



## Introduction to SIQ

Fields of activity | Accreditations | Recognitions and international co-operation | Authorisations | Contacts



SIQ Ljubljana is a professional, independent, impartial, and not-for-profit institution providing comprehensive certification, inspection, testing, calibration, validation, verification, and training services.

The activities of SIQ Ljubljana are managed and supervised by the SIQ Council. The Board of Certification Body is responsible for the supervision of the certification systems managed by SIQ Ljubljana. The Institute's governing bodies comprise representatives of interested public, economic, industrial and other associations representing the interests of the customers of the Institute's services.







<b>Full name:</b>	Slovenski institut za kakovost in meroslovje, Ljubljana
<b>Short name:</b>	SIQ Ljubljana
<b>English translation:</b>	Slovenian Institute of Quality and Metrology, Ljubljana
<b>Address:</b>	Mašera-Spasičeva ul. 10, 1000 Ljubljana, Slovenia
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<b>E-mail:</b>	info@siq.si
<b>Webpage:</b>	www.siq.si
<b>Establishment:</b>	1964
<b>Registration of the Institute:</b>	First registration: 199210779 / 1993-01-29 Transfer of registration to a central register: 199308050 / 1996-11-15 Registration body: District Court in Ljubljana
<b>Registration of a research organisation:</b>	Number and date of registration: 26 / 1993-07-07 Registration body: Ministry of Higher Education, Science and Innovation
<b>Registration number:</b>	5700108000
<b>VAT ID number:</b>	SI23509678
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<b>S.W.I.F.T.:</b>	LJBASI2X
<b>IBAN:</b>	SI56 0292 0001 2897 988

## Mission

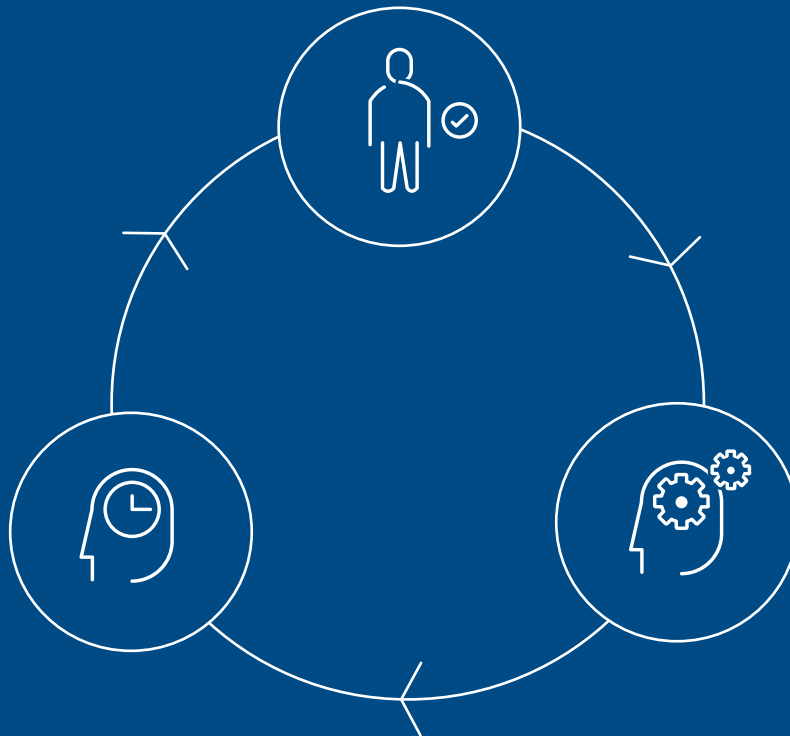
We assess compliance.  
We transfer knowledge.  
We build trust.

## Vision

To be a regional leader in key areas of our operations, to offer the widest range of services in one place, and to be the first choice for partners and top professionals.

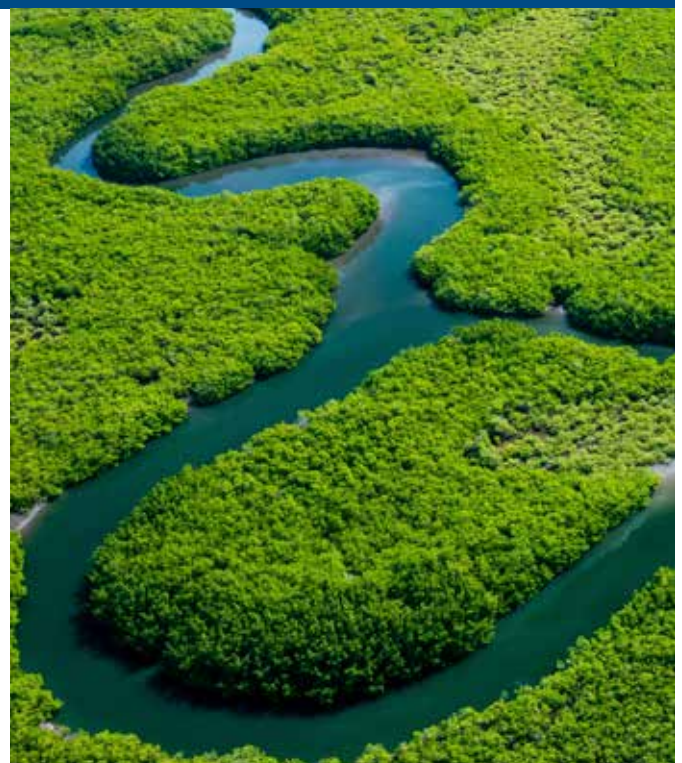
## Competitive advantage

With a dedicated team of top professionals, we have been committed to delivering best-value services for over sixty years.

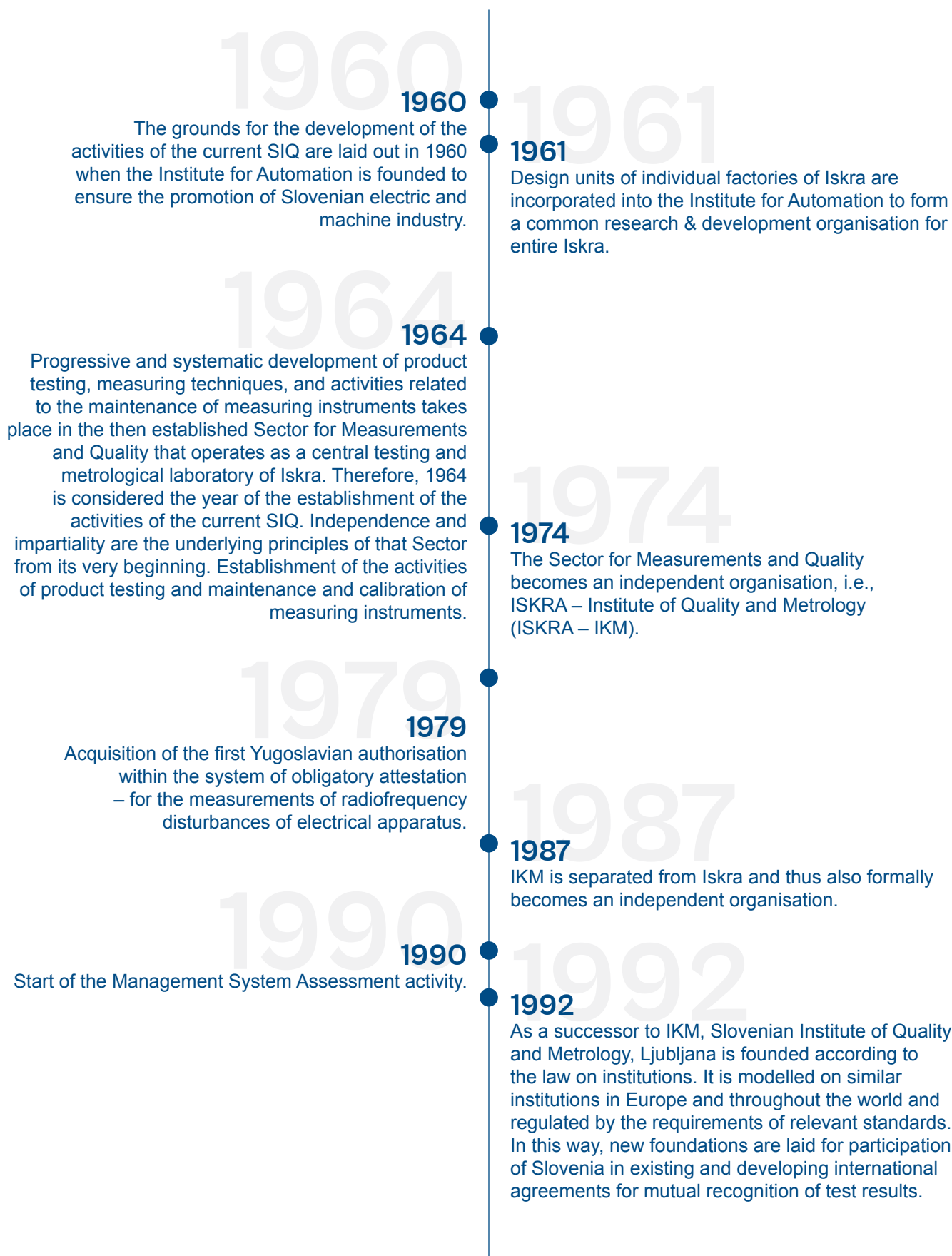


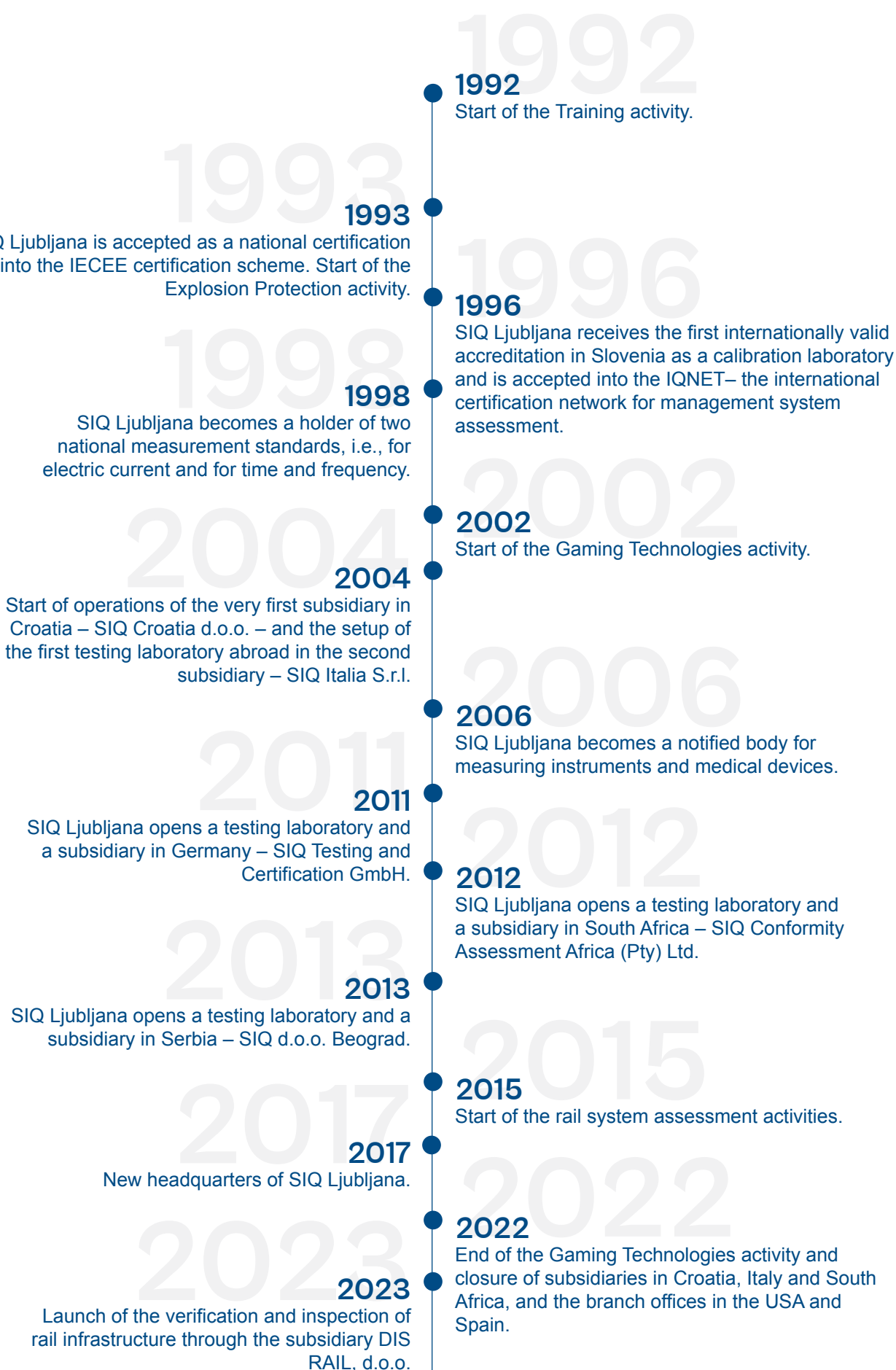
## Values

- **Expertise** | Knowledge, precision, and reliability.
- **Independence and impartiality** | Absolute professional independence and equal treatment of partners and projects.
- **Integrity** | Wholeness, consistency, authenticity, honesty, and credibility.
- **Commitment** | Dedication, responsiveness, and teamwork.
- **Innovation** | Continuous improvement. Seeing solutions where others fail. A growth mindset.



# Milestones in the development of SIQ Ljubljana





# Fields of activity

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## Safety and Electromagnetics

We test and certify electrical products to determine and confirm compliance with safety, environmental, electromagnetic compatibility, radio spectrum, explosion protection, and energy efficiency requirements, as well as other physical performance requirements. We monitor production sites and shipments and help obtain international certificates.

## Management System Assessment

We provide management system assessment and certification services to companies and other organisations, and issue certificates and other documents of compliance. We assess and certify organisations' management systems against selected reference documents, such as recognised international standards.

## Metrology

We calibrate, verify, inspect, and maintain measuring instruments. We are the holder of national measurement standards for electrical quantities, as well as time and frequency. We act as a notified body under the Measuring instruments directive. We work with other European national metrology institutes in the framework of EU research projects to develop new measurement methods and standards and to assist other laboratories in developing their capabilities. We also develop measuring instruments and provide training in metrology.

## Training

In both open and closed groups, we organise seminars, workshops, courses, conferences, panel discussions, and coaching. We offer more than 300 different training programmes. These cover all the practical and applicable knowledge that employees need to perform their work properly and efficiently, relating to management systems, human resource management, applicable national and European technical legislation, and technical issues and normative aspects connected to product testing, calibration, assessment, certification, and inspection.

## Information Technology Assessment

We offer a comprehensive execution of various security assessments of products, applications, and infrastructure. We further enhance our assessment services by offering various types of audits and reviews of information systems, thereby complementing our service portfolio for various companies and organisations.

Our range of services includes penetration testing of external infrastructure, internal infrastructure, web applications and mobile applications; wireless network testing; security audits of connected devices (IoT); and compliance assurance against standards for connected devices (IoT).



# Scope of activities

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## 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 concerning equipment and protective systems intended for use in potentially explosive atmospheres (2014/34/EU–ATEX)
- Radio equipment directive (2014/53/EU–RED)
- Noise emission in the environment by equipment for use outdoors directive (2000/14/EC–Noise)
- Construction products regulation (Regulation (EU) No. 305/2011–CPR)
- Measuring instruments directive (2014/32/EU–MID)
- Directive on the interoperability of rail system within the European Union (2016/797)

*\*As from 26 May 2021, the Notified Bodies designated under Directive 93/42/EEC are no longer able to issue new certificates under that Directive, but only allowed to carry out surveillance activities for certificates validly issued under that Directive in the transitional period, as established in Article 120 of Regulation (EU) 2017/745.*

## The status of a notified body – DIS RAIL

Notified Body No. 2508 under:

- Directive on the interoperability of rail system within the European Union (2016/797)

The scope of operation under an individual directive is published in the NANDO EU database at the following address:

<https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies>.





# Product testing

## Safety

- Testing of electrical, mechanical, thermal, ergonomic, emission, and chemical hazards
- Testing of functional safety
- Cybersecurity testing
- Measuring of noise emission to the environment and vibration from machinery

## Electromagnetic compatibility

- Testing of electromagnetic compatibility (emission, resistance)
- Measuring of exposure to electromagnetic fields

## Radio spectrum

- Measuring of the use of frequency bands and the characteristics of radio signals

## 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 the degree of protection provided by enclosures against ingress of solid foreign objects, ingress of water and against mechanical impacts.

## 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

## Physical properties

- Measuring of photometric properties
- Measuring of laser radiation

# Certification of products, processes, and services

## Product certification

- Product certification based on type testing (type 1 scheme), where we issue:
  - IECEE certificates (CB Test Certificate, E3 Statement of Test Results, Component Certificate of Conformity, Aspect Certificate of Conformity), as a member of the international IECEE Scheme,
  - SIQ certificates of conformity.
- Product certification within the IECEx Scheme (type 5 scheme), where we issue:
  - IECEx certificates (IECEx Certificate of Conformity), as a member of the international IECEx Scheme.
- Product certification based on regular inspection of a product and a manufacturing process (type 5 scheme), where we issue:
  - licences for the common European certification marks »ENEC«, »ENEC+«, »CCA EMC«, as a member of the European association ETICS,
  - notifications of test results (NTR), as a member of the CENELEC Certification Agreement (CCA) of the European association ETICS,
  - licences to use the certification marks »SIQ«, »SIQ Type Approved«, and »SIQ Medical Approved«.

## Service certification

- Certification of qualified trust services (type 6 scheme), where we issue:
  - eIDAS certificates (Certificate of Adequacy) according to Regulation (EU) No. 910/2014 on electronic identification and trust services for electronic transactions in the internal market.

## Inspection services

### Inspection of explosion protection

- Inspection of equipment for use in potentially explosive atmospheres

### Inspection of measuring instruments

- Inspection of tire pressure measuring instruments
- Inspection of blood pressure measuring devices
- Inspection of exhaust gas analysers for motor vehicles

### Inspection in the field of railways

- Inspection of a risk management procedure and the results of its application

## Management system certification

We certify various management systems. Our auditors and experts master a wide range of manufacturing and service industries. For organisations with multiple management systems, we perform integrated audits.

We offer management system assessment and certification services 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 its amendments)
- ISO 50001 standard (energy management system)
- ISO 45001 standard (occupational health and safety management system)
- SA 8000 standard and SR 10 specification (social responsibility)
- ISO 9001 standard including HACCP, HACCP system and ISO 22000 standard (food safety management system), and the IFS family of standards (International Food Standard), IFS Logistics, BRC Global Standard for Food Safety
- Food Supplements Europe Guide to Good Manufacturing Practice (GMP/DPP) for Manufacturers of Food Supplements
- ISO 55001 standard (asset management system)
- ISO/IEC 27001 standard (information security management system)
- ISO/IEC 20000-1 standard (IT service management system)
- ISO 22301 standard (business continuity management system)
- ISO/IEC 27018 standard (code of practice for protection of personally identifiable information in public clouds)
- ISO/IEC 27017:2015 standard (code of practice for information security controls for cloud services)
- ISO/IEC 27701:2019 standard (privacy information management system)
- ISO 13485 standard (quality management system in the design and manufacture 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 Practices (GMP)
- Quality in education model (quality for the future of education and schooling)
- ISO 22716 standard (cosmetics – good manufacturing practices)
- 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 (quality management systems – health care services)
- ISO 28000 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
- ISO 37001 standard (anti-bribery management system)
- ISO/IEC 33061 standard (process assessment model for software life cycle processes)

## Validation and verification

We act as a validation and verification body for:

- **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) 2024/573,
- **verification of sustainability reports** according to GRI standards (Global Reporting Initiative),
- **carbon footprint verification** (ISO 14064-3) or carbon footprint calculation (ISO 14064-1, ISO 14064-2, ISO 14067 standards, and GHG protocol).

## Calibration

We offer calibration services both in the laboratory and on-site in the following areas:

- Electrical quantities
- Time and frequency
- Dimensional quantities
- Mechanical quantities
- Acoustic quantities
- Optical quantities
- Temperature, humidity, and thermo-physical properties

## Training

With our specific expertise, we contribute to the development of products and services, and to orderly, safe, and efficient business operations.

### Training modules

Sustainable development | Quality | Production | Technical legislation | Automotive industry | Medical devices and trade in pharmaceutical products | Laboratories and inspection bodies | Environment | Energy | Occupational safety and health | Information security and business continuity | Food safety | Quality in education and schooling | Sales and procurement | European resources | Digital competences | Artificial intelligence | Management and human resources |

### Training programmes for management system auditors

We offer training programmes that include in-depth knowledge and practical skills in a variety of management systems (ISO 9001, ISO 19011, ISO 14001, ISO 50001, ISO 45001, EN ISO 13485, (EU) GMP, (EU) GDP, ISO 15378, ISO/IEC 27001, ISO/IEC 27002, ISO 22301, ISO 22000, IFS FOOD, ISO/IEC 17025, ISO/IEC 15189, ISO/IEC 42001, ISO 22716, ISO 7101).

We offer the opportunity to gain more comprehensive knowledge and skills and internationally recognised certificates and titles. Programmes with carefully selected content and led by experts with extensive practical experience ensure effective preparation for the challenges of the modern business environment.

- Sustainability management expert
- Quality management representative
- Project manager
- Production team leader
- Lean manager
- Expert in regulatory requirements for medical device manufacturers
- Expert in regulatory requirements for medical device importers and distributors
- Food safety management representative
- Data protection officer – DPO
- Information security risk manager
- Information security manager – ISM
- AI manager



- Incident manager
- EU funding expert
- Future leader academy
- Analytical laboratory academy

We are a partner of CIS – Certification & Information Security GmbH, a certification body specialised in information security, data protection, cloud computing, IT services, data centres, and business continuity management.

We are a member of the PECB network, a global network of partners, trainers, certified individuals, and certificate holders present in more than 150 countries.

## **Research and development**

The areas of conformity assessment and metrology cover, in addition to their primary tasks, also research and development in the fields of quality, metrology, and standardisation. This is the basis for the registration of SIQ Ljubljana as a research organisation.

# International co-operation

*A national certification body in multilateral recognition agreements:*



- **IECEE** 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.



- **IECEx** Scheme for testing and certification of electrical equipment for use in potentially explosive atmospheres and for assessment of competence of service facilities for equipment for potentially explosive atmospheres.



- **ETICS** Agreement (European Testing Inspection Certification System)



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

*Member of IQNET – The International Certification Network*



- International association of organisations providing management system assessment and certification.

*Member of IQNET Academy*



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

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

- Member of 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

Notified Body (No. 1304)

<b>Machinery Directive 2006/42/EC</b>	<p><i>Notified Body for the types of machinery listed in Annex IV to Directive 2006/42/EC</i></p> <p>Annex IX–Module B: EC type-examination</p> <p>Annex X–Module H: Full quality assurance for the types of machinery listed in Annex IV, except for:</p> <ul style="list-style-type: none"> <li>• machinery for underground working (section A12)</li> <li>• machinery for manufacturing pyrotechnics (section A17)</li> <li>• roll-over protective structures–ROPS (section B4)</li> <li>• falling-object protective structures–FOPS (section B5)</li> </ul>
<b>ATEX Directive 2014/34/EU on Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres</b>	<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 and the communication of the technical documentation pursuant to Article 13.1(b)(ii)</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>
<b>EMC Directive 2014/30/EU</b>	<p><i>Notified Body under Directive 2014/30/EU for electrical and electronic devices (Annex III)</i></p> <p>Annex III–Module B: EU type-examination</p>
<b>RE Directive 2014/53/EU</b>	<p><i>Notified Body for entire equipment covered by Directive 2014/53/EU</i></p> <p>Annex III–Module B: EU type-examination</p>
<b>Noise Directive 2000/14/EC</b>	<p><i>Notified Body for the entire equipment from Article 10 of Directive 2000/14/EC</i></p> <p>Annex VI–Module A1: Internal control of production with assessment of technical documentation and periodical checking</p> <p>Annex VII–Module G: Unit verification and validation</p> <p>Annex VIII–Module H: Full quality assurance</p>
<b>Construction Products Regulation (EU) No. 305/2011</b>	<p><i>Notified Body for construction products covered by Regulation (EU) No. 305/2011</i></p> <p>System 1</p> <ul style="list-style-type: none"> <li>• variable message traffic signs (EN 12966-1)</li> <li>• signal heads (EN 12368)</li> </ul>
<b>Measurement Instruments Directive 2014/32/EU</b>	<p><i>Notified Body for or 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><b>Directive 2016/797 on the Interoperability of the Rail System within the European Union</b></p>	<p><i>Notified Body under Directive 2016/797 for the following conventional subsystems:</i></p> <ul style="list-style-type: none"> <li>• Energy (Article 9 (2), Annex IV) <ul style="list-style-type: none"> <li>• ENE CR Dec 2011/274</li> <li>• ENE Reg 1301/2014</li> <li>• SRT Dec 2008/163</li> <li>• SRT Reg 1303/2014</li> </ul> </li> <li>• Control-command and signalling (Article 9 (2), Annex IV) <ul style="list-style-type: none"> <li>• CCS Dec 2012/88</li> <li>• SRT Dec 2008/163</li> <li>• CCS CR Dec 2006/679</li> </ul> </li> <li>• Rolling stock (Article 9 (2), Annex IV) <ul style="list-style-type: none"> <li>• LOC&amp;PAS CR Dec 2011/291</li> <li>• NOI CR Dec 2006/66</li> <li>• PRM Dec 2008/164</li> <li>• WAG CR Dec 2006/861</li> <li>• NOI Reg 2019/774</li> <li>• SRT Dec 2008/163</li> <li>• PRM Reg 1300/2014</li> <li>• SRT Reg 1303/2014</li> <li>• LOC&amp;PAS Reg 1302/2014</li> <li>• NOI CR Dec 2011/229</li> <li>• WAG Reg 321/2013</li> <li>• PRM Reg 2019/772</li> </ul> </li> </ul>
<p><b>Regulation (EU) 2017/745 on Medical Devices</b></p>	<p><i>Notified Body for the following categories of medical devices and the following procedures covered by Regulation (EU) 2017/745:</i></p>
	<p><b>I. CODES THAT REFLECT DESIGN AND INTENDED PURPOSE OF THE DEVICE</b></p> <p><b>A. Active devices</b>  Active non-implantable devices for imaging, monitoring and/or diagnosis</p> <ul style="list-style-type: none"> <li>• active non-implantable imaging devices utilising non-ionizing radiation (Annexes IX (I), IX (II), X, XI (A), XI (B))</li> <li>• active non-implantable devices for monitoring of vital physiological parameters (Annexes IX (I), IX (II), X, XI (A), XI (B))</li> <li>• other active non-implantable devices for monitoring and/or diagnosis (Annexes IX (I), IX (II), X, XI (A), XI (B))</li> </ul> <p>Active non-implantable therapeutic devices and general active non-implantable devices</p> <ul style="list-style-type: none"> <li>• active non-implantable devices utilising non-ionizing radiation (Annexes IX (I), IX (II), XI (A))</li> <li>• active non-implantable devices for stimulation or inhibition (Annexes IX (I), IX (II), X, XI (A), XI (B))</li> <li>• active non-implantable respiratory devices (Annexes IX (I), IX (II), XI (A))</li> <li>• active non-implantable devices for wound and skin care (Annexes IX (I), IX (II), X, XI (A), XI (B))</li> <li>• active non-implantable ophthalmologic devices – Annexes X and XI (B) for lasers only. Other Annexes without limitations (Annexes IX (I), IX (II), X, XI (A), XI (B))</li> <li>• active non-implantable devices for ear, nose and throat (Annexes IX (I), IX (II), X, XI (A), XI (B))</li> <li>• active non-implantable dental devices – Annexes X and XI (B) for lasers only. Other Annexes without limitations (Annexes IX (I), IX (II), X, XI (A), XI (B))</li> <li>• other active non-implantable surgical devices (Annexes IX (I), IX (II), XI (A))</li> <li>• active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport (Annexes IX (I), IX (II), XI (A))</li> <li>• software (Annexes IX (I), IX (II), XI (A))</li> <li>• active non-implantable devices for cleaning, disinfection and sterilisation (Annexes IX (I), IX (II), XI (A))</li> <li>• other active non-implantable devices (Annexes IX (I), IX (II), XI (A))</li> </ul> <p><b>B Non-active devices</b>  Non-active implants and long term surgically invasive devices</p> <ul style="list-style-type: none"> <li>• non-active osteo- and orthopaedic implants (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active dental implants and dental materials (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active soft tissue and other implants – non-absorbable sutures only (Annexes IX (I), IX (II), XI (A))</li> </ul> <p>Non-active non-implantable devices</p> <ul style="list-style-type: none"> <li>• non-active non-implantable devices for administration, channelling and removal of substances (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active non-implantable devices for wound and skin care (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active non-implantable orthopaedic and rehabilitation devices (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active non-implantable ophthalmologic devices (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active non-implantable diagnostic devices (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active non-implantable instruments (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active non-implantable dental materials (Annexes IX (I), IX (II), XI (A))</li> <li>• non-active non-implantable devices for disinfecting, cleaning and rinsing (Annexes IX (I), IX (II), XI (A))</li> </ul>

- non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route (Annexes IX (I), IX (II), XI (A))
- general non-active non-implantable devices used in health care and other nonactive non-implantable devices (Annexes IX (I), IX (II), XI (A))

## II. HORIZONTAL CODES

### Devices with specific characteristics

- devices incorporating medicinal substances
- 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
- devices in sterile condition – included: aseptic processing, filtration, steam sterilisation, ethylene oxide gas sterilisation, irradiation included
- reusable surgical instruments
- devices incorporating or consisting of nanomaterial
- 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 – excluded: biologically active coatings and/or materials excluded
- 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
- devices with a measuring function
- devices in systems or procedure packs
- products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
- class III custom-made implantable devices – orthopaedic implantable devices only

### Devices for which specific technologies or processes are used

- devices manufactured using metal processing
- devices manufactured using plastic processing
- devices manufactured using non-metal mineral processing (e.g. glass, ceramics)
- devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)
- devices manufactured using chemical processing
- devices which require knowledge regarding the production of pharmaceuticals
- devices manufactured in clean rooms and associated controlled environments
- devices manufactured using electronic components including communication devices
- devices which require packaging, including labelling
- devices which require installation, refurbishment
- devices which have undergone reprocessing

**Directive 93/42/EEC on Medical Devices\***

*\*As from 26 May 2021, the Notified Bodies designated under Directive 93/42/EEC are no longer able to issue new certificates under that Directive, but only allowed to carry out surveillance activities for certificates validly issued under that Directive in the transitional period, as established in Article 120 of Regulation (EU) 2017/745.*

*The surveillance activities for the certificates validly issued under Directive 93/42/EEC are carried out for the following categories of medical devices:*

*A: General non-active medical devices*

- non-active devices for anaesthesia, emergency and intensive care (Annexes II, V, VI)
- non-active devices for injection, infusion and transfusion (Annexes II, V, VI)
- non-active orthopaedic and rehabilitation devices (Annexes II, V, VI)
- non-active medical devices with measuring function (Annexes II, V, VI)
- non-active ophthalmologic devices (Annexes II, V, VI)
- non-active instruments (Annexes II, V, VI)
- contraceptive medical devices (Annexes II, V)
- non-active devices for disinfecting, cleaning, rinsing (Annexes II, V)
- non-active medical devices for ingestion (Annexes II, V)
- non-active orthopaedic implants (Annexes II, V)
- bandages and wound dressings (Annexes II, V, VI)
- suture material and clamps (Annexes II, V, VI)
- other medical devices for wound care (Annexes II, V, VI)
- non-active dental equipment and instruments (Annexes II, V, VI)

*B: General active medical devices:*

- devices for extra-corporal circulation, infusion and haemopheresis – only infant incubators included (Annexes II, V, VI)
- respiratory devices (Annexes II, V, VI)
- devices for stimulation or inhibition (Annexes II, III, IV, V, VI)
- active surgical devices (Annexes II, V, VI)
- active ophthalmologic devices (Annexes II, III, IV, V, VI)
- active dental devices (Annexes II, III, IV, V, VI)
- active devices for disinfection and sterilisation (Annexes II, V, VI)
- active devices for patients positioning and transport (Annexes II, V, VI)
- software (Annexes II, V, VI)
- imaging devices utilising ionizing radiation (Annexes II, V, VI)
- imaging devices utilising non-ionizing radiation (Annexes II, III, IV, V, VI)
- monitoring devices of non-vital physiological parameters (Annexes II, III, IV, V, VI)
- monitoring devices of vital physiological parameters (Annexes II, III, IV, V, VI)
- devices utilising non-ionizing radiation (Annexes II, V, VI)

*C: Specifics of medical devices*

- medical devices incorporating medicinal substances, according to Directive 2001/83/EC
- medical devices referencing the Directive 2006/42/EC on machinery
- medical devices in sterile condition – excluding sterilisation with formaldehyde
- medical devices incorporating software/utilising software/controlled by software



## Product testing

SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number LP-009 in the field of testing (SIST EN ISO/IEC 17025).

*certificate: LP-009*

*standard: SIST EN ISO/IEC 17025*

### *Testing of safety of products:*

- 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

### *Testing of electromagnetic compatibility of products*

### *Testing of radio spectrum*

### *Testing of human exposure to electromagnetic fields*

### *Testing of environmental impacts*

### *Testing of physical properties:*

- photometric properties
- laser radiation

### *Testing of equipment for use in potentially explosive atmospheres*

### *Testing of energy consumption*

### *Testing of product safety in SIQ Testing and Certification GmbH in a partial scope:*

- information technology, audio-video, power electronics
- electrical medical equipment
- laboratory, measuring and inspection equipment

SIQ d.o.o. Beograd Ljubljana is accredited by Serbian accreditation body ATS with accreditation number 01-439 in the field of testing (SRPS EN ISO/IEC 17025).

*certificate: 01-439*

*standard: SRPS EN ISO/IEC 17025*

### *Testing of electromagnetic compatibility and safety of products in SIQ d.o.o. Beograd*

### *Product categories:*

- household and similar electrical appliances
- audio/video, IT and communication technology equipment
- electrical machinery equipment

## Certification of products, processes and services

<p>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).</p>	<p><i>Certification of products:</i></p> <ul style="list-style-type: none"> <li>• on the basis of type testing, according to type 1b scheme</li> <li>• on the basis of type testing and assessment of factory quality system control and its acceptance followed by surveillance that takes into account the audit of factory quality control and the testing of samples from the factory, according to type 5 scheme</li> </ul>
<p><i>certificate:</i> CP-001 <i>standard:</i> SIST EN ISO/IEC 17065</p>	<p><i>Product safety</i></p> <p><i>Electromagnetic compatibility</i></p> <p><i>Radio spectrum</i></p> <p><i>Certification of machinery</i></p> <p><i>Equipment for use in potentially explosive atmospheres</i></p> <p><i>Certification of services:</i></p> <p>Certification of qualified trust services according to Regulation (EU) No. 910/2014 on electronic identification and trust services for electronic transactions in the internal market (EIDAS)</p> <p>Accreditation for notification purposes:</p> <p>Construction products – Regulation (EU) No. 305/2011, System 1:</p> <ul style="list-style-type: none"> <li>• traffic control equipment – signal heads</li> <li>• road vertical signs – variable message traffic signs</li> </ul> <p>Radio equipment – Directive 2014/53/EU, Module B: EU type-examination: Articles 3.1.a, 3.1.b, 3.2, 3.3.d, 3.3.e, 3.3.f, 3.3.g, 3.4</p> <p>Measuring instruments – Directive 2014/53/EU, Module B: EU type-examination, Module D: Conformity to type based on quality assurance of the production process, Module H1: Conformity based on full quality assurance:</p> <ul style="list-style-type: none"> <li>• active electrical energy meters (MI-003)</li> </ul>

## Inspection services

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

## Calibration

<p>SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number LK-001 in the field of calibration (SIST EN ISO/IEC 17025).</p> <p>certificate: LK-001 standard: SIST EN ISO/IEC 17025</p>	<p><i>Calibration of measuring instruments and measurement standards for:</i></p> <ul style="list-style-type: none"> <li>• electrical quantities: <ul style="list-style-type: none"> <li>• DC and low-frequency (LF) quantities: <ul style="list-style-type: none"> <li>- voltage: DC and AC voltage, power quality parameters, high voltage (DC, AC), pulse amplitude</li> <li>- current: DC and AC current, power quality parameters</li> <li>- voltage ratio</li> <li>- AC/DC voltage transfer</li> <li>- AC/DC current transfer</li> <li>- power and energy: apparent, active, reactive</li> <li>- resistance: AC and DC resistance, impedance</li> <li>- capacitance: LF and HF capacitance</li> <li>- inductance</li> <li>- dissipation factor</li> </ul> </li> <li>• high-frequency (HF) quantities: <ul style="list-style-type: none"> <li>- HF voltage: CW flatness, matched output voltage of generator, voltmeters indicating incident voltage, voltmeters indicating voltage at input terminal</li> <li>- impedance: voltage reflection coefficient (VRC; scalar), directivity (D; scalar), S-parameters; reflection and transmission (S<sub>ii</sub> and S<sub>ij</sub>; real and imaginary)</li> <li>- HF power: absolute, relative</li> <li>- attenuation</li> <li>- EMC; artificial mains network</li> <li>- longitudinal conversion loss (LCL)</li> <li>- EMC; coupling-decoupling networks</li> <li>- EMC; transients</li> <li>- EMC; electrostatic discharge</li> <li>- EMC CISPR detectors</li> </ul> </li> </ul> </li> <li>• time and frequency: <ul style="list-style-type: none"> <li>• time: <ul style="list-style-type: none"> <li>- time scale difference: local clock vs. UTC, local clock vs. UTC(SIQ)</li> <li>- time interval</li> <li>- rise time</li> </ul> </li> <li>• frequency: <ul style="list-style-type: none"> <li>- frequency</li> <li>- modulation: amplitude, frequency and phase modulation</li> <li>- distortion</li> <li>- harmonic content</li> </ul> </li> </ul> </li> <li>• dimensional quantities: <ul style="list-style-type: none"> <li>• length: diameter</li> <li>• angle</li> <li>• speed (speedometer)</li> </ul> </li> <li>• mechanical quantities: <ul style="list-style-type: none"> <li>• force</li> <li>• balances</li> <li>• gauge pressure</li> <li>• acceleration</li> </ul> </li> <li>• acoustical quantities: <ul style="list-style-type: none"> <li>• acoustical pressure</li> <li>• sound exposure</li> <li>• vibration: acceleration, velocity, displacement</li> <li>• transducers (electrical quantities): charge sensitivity of accelerometer, charge sensitivity of charge amplifier, microphones, sound level meters, electroacoustic filters</li> </ul> </li> <li>• optical quantities: <ul style="list-style-type: none"> <li>• optical power: absolute power, attenuation, attenuation linearity</li> <li>• optical time domain reflectometers: loss scale attenuation coefficient, offset error, distance scale deviation, event and attenuation deadzone, dynamic range of OTDR</li> <li>• glass fibres: optical length at known group refractive index</li> <li>• opacity and light transmittance: opacity rate, opacity coefficient, light transmittance</li> </ul> </li> <li>• temperature, humidity and thermo-physical properties: <ul style="list-style-type: none"> <li>• temperature: <ul style="list-style-type: none"> <li>- internal reference junction</li> <li>- resistance temperature indicators and simulators – direct measurement</li> <li>- resistance temperature indicators and simulators</li> <li>- thermocouple temperature indicators and simulators – direct measurement</li> <li>- direct voltage temperature simulators and indicator</li> </ul> </li> <li>• evaluation of climatic controlled chambers: <ul style="list-style-type: none"> <li>- temperature chambers</li> </ul> </li> <li>• humidity: <ul style="list-style-type: none"> <li>- humidity chambers</li> </ul> </li> </ul> </li> </ul>
<p><b>MIRS</b> decision no.: 6401-2/2023/59</p>	<p><i>Holder of national measurement standards for:</i></p> <ul style="list-style-type: none"> <li>• electrical quantities</li> <li>• time and frequency</li> </ul>



<b>MIRS</b> decision no.: 6416-1/2021/7 official stamp identification: 349	Appointed body for carrying out compliance assessment and first, regular and additional verifications of: <ul style="list-style-type: none"> <li>• instruments for tire pressure measuring and instruments for tire pressure measuring, which can carry EEC marks and signs</li> <li>• exhaust gas analysers and instruments for measuring the exhaust gas of motor vehicles (compression-ignition)</li> <li>• blood pressure measuring devices</li> </ul>
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### Management system 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	Assessment and certification of quality management systems according to ISO 9001:2015 standard, taking into account ISO/IEC 17021-3:2019: <ul style="list-style-type: none"> <li>• agriculture, forestry and fishing</li> <li>• mining and quarrying</li> <li>• food products, beverages and tobacco</li> <li>• textiles and textile products</li> <li>• leather and leather products</li> <li>• wood and wood products</li> <li>• pulp, paper and paper products</li> <li>• publishing companies</li> <li>• printing companies</li> <li>• manufacture of coke and refined petroleum products (only 19.2)</li> <li>• chemicals, chemical products and fibres</li> <li>• pharmaceuticals</li> <li>• rubber and plastic products</li> <li>• non-metallic mineral products</li> <li>• concrete, cement, lime, plaster etc.</li> <li>• basic metals</li> <li>• machinery and equipment</li> <li>• electrical and optical equipment</li> <li>• other transport equipment</li> <li>• manufacturing not elsewhere classified</li> <li>• recycling</li> <li>• electricity supply</li> <li>• gas supply</li> <li>• water supply</li> <li>• construction</li> <li>• wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods</li> <li>• hotels and restaurants</li> <li>• transport, storage and communication</li> <li>• financial intermediation, real estate, renting</li> <li>• information technology</li> <li>• engineering services</li> <li>• other services</li> <li>• public administration</li> <li>• education</li> <li>• health and social work</li> <li>• other social services</li> </ul>
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<p>certificate: CS-001 standard: SIST EN ISO/IEC 17021-1</p>	<p><i>Certification of environmental management systems according to ISO 14001:2015 standard, taking into account ISO/IEC 17021-2:2019:</i></p> <ul style="list-style-type: none"> <li>• agriculture, forestry and fishing</li> <li>• mining and quarrying</li> <li>• food products, beverages and tobacco</li> <li>• textiles and textile products</li> <li>• leather and leather products</li> <li>• wood and wood products</li> <li>• pulp, paper and paper products</li> <li>• publishing companies</li> <li>• printing companies</li> <li>• chemicals, chemical products and fibres</li> <li>• pharmaceuticals</li> <li>• rubber and plastic products</li> <li>• non-metallic mineral products</li> <li>• concrete, cement, lime, plaster etc.</li> <li>• basic metals</li> <li>• machinery and equipment</li> <li>• electrical and optical equipment</li> <li>• other transport equipment</li> <li>• manufacturing not elsewhere classified</li> <li>• recycling</li> <li>• electricity supply</li> <li>• gas supply</li> <li>• water supply</li> <li>• construction</li> <li>• wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods</li> <li>• hotels and restaurants</li> <li>• transport, storage and communication</li> <li>• financial intermediation, real estate, renting</li> <li>• information technology</li> <li>• engineering services</li> <li>• other services</li> <li>• public administration</li> <li>• education</li> <li>• health and social work</li> <li>• veterinary activities</li> <li>• other social services</li> </ul>
<p>certificate: CS-001 standard: SIST EN ISO/IEC 17021-1</p>	<p><i>Certification of occupational health and safety management systems according to ISO 45001:2018 standard, taking into account ISO/IEC 17021-10:2018:</i></p> <ul style="list-style-type: none"> <li>• agriculture, forestry and fishing</li> <li>• mining and quarrying</li> <li>• food products, beverages and tobacco</li> <li>• textiles and textile products</li> <li>• leather and leather products</li> <li>• wood and wood products</li> <li>• pulp, paper and paper products</li> <li>• publishing companies</li> <li>• printing companies</li> <li>• chemicals, chemical products and fibres</li> <li>• pharmaceuticals</li> <li>• rubber and plastic products</li> <li>• non-metallic mineral products</li> <li>• concrete, cement, lime, plaster etc.</li> <li>• basic metals</li> <li>• machinery and equipment</li> <li>• electrical and optical equipment</li> <li>• other transport equipment</li> <li>• recycling</li> <li>• electricity supply</li> <li>• gas supply</li> <li>• water supply</li> <li>• construction</li> <li>• wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods (except 95.21)</li> <li>• hotels and restaurants</li> <li>• transport, storage and communication</li> <li>• financial intermediation, real estate, renting</li> <li>• information technology</li> <li>• engineering services</li> <li>• other services</li> <li>• public administration</li> <li>• education</li> <li>• health and social work</li> <li>• other social services</li> </ul>

<p>certificate: CS-001 standard: SIST EN ISO/IEC 17021-1</p>	<p><i>Certification of food safety management systems according to ISO 22000:2018 standard and taking into account SIST 22003:2022:</i></p> <ul style="list-style-type: none"> <li>• processing of perishable animal products</li> <li>• processing of perishable plant-based products</li> <li>• processing of perishable animal and plant products (mixed products)</li> <li>• processing of ambient stable products</li> <li>• catering/food service</li> <li>• transport and storage services</li> <li>• production of packaging materials</li> </ul>
<p>certificate: CS-001 standard: SIST EN ISO/IEC 17021-1</p>	<p><i>Certification of medical devices quality management systems according to ISO 13485:2016 standard:</i></p> <ul style="list-style-type: none"> <li>• Medical devices, non-active <ul style="list-style-type: none"> <li>• General non-active non-implantable medical devices <ul style="list-style-type: none"> <li>- non-active devices for anaesthesia, emergency and intensive care</li> <li>- non-active devices for injection, infusion, transfusion and dialyses</li> <li>- non-active orthopaedic and rehabilitation devices</li> <li>- non-active medical devices with measuring function</li> <li>- non-active ophthalmologic devices</li> <li>- non-active instruments</li> <li>- contraceptive medical devices</li> <li>- non-active medical devices for disinfecting, cleaning, rinsing</li> <li>- non-active medical devices for ingestion</li> </ul> </li> <li>• Non-active implants <ul style="list-style-type: none"> <li>- non-active orthopaedic implants</li> <li>- non-active soft tissue implants</li> </ul> </li> <li>• Devices for wound care <ul style="list-style-type: none"> <li>- bandages and wound dressings</li> <li>- suture materials and clamps</li> <li>- other medical devices for wound care</li> </ul> </li> <li>• Non-active dental devices and accessories <ul style="list-style-type: none"> <li>- non-active dental equipment and instruments</li> <li>- dental materials</li> </ul> </li> <li>• Non-active medical devices other than specified above <ul style="list-style-type: none"> <li>- general non-active non implantable devices used in health care that are not included in the technical files mentioned above</li> </ul> </li> </ul> </li> <li>• Active medical devices (non-implantable) <ul style="list-style-type: none"> <li>• General active medical devices <ul style="list-style-type: none"> <li>- devices for extracorporeal circulation, infusion and haemopheresis – only incubators for children included</li> <li>- respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia – only respiratory devices included</li> <li>- devices for stimulation and inhibition</li> <li>- active surgical devices</li> <li>- active ophthalmologic devices</li> <li>- active dental devices</li> <li>- active devices for disinfection and sterilisation</li> <li>- active devices for patient positioning and transport</li> <li>- software, including software design for medical devices</li> <li>- active rehabilitation devices and active prostheses</li> </ul> </li> <li>• Devices for imaging <ul style="list-style-type: none"> <li>- imaging devices utilising ionizing radiation</li> <li>- imaging devices utilising non-ionizing radiation</li> </ul> </li> <li>• Monitoring devices <ul style="list-style-type: none"> <li>- monitoring devices of non-vital physiological parameters</li> <li>- monitoring devices of monitoring of vital physiological parameters</li> </ul> </li> <li>• Devices for radiation therapy and thermo therapy <ul style="list-style-type: none"> <li>- devices utilising non-ionizing radiation</li> </ul> </li> <li>• Active (non-implantable) medical devices other than specified above <ul style="list-style-type: none"> <li>- active non-implantable therapeutic devices and general active non-implantable devices</li> </ul> </li> </ul> </li> <li>• In vitro diagnostic medical devices <ul style="list-style-type: none"> <li>• In vitro medical devices – devices for evaluation performance – all medical devices referring to Directive IVD 98/79/ES, except medical devices from lists A and B as well as products for selftesting</li> </ul> </li> <li>• Sterilization method for medical devices <ul style="list-style-type: none"> <li>• Ethylene oxide (EIO) sterilization (all relevant devices from list listed above)</li> <li>• Moist sterilization (all relevant devices from list listed above)</li> <li>• Gamma ray sterilization (e.g. gamma, x-rax, electron beam) (all relevant devices from list listed above)</li> <li>• Aseptic processing (all relevant devices from list listed above)</li> <li>• Thermic sterilization with dry heat (all relevant devices from list listed above)</li> </ul> </li> <li>• Medical devices subject of Directive 2006/42/EC about machinery (all relevant devices listed above)</li> </ul>

	<ul style="list-style-type: none"> <li>• Medical devices subject of Directive 2006/42/EC about machinery (all relevant devices listed above)</li> <li>• Parts or services <ul style="list-style-type: none"> <li>• Raw materials</li> <li>• Components</li> <li>• Subassemblies</li> <li>• Calibration services</li> <li>• Distribution services</li> <li>• Maintenance services</li> <li>• Transportation services</li> <li>• Other services</li> </ul> </li> </ul>
certificate: CS-001 standard: SIST EN ISO/IEC 17021-1	<i>Certification of quality management systems according to ISO 9001:2015 standard including HACCP:</i> <ul style="list-style-type: none"> <li>• production</li> <li>• food and feed processing</li> <li>• food and beverage supply</li> <li>• trade, transport, storage</li> <li>• auxiliary services</li> <li>• production of biochemical substances</li> </ul>
certificate: CS-001 standard: SIST EN ISO/IEC 17021-1	<i>Certification of energy management systems according to ISO 50001:2018 standard and taking into account ISO 50003:2021:</i> <ul style="list-style-type: none"> <li>• industry–light to medium</li> <li>• heavy industry (excluding EA 10 and EA 11)</li> <li>• buildings</li> <li>• building complexes</li> <li>• transport</li> <li>• mining</li> <li>• agriculture</li> <li>• energy supply</li> </ul>
certificate: CS-001 standard: SIST EN ISO/IEC 17021-1	<i>Certification of quality management systems according to End-of-waste regulations:</i> <ul style="list-style-type: none"> <li>• Regulation (EU) No. 715/2013, type of scrap cease: waste copper</li> <li>• Regulation (EU) No. 333/2011, type of scrap cease: waste iron, steel and aluminium</li> </ul>

<p>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).</p> <p><i>certificate: SI-V-0001</i>  <i>standard: SIST EN ISO/IEC 17021-1</i></p>	<p><i>Verification and attestation in accordance with Regulation (EC) No. 1221/2009:</i></p> <ul style="list-style-type: none"> <li>• manufacture of dairy products and cheese making</li> <li>• manufacture of ice cream</li> <li>• distilling, rectifying and blending of spirits</li> <li>• manufacture of wine from grapes</li> <li>• other printing</li> <li>• manufacture of dyes and pigments</li> <li>• manufacture of paints, varnishes and similar coatings, printing ink and mastics</li> <li>• manufacture of soap and detergents, cleaning and polishing preparations</li> <li>• manufacture of basic pharmaceutical products</li> <li>• manufacture of pharmaceutical preparations</li> <li>• manufacture of plastic packing goods</li> <li>• manufacture of electronic components</li> <li>• manufacture of computers and peripheral equipment</li> <li>• manufacture of electric motors, generators and transformers</li> <li>• manufacture of electricity distribution and control apparatus</li> <li>• installation of machinery and apparatus for industrial use</li> <li>• manufacture of other electronic and electric wires and cables</li> <li>• manufacture of sockets, switches, and other wiring devices</li> <li>• manufacture of lighting devices and equipment</li> <li>• manufacture of electric domestic appliances</li> <li>• repair of machinery</li> <li>• repair of electrical equipment</li> <li>• installation of industrial machinery and apparatus</li> <li>• steam and air conditioning supply</li> <li>• water collection, treatment and supply</li> <li>• collection of non-hazardous waste</li> <li>• collection of hazardous waste</li> <li>• treatment and disposal of hazardous waste</li> <li>• treatment and disposal of non-hazardous waste</li> <li>• dismantling of wrecks</li> <li>• recovery of sorted materials</li> <li>• wholesale of pharmaceutical and medical goods</li> <li>• wholesale of office machinery and equipment</li> <li>• service activities incidental to water transportation</li> <li>• holiday and other short-stay accommodation</li> <li>• sweetshops and coffee-houses</li> <li>• line telecommunication activities</li> <li>• wireless telecommunication activities</li> <li>• other information technology and computer service activities</li> <li>• real estate activities on a fee or contract basis</li> <li>• security activities</li> <li>• combined facilities support activities</li> <li>• general cleaning of buildings</li> <li>• road cleaning and other cleaning</li> <li>• landscape service activities</li> <li>• combined office administrative service activities</li> <li>• photocopying, document preparation and other specialised office support activities</li> <li>• general public administration activities</li> <li>• pre-primary education</li> <li>• primary education</li> <li>• general secondary education</li> <li>• technical and vocational secondary education</li> <li>• tertiary education</li> <li>• other education n.e.c</li> <li>• funeral services</li> </ul>
<p>SIQ Ljubljana is accredited by Serbian accreditation body ATS with accreditation number 08-022 in the field of management system certification (SRPS EN ISO/IEC 17021-1).</p> <p><i>certificate: 08-022</i>  <i>standard: SRPS EN ISO/IEC 17021-1</i></p>	<p><i>Management system certification for information security management system according to ISO/IEC 27001 standard</i></p>



## 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</p>	<p><i>Verification of greenhouse gas emissions according to 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.</i></p> <ul style="list-style-type: none"><li>• Activity group No. 1a:<ul style="list-style-type: none"><li>• combustion of fuels in installations, where only commercial standard fuels as defined in Commission Implementing Regulation (EU) 2018/2066 are used, or where natural gas is used in category A or B installations</li></ul></li><li>• Activity group No. 1b:<ul style="list-style-type: none"><li>• combustion of fuels in installations, without restrictions</li></ul></li><li>• Activity group No. 3:<ul style="list-style-type: none"><li>• production of pig iron or steel (primary or secondary fusion) including continuous casting</li></ul></li><li>• Activity group No. 4:<ul style="list-style-type: none"><li>• production of secondary aluminium</li></ul></li><li>• Activity group No. 5:<ul style="list-style-type: none"><li>• production of primary aluminium (CO<sub>2</sub> and PFC emissions)</li></ul></li><li>• Activity group No. 6:<ul style="list-style-type: none"><li>• production of lime or calcination of dolomite or magnesite</li><li>• manufacture of glass including glass fibre</li><li>• manufacture of ceramic products by firing</li><li>• manufacture of mineral wool insulation material</li></ul></li><li>• Activity group No. 7:<ul style="list-style-type: none"><li>• production of pulp from timber or other fibrous materials</li><li>• production of paper or cardboard</li></ul></li><li>• Activity group No. 98:<ul style="list-style-type: none"><li>• other activities pursuant to Article 10a of Directive 2003/87/EC</li></ul></li></ul>
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## Multilateral Agreements: testing and certification of products

<p><b>IECEE Scheme</b> Scheme for Mutual Recognition of Test Certificates</p>	<p><i>National Certification Body (NCB)</i></p> <p><i>Recognized CB Testing Laboratory (CBTL)</i> for testing of electrical safety and electromagnetic compatibility of products according to IEC standards</p> <p><i>SIQ Ljubljana can issue test certificates for the following product categories:</i></p> <ul style="list-style-type: none"><li>• information technology and office equipment (OFF)</li><li>• information technology, audio and video equipment (ITAV)</li><li>• household and similar equipment (HOUS)</li><li>• electrical equipment for medical use (MED)</li><li>• safety transformers and similar equipment (SAFE)</li><li>• luminaires (LITE)</li><li>• measurement, control and laboratory equipment (MEAS)</li><li>• portable tools (TOOL)</li><li>• switches for appliances and automatic controls for electrical household appliances (CONT)</li><li>• installation accessories and connection devices (INST)</li><li>• electronics, entertainment (TRON)</li><li>• electrical vehicles (ELVH)</li><li>• industrial automation (INDA)</li><li>• energy efficiency (E3)</li><li>• low voltage, high power switching equipment (POW)</li><li>• electromagnetic compatibility (EMC)</li><li>• batteries (BATT)</li></ul>
<p><b>IECEX Scheme</b> Scheme for Certification to Standards for Electrical Equipment for Explosive Atmospheres</p>	<p><i>IECEX Assessment and Testing Laboratory (ExTL)</i></p> <p><i>IECEX Certification Body (ExCB)</i></p> <p><i>SIQ Ljubljana can issue IECEX certificates for equipment in the following types of protection:</i></p> <ul style="list-style-type: none"><li>• flameproof enclosure Ex d</li><li>• increased safety Ex e</li><li>• intrinsic safety Ex i</li><li>• encapsulation Ex m</li><li>• non-sparking apparatus Ex n</li><li>• dust ignition protection by enclosures Ex t</li><li>• protection of equipment using optical radiation EX op</li><li>• non-electrical Ex-equipment Ex h</li><li>• Ex-equipment assemblies</li><li>• and certificates for Service Facilities</li></ul>

<b>CCA</b> Mutual recognition agreement within CENELEC	<i>National Certification Body (NCB)</i>  <i>Recognized Testing Laboratory (TL)</i>  <i>SIQ Ljubljana can issue NTR certificates for the following product categories:</i> <ul style="list-style-type: none"> <li>• information technology and audio and video equipment (ITAV)</li> <li>• information technology and office equipment (OFF)</li> <li>• household and similar equipment (HOUS)</li> <li>• electrical equipment for medical use (MED)</li> <li>• safety transformers and similar equipment (SAFE)</li> <li>• luminaires (LITE)</li> <li>• measurement, control and laboratory equipment (MEAS)</li> <li>• portable tools (TOOL)</li> <li>• switches for appliances and automatic controls for electrical household appliances (CONT)</li> <li>• installation accessories and connection devices (INST)</li> <li>• electronics, entertainment (TRON)</li> <li>• baterije (BATT)</li> <li>• electrical vehicles (ELVH)</li> </ul>
<b>CCA-EMC</b> Mutual recognition agreement on the use of a common European mark of conformity to standards concerning electromagnetic compatibility	<i>National Certification Body (NCB)</i> <i>Recognized Testing Laboratory (TL)</i>
<b>ENEC</b> Mutual recognition agreement on the use of a common European mark of conformity to standards	<i>National Certification Body (NCB)</i>  <i>Recognized Testing Laboratory (TL)</i>  <i>SIQ Ljubljana can grant licences for the ENEC mark for the following product categories:</i> <ul style="list-style-type: none"> <li>• luminaires (LITE)</li> <li>• information technology, audio and video equipment (ITAV)</li> <li>• household and similar equipment (HOUS)</li> <li>• switches for appliances and automatic controls for electrical household appliances (CONT)</li> <li>• safety transformers and similar equipment (SAFE)</li> <li>• portable tools (TOOL)</li> <li>• measurement, control and laboratory equipment (MEAS)</li> <li>• batteries (BATT)</li> <li>• installation accessories and connection devices (INST)</li> </ul>
<b>ENEC+</b> Mutual recognition agreement on the use of a common European mark of conformity to standards	<i>National Certification Body (NCB)</i>  <i>Recognized Testing Laboratory (TL)</i>  <i>SIQ Ljubljana can grant licences for the ENEC+ mark for the following product categories:</i> <ul style="list-style-type: none"> <li>• technical characteristics of products within ENEC for LED modules and LED based luminaires</li> </ul>
<b>FCC</b> <b>(Federal Communication Commission), USA</b> Notification: SI0001	Recognized testing laboratory for testing of electromagnetic radiation from electronic, electrical, industrial and medical equipment
<b>ISED</b> <b>(Innovation, Science and Economic Development), Canada</b> Laboratory No.: 21434 Notification: SI0001	Recognized testing laboratory for testing of wireless devices according to Canadian requirements for radio equipment
<b>Republic of Serbia, Ministry of Economy</b> SIQ d.o.o. Beograd Number: 119-01-503/2017-07	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)
<b>Republic of Serbia, Ministry of Economy</b> SIQ d.o.o. Beograd Number: 119-01-504/2017-07	Appointment as a conformity assessment body according to the Rules on electromagnetic compatibility (Official Gazette of the Republic of Serbia 25/16)
<b>Republic of Serbia, Ministry of Economy</b> SIQ d.o.o. Beograd Number: 119-01-307/2019-07	Appointment as a conformity assessment body according to the Rules on machinery safety (Official Gazette of the Republic of Serbia 58/2016)

## Multilateral Agreements: management system certification

<b>IQNET</b>	Co-operation and mutual recognition and promotion of issued certificates for management systems
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## Authorizations: inspection and other professional tasks

<b>Ministry of the Economy of the Republic of Slovenia</b> Decision No.: 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).
<b>Public Agency of the Republic of Slovenia for Railway Transport</b>	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"><li>• energy</li><li>• control-command and signalling</li><li>• rolling stock</li></ul>

# SIQ Ljubljana

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