authorizations: testing and other professional tasks

Licences, registrations and appointments for conformity assessment of gaming technologies	Conformity assessment of gaming technologies according to national and regional regulations globally, which includes: <ul style="list-style-type: none"> - almost all regulations in Europe, Africa, Asia, Latina America and Caribbean, - a large number of US federal states and tribal jurisdictions, the majority of Canadian provinces. A detailed list is submitted on request.
Ministry of the Economy decision: 3261-1/2004-7	Appointed technical service carrying out as a technical body and on behalf of the Ministry of transport, DRRS, testing, inspection and verification of systems, components and separate technical units of vehicles according to the Rules on EC-homologation of motor vehicles (Official Gazette of RS, Nos. 84/02, 80/04 and 75/05), Rules on EC-homologation of three-wheel motor vehicles (Official Gazette of RS, Nos. 125/03, 80/04 and 75/05) and Rules on homologation of agricultural and forestry tractors (Official Gazette of RS, Nos. 125/03, 80/04, 103/04 and 75/05).
Public Agency of the Republic of Slovenia for Railway Transport	Competent national body (DeBo) for the implementation of the verification procedure according to the requirements of Article 15(8) of Directive 2016/797 in connection with national technical regulations covering the following structural fields: <ul style="list-style-type: none"> - energy - control-command and signalling - rolling stock



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