SIQ report

Year 30/82 — May 2022

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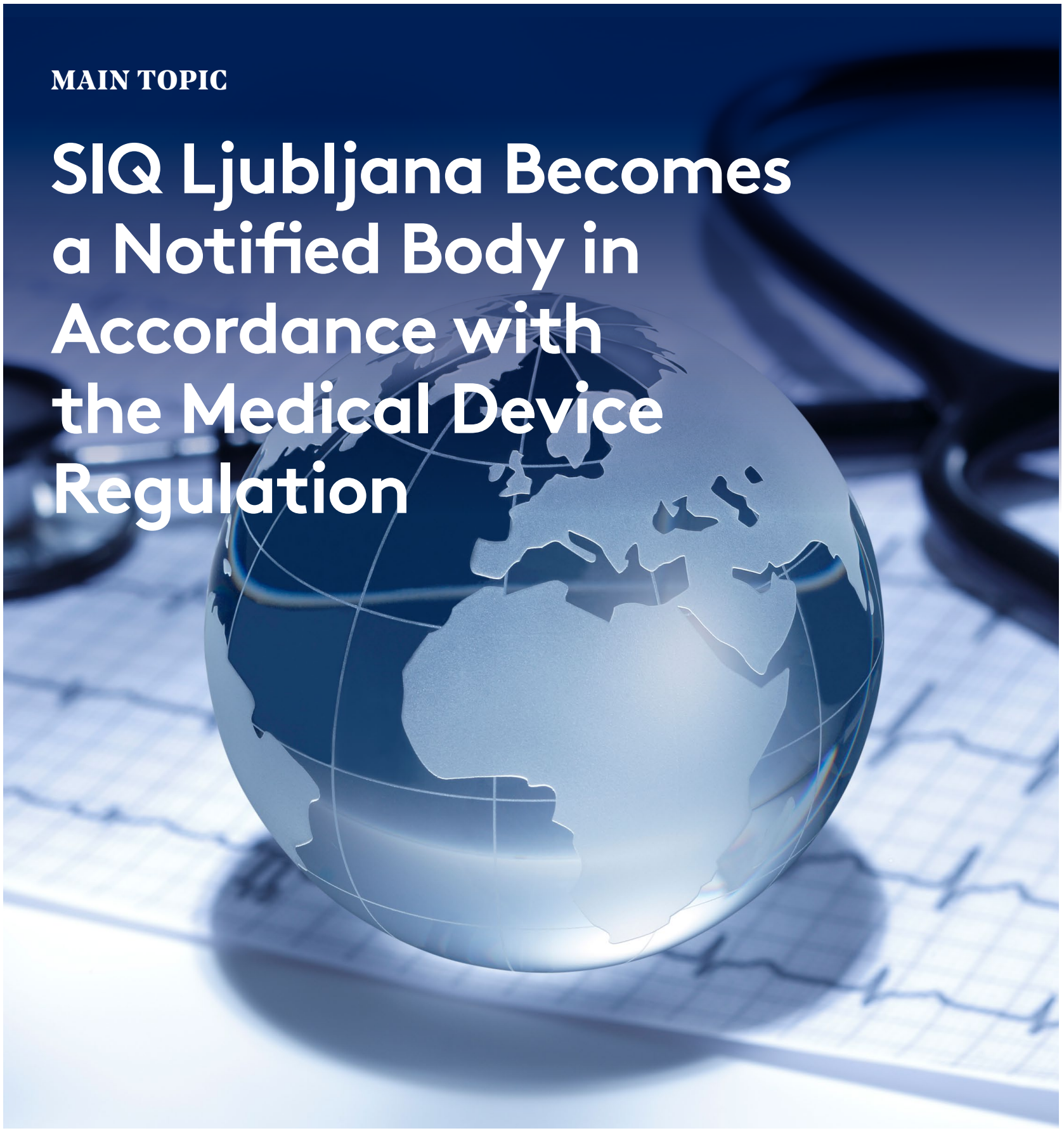
MAIN TOPIC

SIQ Ljubljana Becomes a Notified Body in Accordance with the Medical Device Regulation



You May Not Have Known

27,6%
OF THE WORLD MARKET
is accounted for by the European medical technology market.

28
notified bodies
have so far been designated according to Regulation (EU) 2017/745 on Medical Devices.

140
bn euros
is the value of the European medical technology market.

500.000
medical technologies
and more are available in hospitals, care homes and our homes.

760.000
people
and counting are employed in medical technology in Europe.

33.000
companies in Europe
are active in the field of medical technology, 95% of which are SMEs.

In March this year, we became a designated notified body in accordance with the new Medical Device Regulation. This is a great achievement for Slovenia, Slovenian manufacturers and, of course, for SIQ.

Among Twenty-Eight in the World

Gregor Schoss
Managing Director

Medical devices play a key role in saving lives. They account for more than a quarter of the world market. This is a sector that is constantly and rapidly evolving and that requires constant adaptation of all stakeholders. The human population is ageing, so rehabilitation devices are also gaining importance. Like medical devices, they are becoming increasingly technologically complex, as is the testing and certification that we carry out.

As a professional, independent and impartial institution, SIQ enables manufacturers of medical devices to place safe medical devices on the market, in conformity with the relevant European legislation. In addition to providing services for the automotive industry, the certification of medical devices is one of our strategic activities.

In March this year, we became a designated notified body in accordance with the new Medical Device Regulation. This is a great achievement for Slovenia, Slovenian manufactures and, of course, for SIQ. The path from lodging the application to being designated as a notified body took four years. During this period, we devoted a great deal of time to the training and professional development of our staff in order to keep up with the progress of science and engineering, and with the requirements for ensuring the safety and performance of devices.

At SIQ, we are proud to be one of only 28 such notified bodies in the world at the moment.

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SIQ LJUBLJANA BECOMES A NOTIFIED BODY IN ACCORDANCE WITH THE MEDICAL DEVICE REGULATION

Following the successful completion of the designation and notification procedure under Regulation (EU) 2017/745 on Medical Devices (MDR), SIQ Ljubljana became a notified body for medical devices on 31 March 2022 and was registered in the NANDO database of the European Commission.

We can offer medical device certification services in accordance with the MDR to medical device manufacturers worldwide so they can enter the European market. The scope of SIQ Ljubljana's designation covers a wide range of medical device groups (active, inactive, devices that incorporate software, sterile devices, etc.), specific expertise and medical device technologies. We are currently one of 28 notified bodies designated in accordance with the new regulation, while the procedures for designating other notified bodies are still ongoing.

On 26 May 2021, the new MDR fully replaced Directive 93/42/EEC on Medical Devices (MDD), under which 50 notified bodies were designated. As of that date, certificates under the MDD can no longer be issued. From 26 May 2024, the requirements of the new MDR must be complied with by all medical devices regardless of their risk class. However, manufacturers may place devices already certified under the MDD on the market until 26 May 2024, provided the design and intended purpose of the medical device have not changed significantly. The new regulation places great emphasis on demonstrating the effects of operation and on new requirements for the safety and performance of medical devices, while software safety is also emphasised.

The Medical Device Regulation requires manufacturers of medical devices to mark their products with the CE marking before they are offered on the EU market. In so doing, they declare that the medical device complies with EU rules governing the field of medical devices and ensure that their medical device is safe and effective. In the case of class Is, Im, Ir, IIa, IIb and III medical devices (MDR), a notified body must also be included in the conformity assessment procedure of the medical device. Compliance with the requirements of the EU rules governing medical devices is demonstrated by the issuing of an EU certificate.

SIQ Ljubljana operates on the world market in the field of medical devices and currently has just under 150 valid certificates for various medical devices under the MDD Directive. Our largest markets are the countries of Central and South-East Europe.

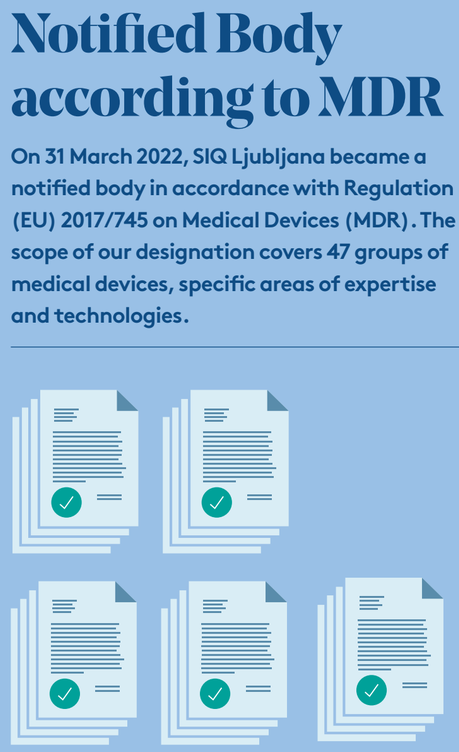
According to MedTech Europe data (https://www.medtecheurope.org/datahub/market/), the European medical technology market was estimated at around €140 bn in 2020 and accounted for 27.6% of the global market. The largest medical device markets in Europe are Germany, France, the United Kingdom, Italy and Spain. The European medical device market has grown by an average of 2% per year over the last ten years.

In the field of medical devices, SIQ Ljubljana operates on the world market and there are currently just under 150 valid certificates for various medical devices issued by SIQ Ljubljana under the MDD Directive. Our largest markets are the countries of Central and South-East Europe – Austria, Germany, Slovenia, Serbia and Croatia. However, we have issued medical device certificates under the MDD on four continents – mostly in Europe, but also in North America, South America and Asia.

SIQ Ljubljana offers manufacturers of medical devices seeking to access the European and global market and comply with the relevant legislation a comprehensive range of services, including safety and electromagnetic compatibility (EMC) testing of devices, cybersecurity testing, testing across a wide range of harmonised standards, and certification of quality management systems according to various standards (ISO 13485, ISO 9001 etc.). SIQ involves top professionals and experts in the certification and testing procedures, including clinical specialists who review clinical evaluations of medical devices. Our experts take part in regular trainings for individual medical device groups.

Notified Body according to MDR

On 31 March 2022, SIQ Ljubljana became a notified body in accordance with Regulation (EU) 2017/745 on Medical Devices (MDR). The scope of our designation covers 47 groups of medical devices, specific areas of expertise and technologies.



56

competent experts are involved in medical device testing and certification at SIQ.

2505

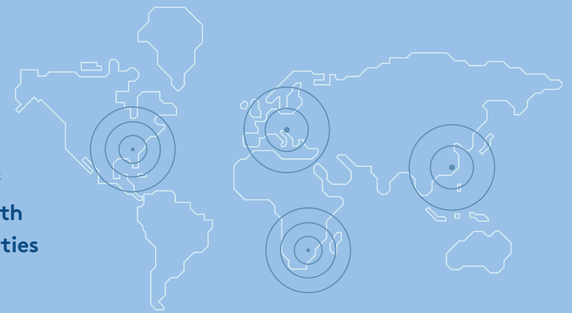
audit and/or test reports have been issued by SIQ in the field of medical devices in the last five years.

484

audit and/or test reports were issued by SIQ in the field of medical devices in 2021 alone.

30

countries on four continents of the world are covered by SIQ with testing and certification activities in the field of medical devices.



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Complete Solutions for Medical Devices

We provide support to manufacturers of medical devices all the way from the idea and design to the placing of the device on the market with a variety of services – we train, test and certify.

"SOT Medical Systems helps vascular specialists in early diagnosis of blood flow disorders and in the prevention of amputations. Our goal is to offer our customers the most advanced, comprehensive and accurate systems for vascular diagnostics.

Our AngE™ products (pictured: PHLEBO, PRO4 and PRO8) are designed, manufactured and assembled at our headquarters in Carinthia, Austria, taking into account the highest quality standards and in cooperation with SIQ Ljubljana. We are holders of the EC certificate MDD-157 in accordance with MDD Directive 93/42/EEC and the ISO certificate 13485:2016 M-166. Both were issued by SIQ.

Our employees regularly take part in training and retraining at SIQ Ljubljana, thus obtaining the latest knowledge. We are pleased that we have such a reliable partner on our side and that we will overcome future challenges together. This is facilitated by the wide range of testing options in the relevant testing laboratories (e.g., IEC 60601-1, IEC 60601-1-6, IEC 80601-2-30), going beyond the mere activity of the notified body.

Quick and professional communication and support on the part of SIQ employees ensure the identification of any possible improvements and the development of quick and feasible solutions." Management of SOT Medical Systems

The comprehensive range of services we offer includes testing of the safety and electromagnetic compatibility (EMC) of products, cybersecurity testing, testing according to different harmonised standards, personnel training, interpretation of standards, legislation and certification procedures, as well as management system certification according to different standards (ISO 13485, ISO 9001, ISO 14001, etc.) and certification according to relevant legislation. With these services, we support manufacturers in entering the Slovenian market as well as European and global markets.

The experience we have with the certification of medical devices under the current legislation concerning medical devices (Medical Device Directive 93/42/EEC) shows that manufacturers of medical devices who have a good knowledge of legislative requirements, harmonised standards and guidance documents usually complete the medical device certification procedure faster.

It is therefore recommended that manufacturers first undergo training to familiarise themselves with the requirements of the Regulation (EU) 2017/745 on medical devices (MDR), harmonised standards and the European guidance documents of the Medical Device Coordination Group (MDCG). Information on such training courses, which are available in Slovenian, English, Serbian and Croatian, can be found on the SIQ website (www.siq.si/en/) under Training – Program – Medical Devices.

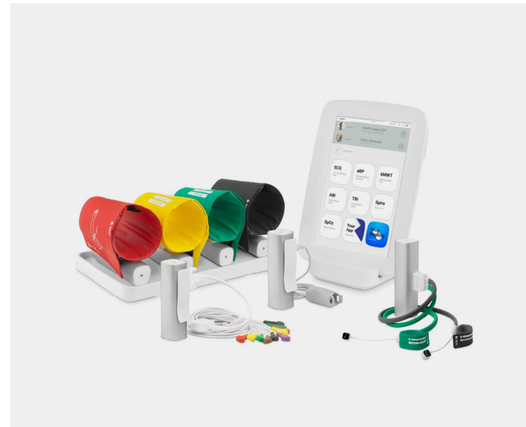
In the development phase of a medical device, the manufacturer must involve various experts with specific skills, such as clinical specialists – doctors who, by examining existing scientific literature, establish a scientific medical basis for the development of the device. During the development planning phase, the manufacturer must carry out the first risk assessment involving personnel with technical and medical knowledge. At this stage, the manufacturer must also review the general safety and performance requirements (MDR,

PRIZMA KRAGUJEVAC DOO is our oldest Serbian partner in the field of medical device testing and certification. We initiated the first certification procedure in accordance with the requirements of MDD 93/42/EEC together 15 years ago, in 2007. Prizma is also the most loyal attendee of our seminars organised by SIQ Belgrade in the field of medical devices. In 2021, the company's staff participated in all of the seminars we organised. The photo shows PROFI SONIC, an ultrasonic nebuliser for professional use, certificate MDD-006.

Experience has shown that medical device manufacturers who are more aware of regulatory requirements, harmonised standards and guidance documents complete the certification procedure for their medical device faster.

Annex I) to identify the requirements relevant to the device and production. This enables the manufacturer to determine which tests and verifications will have to be carried out and which experts will need to be involved – for example, experts in sterilisation, biocompatibility, or electrical safety and electromagnetic compatibility testing. Testing according to the EN 60601 series of standards and other relevant standards can be carried out in our safety and electromagnetic compatibility laboratories. The range of accredited services and other services provided by SIQ laboratories is published on the SIQ website (www.siq.si/en/) under Our Services – Product Testing and Certification – About Us.

If the manufacturer performs the first testing at the device development stage, any defects will come to light early and can be corrected during the development phase. This saves time and ensures that the device can enter the market sooner.



Healthcare needs dictate the development and adaptation of existing medical devices to the new needs of users and patients. Already in the development phase of a device or when introducing modifications to its medical devices, the manufacturer MESI Ltd meets with SIQ experts to discuss the steps necessary to initiate the procedure for testing or certification of a medical device. In February, it presented us with the changes to one of its products, ABPI MDD, EC certificate MDD-037, and an assessment of the significance of these changes.

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Procedure for Certification of Medical Devices in Accordance with the Regulation (EU) 2017/745 on Medical Devices (MDR)

The path for the entry of a medical device to the market starts with an idea and leads through its production and testing to the eventual certification. It is recommended that the manufacturer contact the notified body already at the development stage of a device and obtain information on the certification procedure and the requirements that the medical device must meet.

FIGURE 1.1.

First steps leading to the certification procedure.

The MDR introduces stricter and more comprehensive requirements for demonstrating the conformity of medical devices. The entire testing and certification procedure is lengthy and can take up to two years, which many manufacturers do not expect.

The first steps towards starting the certification procedure, ranging from our first contact with the customer to the confirmation of the offer and the planning of the assessment and audit, are shown in Figure 1.1.

How is the certification procedure conducted?

The organisation submits the technical documentation to the notified body. The latter carries out a brief review, i.e., a preliminary review of the documentation, which involves verifying the adequacy of the documentation structure and determining whether all of the required documents have been included. After confirming the adequacy and completeness of the documentation, the certification procedure can finally be initiated.

The first part of the procedure is the assessment of the technical documentation and the clinical evaluation of the device. SIQ involves a range of qualified professionals, including clinical specialists and specialists with specific skills (in software, biocompatibility, sterilisation, etc.), where necessary.

Once the assessment of the technical documentation and the clinical evaluation has been completed and the documentation is in compliance with the MDR, the certification procedure continues according to the chosen conformity assessment procedure (See Figure 1.2).

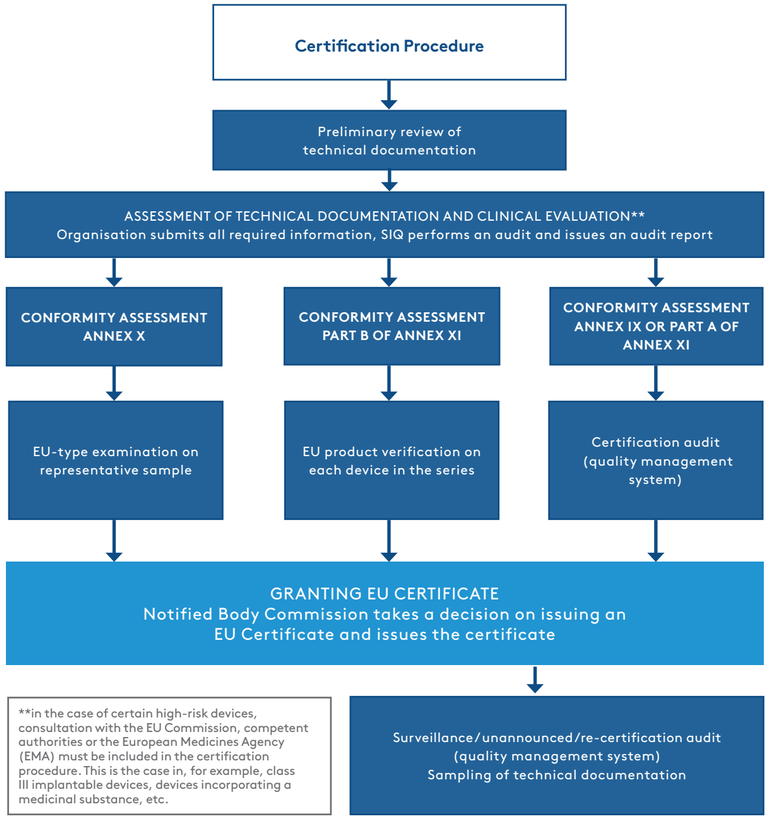

FIGURE 1.2.

Certification procedure according to various conformity assessment procedures.

Most often, manufacturers decide on a conformity assessment procedure set out in Annex IX or Part A of Annex XI, which involves an audit of the established quality management system. In such cases, the certification procedure continues with a certification audit, which may be combined with an audit according to the ISO 13485:2016 standard.

It should be noted that in the entire certification procedure, it is the assessment of the technical documentation and the clinical evaluation (part one of the assessment) that takes the longest, in some cases lasting up to one or two years.

Once all non-compliances have been eliminated by the organisation and all requirements have been met, the notified body issues a certificate (EU) that enables medical device manufacturers to enter the EU market.

In the case of conformity assessment according to Annex IX or Part A of Annex XI, the notified body carries out surveillance audits of the certified quality management system once a year, followed by a re-certification audit every fifth year. During the surveillance and re-certification audits, the auditors also review the manufacturer's reports on post-market follow-up on devices and possible complications, which are called vigilance cases. The notified body carries out an unannounced audit at least once every five years (except in the case of a Class III medical device, where the audit is carried out at least once every two years) to verify how the certificate holder is maintaining and updating its quality management system.

Although the overall certification procedure in accordance with the MDR is a completely new procedure, it may be partially adapted if the organisation is already a holder of a valid EC certificate in accordance with the MDD – in the case of an audit according to Annex IX or Part A of Annex XI, a combined MDD and MDR audit is carried out.

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Quality Management System according to the MDR

Medical devices may be placed on the market or put into service only if they comply with legal requirements. The Regulation (EU) 2017/745 on Medical Devices (MDR) provides that manufacturers of medical devices must affix the CE marking to their products before they are placed on the EU market. The CE marking indicates that devices are in conformity with the regulations governing the field of medical devices and are therefore safe and effective.

The requirements for the quality management system of medical device manufacturers are laid down in Article 10 of the Regulation (EU) 2017/745 on Medical Devices, which started to apply on 26 May 2021, and the Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices, which will apply from 26 May 2022.

Manufacturers of medical devices must establish procedures whereby series production remains in conformity with the requirements of the MDR. In order to ensure compliance with the legal requirements, they must establish, document, implement, maintain, update and continuously improve their quality management system in a manner that is proportionate to the risk class of the device.

The requirements for the quality management system of medical device manufacturers are laid down in Article 10 of the MDR, which started to apply on 26 May 2021, and in Article 10 of the Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR), which will apply from 26 May 2022.

Manufacturers may also comply with the general requirements for the quality management system referred to in Article 10 (indent 9) and the requirements of the selected conformity assessment procedure set out in Annex IX (Conformity assessment based on a quality management system and on assessment of technical documentation) or Part A of Annex XI (Conformity assessment based on product conformity verification, Production quality assurance) of the MDR by meeting the requirements of the ISO 13485:2016 standard published on 5 January 2022 in the Official Journal of the European Union as an MDR harmonised standard: EN ISO 13485:2016/A11:2021 Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes.

The harmonised standard EN ISO 13485:2016 in Annex ZA shows the relationship between the standard and the requirements of the MDR. With its publication in the Official Journal of the European Union, compliance with the quality management system according to the points of the ISO 13485:2016 standard listed in Tables ZA.1, ZA.2 or ZA.3 must be presumed as compliance with the relevant requirements of the MDR.

Table ZA.1 in the Annex to the standard shows the links between each general requirement for the manufacturer referred to in Article 10 of the MDR and a specific point or points of the standard. In addition, it states in which points of the standard the requirements of the Regulation are fully or partially covered and which requirements of the Regulation are not covered by the standard. The manufacturer must nevertheless comply with any requirement of the MDR that is not covered by the standard.

For manufacturers of medical devices classified in a higher risk class, in the case of the selected conformity assessment procedure according to Annex IX or Part A of Annex XI, the correspondence between the requirement in the point and/or paragraph of the selected MDR Annex and a specific point or points of the standard is shown in Tables ZA.2 and ZA.3. The same applies as above: partially covered requirements and requirements not included in the quality management system according to the ISO 13485:2016 standard must be fulfilled according to the requirements of the chosen procedure set out in Annex IX or Part A of Annex XI of the MDR.

The application of the standard is not a regulatory obligation. However, when assessing the manufacturer's quality management system, the notified body must apply all of the guidelines, common specifications and harmonised standards available, even if they have not been used by the manufacturer to demonstrate the conformity of their quality management system. Any non-compliances must be identified in the event of non-fulfilment of the requirements of the MDR and not with regard to the requirements of the standard or guidelines.

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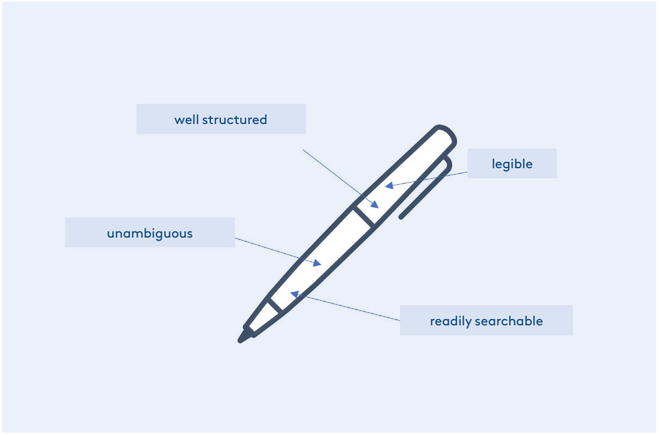
Technical Documentation according to MDR Requirements

How does the manufacturer demonstrate that glaucoma laser surgery using their device is safe for the patient and that it effectively lowers eye pressure? Why do we believe that we can discover blocked arteries and reduced blood flow in the arteries of the limbs in a timely manner using a device to measure the ankle brachial index?

Technical documentation is a group of related documents by which the manufacturer explains the use, operation, manufacture and architecture of a medical device and demonstrates its safety and usefulness for a specific purpose. It is a guide for both the manufacturer as such and for users, certification bodies, competent national authorities and others who need to be familiar with the functioning of the device.

In accordance with Article 10 of Regulation (EU) 2017/745 on Medical Devices (MDR), the manufacturer of the device must draw up the technical documentation and then regularly update it in accordance with the development of the device and the state of technology. The documentation must be retained for a period of 10 years after the last device is placed on the market, or 15 years in the case of implantable devices.

Any manufacturer that has already placed its product on the market in accordance with the MDD (Directive 93/42/EEC) may use parts of the previous technical documentation in the technical documentation under the MDR. It must, however, carefully review the requirements of the MDR, add any new elements, obtain proof of new and amended safety and performance requirements, and allow an appropriate period of time for all of this.



Annexes II and III of the Medical Device Regulation specifically require that technical documentation be well structured, unambiguous and legible.

The necessary elements of the technical documentation are laid down in Annexes II and III of the MDR. The required content must be divided by the manufacturer into six parts: description and specification of the device, manufacturer information, design and manufacture information, general safety and performance requirements, benefit-risk ratios and risk management, and verification and validation. Any manufacturer who wishes to have a medical device certified by SIQ must follow the structure of the technical documentation prescribed in the relevant SIQ system document. Upon receiving each part of documentation, we first review it to determine whether it fulfils the structural criteria and contains all of the necessary documents. If this is not the case, we ask the organisation to submit the missing documents. This shortens the time needed by the audit team to assess the documentation and its supplements.

Manufacturers can submit their technical documentation to SIQ in three EU languages: Slovenian, English or Croatian.

What are the specific features of technical documentation according to the MDR? Let's look at some of them:

- The first part, i.e., Device description and specification, must contain the rationale for the qualification of the product as a device, as well as an overview of the previous generations of the device and similar devices available on the market.
- The instructions for use must be in the languages of the EU Member States in which it is envisaged that the device will be sold.
- All sites of the manufacturer where design and manufacture of the device are performed, including suppliers and subcontractors, must be identified.
- The manufacturer must address and demonstrate compliance with the new or amended safety and performance requirements introduced by the MDR.
- For any known and foreseeable risk and any side effects, solutions for risk mitigation, or justification for why this is not possible, must be provided.
- The results and critical analyses of all verifications and validation tests and studies undertaken to demonstrate conformity of the device with the requirements of the MDR, in particular safety and performance requirements, must be recorded in the technical documentation.

As a general rule, reports must be attached. However, the organisation may also only refer to reports relating to production processes, which SIQ then verifies during the quality management system audit. If SIQ needs any of these documents in the assessment of the technical documentation, it will request them at a later stage.

Any manufacturer that has already placed its product on the market in accordance with the MDD (Directive 93/42/EEC) may use parts of the previous technical documentation in the technical documentation under the MDR. It must, however, carefully review the requirements of the MDR, add any new elements, obtain proof of new and amended safety and performance requirements, and allow an appropriate period of time for all of this.

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Post-Market Surveillance

'Post-market surveillance' means all the activities carried out by manufacturers to institute a systematic procedure to proactively collect and review experience gained from devices that they place on the market for the purpose of identifying any need to immediately apply any necessary corrective or preventive action.

Medical device post-market surveillance (PMS) activities have already been described in the European Medical Device Directive (93/42/EEC) and are part of the Quality Management System (QMS) certification under EN ISO 13485:2016. However, for various reasons, such as PIP implants, PMS activities have been tightened. Consequently, the new Regulation (EU) 2017/745 on Medical Devices (MDR) has included new PMS requirements and supplemental reporting to Notified Bodies (NB) or Competent Authorities (CA) that are in proportion to the risk class and the type of device.

For each device, manufacturers must plan, establish, document, implement, maintain and update a post-market surveillance system (Article 83) in a manner that is proportionate to the risk class and appropriate to the type of device. This system must be an integral part of the manufacturer's quality management system referred to in Article 10(9) of the MDR. For devices which are subject to a transition period until 26 May 2024 according to Article 120(3) of the MDR and are not yet certified under the MDR, the procedure must be based on the existing classification under the MDD. To facilitate the understanding of the requirements of Article 120(3) MDR, manufacturers may use the EU guidance documents (MDCG 2020-25).

The post-market surveillance system must be suited for actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective action. A PMS System consists of the PMS procedure, PMS plan (product specific) and PMS report or PSUR (Periodic Safety Update Report), depending on the risk class of the device. The post-market surveillance system must be based on a post-market surveillance plan; its requirements are set out in Section 1.1 of Annex III of the MDR.

The post-market surveillance system consists of the PMS procedure, PMS plan (product specific) and PMS report or PSUR (Periodic Safety Update Report), depending on the risk class of the device. It must be based on a post-market surveillance plan. Its requirements are set out in Section 1.1 of Annex III of the MDR.

According to Article 84 and Annex III, the MDR requires manufacturers to consider various PMS activities such as: market feedback, customer feedback and complaints, vigilance, Field Safety Corrective Action (FSCA), the collection of new data from literature or databases. The PMS plan should be product-specific. It covers methods and protocols to manage incidents subject to the trend report, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents, as well as the observation period. Methods and protocols for effective communication with CAs, NBs, economic operators and users should be included in the PMS plan. The PMS plan should reference the PMS procedures (Articles 83, 84 and 86) to identify and initiate appropriate measures including corrective actions, and effective tools to trace and identify devices for which corrective actions may be necessary, as well as a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.

The Post-Market Surveillance Report (PMSR) and Periodic Safety Update Report (PSUR) from MDR Articles 85 and 86 are documents that must be included in the technical documentation from Annexes II and III of the MDR.
The PMSR is required for Class I devices and must be made available to the Competent Authorities. The PMSR summarises the results and conclusions of the analyses of the PMS data gathered because of the PMS plan, together with a rationale and description of any preventive and corrective action taken. The report must be updated when necessary and made available to the competent authority upon request.

The PSUR is required for Class IIa, IIb and III devices. For implantable and Class III devices, the PSUR must be submitted via EUDAMED to the NB for review. For Class IIa and non-implantable IIb devices, the PSUR should be sent to the NB. The PSUR must be updated at least every two years for Class IIa devices and every year for Class IIb and III devices. In addition, the PSUR must include the conclusion of the benefit-risk ratio resulting from the risk analysis, the PMCF findings, the volume of sales, an estimation of the population size using the device, and the usage frequency in the case of reusable devices. To maintain consistency with the data resulting from the CER, the PMS records under the PMSR or PSUR must also be carefully designed to present how device performance is achieved, especially regarding similar devices on the market.

According to Annex XIII of the MDR, the manufacturer must review and document experience gained in the post-production phase, including from the Post-Marketing Clinical Follow-up (PMCF) as referred to in Part B of Annex XIV of the MDR, and implement appropriate means to apply any necessary corrective action.

As for post-market surveillance, a report for Class I devices according to Article 85 MDR and a Periodic Safety Update Report for Class IIa, IIb and III according to Article 86 of the MDR, should be established by the Custom-Made Device (CMD) manufacturer. Both the PMSR and the PSUR must be part of the CMD documentation according to Section 2 of Annex XIII of the MDR. In the case of Class III implantable CMDs, PSURs are not required to be sent to NBs but must be part of the CMD documentation according to Section 2 of Annex XIII of the MDR.

PMS activities may have an impact on different QMS documents such as the Clinical Evaluation Report (CER), IFU and the risk analysis, and therefore the consistency in recording data is extremely important.

According to Annex XIII of the MDR, the manufacturer must review and document experience gained in the post-production phase, including from the Post-Marketing Clinical Follow-up (PMCF) as referred to in Part B of Annex XIV of the MDR, and implement appropriate means to apply any necessary corrective action.

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Certification of Distributors and Importers in Accordance with Article 16 of the MDR

Manufacturers of medical devices place their products on the market through a network of distributors, importers or other natural and/or legal persons (hereinafter: contractors) with whom they have signed cooperation contracts.

»It is only when you take responsibility for your life that you discover how powerful you truly are«

Allanah Hunt

This interaction is addressed in the light of the continued safety and performance of the product in accordance with Article 16 of Regulation (EU) 2017/745 on Medical Devices (MDR). As a notified body, SIQ carries out procedures and issues certificates in accordance with this Article.

Some important items from Article 16 are summarised below:

In so far as the importer or distributor carries out any of the activities referred to in Article 16 of the MDR, such as:

- provision, including translation, of information relating to a medical device already placed on the market and of further information required in order to market the medical device in the relevant Member State,
- changes to the outer packaging of a device already placed on the market, including a change of packaging size, if the repackaging is necessary in order to market the device in the relevant Member State,

it must, at least 28 days prior to making the relabelled or repackaged device available on the market, inform the manufacturer and the competent authority of the Member State in which it plans to make the device available of this and, upon request, must provide the manufacturer and the competent authority with a sample of the adequately relabelled or repackaged device.

With the new Regulation (EU) 2017/745 on Medical Devices (MDR) some obligations for manufacturers also apply to importers, distributors and other related economic operators. Are we aware of them?

Changes to the packaging must be made under such conditions that they do not affect the original condition of the medical device. For sterile medical devices it is, of course, presumed that they are no longer in their original condition if the packaging that is necessary for maintaining the sterile conditions is opened or damaged in any way.

During the same period, i.e., 28 days, the contractor must submit to the competent authority a certificate attesting that its quality management system has been established, implemented and maintained.

In order to facilitate understanding of the requirements of Article 16 of the MDR, contractors may use the MDCG 2021-23 Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746. The guidance also serves as the basis for the notified body to carry out the certification process.

The contractor's quality management system must include procedures in place to ensure that the translation of the information is accurate and up to date and that the modified packaging is not defective, of poor quality or untidy. The quality management system should adequately address and maintain at least the following areas: documentation, resources, responsibilities, communication, corrective actions, traceability and records. SIQ verifies contracts concluded between contractors to determine whether they provide for timely information on changes and corrective measures with a view to maintaining safety and compliance.

Through continuous staff training and updating of knowledge in the field of current regulations and guidelines, SIQ further ensures:

- selection of the staff concerned based on specified criteria,
- documentation and maintenance of staff qualifications,
- carrying out of certification procedures in accordance with relevant guidelines and legislation,
- correct definition of the certification scope,
- appropriate supervision to ensure that the contractor's quality management system is properly maintained.

The contract concluded by SIQ with the importer or distributor should provide that the audits are to be carried out at the contractor's site.

SIQ can perform certification activities for the types of medical devices for which we are designated by the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP).

The MDCG provides further explanations in their document MDCG 2021-26 Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

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Medical Device Trainings

Last year, SIQ marked 30 years since carrying out the first training course on quality management systems for an external organisation, and it is almost 20 years since the first course for internal auditors for quality management systems according to the ISO EN 13485 series of standards in the field of medical devices.

To date, more than 450 internal auditors have been trained in the field of medical devices. In the last year, upon successfully completing the course, they receive not only the SIQ certificate, but also the internationally recognised IQNet certificate.

As SIQ has become increasingly recognised as a notified and independent body for testing and certification of medical devices, there has been growing interest in professional educational content in the field of ensuring compliance of medical devices. Together with renowned experts from practice, we provide 23 different training programmes on medical device legislation and related standards. We are also expanding the offer of these professional trainings to foreign markets, in particular to the EU market.

Since the new Medical Device Regulation (MDR) entered into force last year, consistent compliance with its general requirements has been required for all organisations dealing with medical devices, i.e., not only manufacturers, but also importers and distributors of various types of medical devices. From the outset, it is good to clarify any questions regarding the classification of medical devices and certification procedures, requirements for economic operators, and the documentation requirements regarding medical devices. This is very important in drawing up technical documentation. To this end, a more comprehensive workshop is available to participants, Medical Devices – Guidelines for Drawing Up the Technical File.

All manufacturers, irrespective of the class of the medical device, must establish a quality management system. If they decide to establish a quality management system according to the EN ISO 13485 series of standards, they can acquire the relevant competences by attending our workshop EN ISO 13485:2016 – The Basics of the Quality Management System for Medical Devices, ISO 13485:2016 Medical Devices - Quality Management System Internal Auditor Training Course, and the workshop Regulation (EU) 2017/745 (MDR) on Medical Devices (MDR).

In the case of medical devices, it is important to demonstrate (with a technical file) that there is a favourable relationship between the performance or clinical benefit of the device and the risks of its use, which must be managed (benefit-risk ratio). The participants of two of our workshops, Risk-Based Approach and Risk Assessment for Medical Devices, are provided with the key knowledge and insights necessary for the effective establishment of a risk management system. We also share knowledge on demonstrating performance – clinical evaluation of medical devices, biocompatibility and sterility.

Key knowledge regarding the implementation of a post-market surveillance system and a system for recording and reporting complications and safety corrective actions is given to the participants of the workshop on Traceability of Medical Devices and Obligations of Manufacturers in Connection with After-Sales Activities.

Depending on the classification of the medical device/class and the associated level of risk to users, it is necessary to ensure the conformity of medical software and cybersecurity management. We have training courses on that topic as well.

We also offer training for manufacturers of custom-made medical devices (dental devices, prosthetics, orthotics, etc.), who must be attentive to Annex XIII (MDR), which lists the procedure for medical devices designed for individual users (custom-made devices), while Annex XVI (MDR) includes a list of groups of devices without an intended medical purpose (contact lenses, products intended to be introduced into the human body, dermal fillers, etc.).

We also share our knowledge on Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR), which enters into force in May this year. Unlike medical devices or pharmaceuticals, in vitro diagnostic medical devices never come into contact with a person and do not treat patients, but rather provide information about the condition of the body.

For organisations selling medical devices on the US market, we have a workshop on the US Code of Federal Regulation (21 CFR 820) to ensure the conformity of medical devices, and on 510(k) registration procedures, where the participants can familiarise themselves with the relevant US legislation in this field and get to know the basic procedures for registering medical devices in the USA.

News

Calculating the Carbon Footprint of an Organisation, Product or Service

Organisations are becoming more and more sustainability-oriented as standards and EU policies, guidelines and customers become more demanding.

Monitoring the carbon footprint of individual activities, products and/or services is one of the fundamental tools for managing greenhouse gas emissions, increasing energy efficiency, and promote the usage of renewable energy resources.

In the practical workshops we organise, we provide knowledge on how to calculate the carbon footprint of a company, product or service. We also verify the carbon footprint calculations ourselves. In this way, we help and support organisations to make the impact of their sustainability measures on the environment measurable.

The workshops introduce the basic concepts of the carbon footprint and the associated standards and methods for calculating and managing carbon footprint. Through the discussion of practical examples, participants acquire useful and practical knowledge for the correct calculation of their carbon footprint in practice.

Conducting Training Courses Abroad

With the development of online training as part of the measures to contain the epidemic, we took the opportunity to enter the EU market with courses in English. We started with e-learning in the field of medical devices, offering the market a course for internal auditors in accordance with the requirements of ISO 13485, a workshop on the EU Medical Devices Regulation (2017/745), and training on sterility, biocompatibility and conformity assurance of medical devices. Most of the participants in these training sessions come from Austria and Germany, but also from Belgium, Switzerland, Lithuania and England, with a surprisingly high number of participants from Slovenia. This year we are expanding our offer for foreign markets in the areas of laboratories and inspection bodies, automotive industry and technical legislation.

Due to geographical proximity, shared history and language skills, we have also started e-learning courses in the areas of quality and environmental management systems in the markets of the former Yugoslavia. In the future, we want to extend them to the automotive and laboratory sectors in these markets.

Second Track of the Divača–Koper Railway Line

One of the most important railway infrastructure projects in Slovenia in recent years is undoubtedly the construction of the second track on the Divača–Koper railway line. SIQ Ljubljana is involved in this project as one of the testing bodies for railway interoperability. In order to ensure sufficient technical capacity to carry out the verification within the expected timeframe, the Slovenian bodies active in the field of railway interoperability verification joined together in a consortium and submitted a joint bid to carry out the work. The consortium was successful with its joint bid and signed a contract with 2TDK for the verification in August 2020. The consortium includes QTechna d.o.o., DIS Consulting d.o.o., Bureau Veritas d.o.o., and SIQ Ljubljana. SIQ Ljubljana is involved in the verification of the Energy (ENE) and Control–Command and Signalling (CCS) subsystems. The contract value of our work is approximately 27% of the total value of the review.

The construction of the second track will take place in phases, with completion scheduled for the second half of 2026 according to the current timetable. To date, preparatory works (construction of access roads and preparation of individual construction sites) have been carried out along the entire route. In 2021, construction works on individual sections also started. As for the review, activities are currently underway on the infrastructure subsystem (INF), in which we are not involved. According to the schedule, we will be involved in the verification activities for the CCS subsystem at the end of this year. In November 2021, the consortium visited the entire second track route together with representatives from 2TDK. The visit was organised to learn about the specifics of each section and the current status of construction.

In Bled.

A tour of the Gaming Technologies Test Lab at SIQ, led by Primož Bogataj (bottom left).

At Yaskawa Slovenija in Kočevje.

We Hosted a Delegation from Azerbaijan

A delegation from Azerbaijan visited Slovenia from 15 to 19 November 2021 as part of the UNIDO project "Development of Innovation Ecosystem and Support Infrastructure – Digital Education Centre (DIC) of Azerbaijan".

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SIQ Ljubljana, Ljubljana Technology Park and Baku Innovation Agency are cooperating with the Ministry of Economic Development and Technology in this project. One of the activities of the project was the organisation of a study visit of 13 Azerbaijani start-ups and representatives of the Baku Innovation Agency to Slovenia to exchange best practices.

The technical part of the visit was supported by Slovenian organisations and companies. The guests learned about the activities of the Entrepreneurship Fund of Slovenia (EFS), the Slovenian Public Agency SPIRIT and the Digital Innovation Hub of Slovenia (DIH) and received important information about Slovenia's incentives and support for the development of start-up entrepreneurship. They visited the production of industrial robots at Yaskawa Slovenija, the production of printed circuit boards at INTEC TIV d.o.o., the geo-information services business of GEOCODIS d.o.o. and the use of an IT system developed by NETS d.o.o. The important role of technology parks in developing the ecosystem for start-ups was well presented by the Ljubljana Technology Park with success stories and experiences. The guests shared important information about the mechanisms of entering European markets with the Ljubljana University Incubator (LUI), Sežana Incubator and Primorska Technology Park.

Guests were guided through Slovenia's cultural heritage, history and natural beauty by staff from the Slovenian Ethnographic Museum, Ljubljana Castle, Tourist Information Centre (TIC) Bled and Zero Waste Hotel & Glamping Ribno Bled.

We would like to thank all participating Slovenian organisations and especially our project partners – the Ljubljana Technology Park and the Ministry of Economic Development and Technology (MGRT) – for organising the challenging professional programme. The latter, through its financial incentives, co-creates the success stories of UNIDO projects and in this way also fulfils its mandate.

Virtual walk around Ljubljana in the Ljubljana Technology Park.

At Ljubljana Castle.

The guests were welcomed at the Ministry of Regional Development and Trade by State Secretary Andrej Čuš. The participants and hosts were also welcomed virtually by Farrukh Alimidjanov, Project Manager of the United Nations Industrial Development Organisation (UNIDO).

The Sežana Incubator also presented itself.

At INTEC TIV d.o.o.

Calendar

► 12–14 SEPTEMBER 2022

ISO 13485:2016 Medical Devices - Quality Management System Internal Auditor Training Course

Online course.

► 11 OCTOBER 2022

Regulation (EU) 2017/745 (MDR) on Medical Devices

Online workshop.

► 15 NOVEMBER 2022

Biocompatibility of Medical Devices

Online workshop.

► 29 NOVEMBER 2022

Sterilisation of Medical Devices

Online workshop.

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