RECOGNITION OF EU CERTIFICATES FOR MEDICAL DEVICES IN UKRAINE
simplification, shortening of term and reduction of costs for conformity assessment with the requirements of Technical Regulations

Since the Technical Regulations entered into force, discussions on the possibility of simplifying conformity assessment procedures, especially for medical devices of high-risk classes have been underway. Recently, we have had positive and relevant news regarding the recognition procedures in Ukraine for certificates of conformity issued by some notified bodies, accredited in the EU. To put it simply – the recognition of EU certificates for medical devices.

In the Technical Regulations on Medical Devices approved by the Resolutions of CMU No. 753, 754 and 755 dated October 2, 2013, you will find neither a word ***"recognition"*** nor any other references to such procedure. However, it should be borne in mind that Technical Regulations on Medical Devices are only part of Ukrainian legislation on technical regulation and conformity assessment.

After gaining the status of mandatory application by the Technical Regulations in 2015, the Law of Ukraine "On Technical Regulations and Conformity Assessment" came into force in February 2016. Article 45 "Recognition of results of conformity assessment conducted outside Ukraine" of this Law (hereinafter referred to as "the Article") approves the possibility of recognition of conformity assessment results and establishes requirements for such procedure. The Article has opened up new possibilities for the procedure and ways of saving – a significant reduction of costs due to the absence of the need for auditors to visit the manufacturer premises during the initial certification audit, providing almost 100% guarantee in obtaining a positive result of the work and significant reduction of the annual cost of re-certification audits.

Why did the question of the possibility of conducting the recognition procedure begin to be discussed lively one and a half years after the Law came into force? The Article sets out a list of requirements for the recognition procedure. So try to figure out how to meet those requirements, and what we need to do.

Clause 1 of the Article states as follows:

"1. The results of conformity assessment with the requirements of technical regulations conducted in another State are accepted and recognized in Ukraine, if the conformity assessment procedures applied in that State (even if they differ from the Ukrainian procedures) provide the same level of conformity with the relevant technical regulations, as Ukrainian conformity assessment procedures."

Following paragraphs 25-27 of the Action Plan for implementation of the National Program of Adaptation of the Legislation of Ukraine to the Legislation of the European Union for year 2013, approved by the Decree of the Cabinet of Ministers of Ukraine No. 157-p dated March 25, 2013, the Government adopted the Technical Regulation on Medical Devices, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 753 dated October 2, 2013, Technical Regulation on medical devices for in vitro diagnostic, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 754 dated October 2, 2013, and Technical Regulation on active implantable medical devices, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 755 dated October 2, 2013 (hereinafter referred to as the "Technical Regulations"), which have been developed on the basis of EU Council Directives governing the entry into circulation and/or sale of medical devices in the EU, namely the Directive No. 93/42/EEC dated June 14, 1993 on medical devices, Directive No. 98/79/EEC on medical devices for in vitro diagnostic, dated October 27, 1998, and Directive No. 90/385/EEC on active implantable medical devices dated June 20, 1990, accordingly.

Thus, the first clause of the Article provides an opportunity to recognize the results of conformity assessment carried out in accordance with the requirements of the EU Council Directives on medical devices.

According to Clause 2 of the Article:

"2. Documents on conformity to the requirements of the technical regulations issued on the basis of the conformity assessment carried out in another State shall be accepted, if an international agreement of Ukraine on mutual recognition of the conformity assessment results has been concluded between Ukraine and the other State."

As an example, for better understanding of these requirements, the UkrSEPRO system can be cited, the requirements of which have also been extended to medical devices prior to the entry into force of relevant technical regulations and the removal of medical devices from the list of products subject to mandatory certification in Ukraine.

Within the framework of this system, Ukraine has concluded a number of bilateral intergovernmental and interagency agreements on mutual recognition of the results of certification. The vast majority of countries are former USSR republics with which Ukraine has a common (harmonized) regulatory framework, in particular, Azerbaijan, Belarus, Armenia, Kazakhstan, Russian Federation, People's Republic of China and Vietnam.

The objects of recognition were the trial protocols, certificates (marks) of conformity and other certificates of conformity for the products, which were subject to mandatory certification according to the approved list of goods and services.

The main condition for the possibility of mutual recognition was the identity of the basic criteria on which the certification systems of a particular type of products of the UkrSEPRO system and the importing country are based, including the use of procedures that provide the same certification procedures, testing equipment, similar procedures for surveillance of certified products and quality systems (certification) of production.

It is worth noting that the recognition of certificates of conformity issued by the countries, with which the agreements were concluded, was conducted only for products made in that country. That is, the UkrSEPRO system did not provide for the possibility of recognizing certificates of conformity for products manufactured in those countries when the certificate itself was issued by another country.

Unfortunately, in the sphere of conformity assessment of medical devices with the requirements of Technical Regulations, Ukraine has not concluded international agreements on mutual recognition with another state.

On September 1, 2017, the Association Agreement between Ukraine and the European Union entered into force. Article 57 of the Agreement provides for the conclusion of an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) in key sectors, which should take the form of an additional protocol after harmonization of the sectoral and horizontal legislation of Ukraine and standards with the sectoral and horizontal legislation and EU standards.

The sectors scheduled to be covered by the ACAA are listed in Annex III to the Association Agreement. Four industrial sectors are currently prioritized: machinery, low-voltage equipment, electromagnetic compatibility and simple high-pressure vessels. The deadline for adaptation of Ukrainian legislation in these sectors is 2 years after the entry into force of the Association Agreement.

I would like to emphasize that among the listed sectors there is also a sector of medical devices and a deadline for adaptation of the legislation, which is set within 3 years from the entry into force of the Association Agreement.

The conclusion of the ACAA would allow products under its scope to move freely within the EU internal market without further conformity assessment procedures, and vice versa.

Anna Telpiakova,

First Deputy Director, Chief Auditor of the Designated Conformity Assessment Body of the Ukrainian Scientific Institute of Certification (UNI-CERT LLC)

Thus, Clause 2 of the Article describes the possibility of mutual interstate recognition of conformity documents, provided that the relevant agreements are signed.

In this regard, the fundamental point that provides for the possibility of the recognition procedure is Clause 3 of the Article:

"3. Designated bodies have the right to recognize the conformity assessment results to the requirements of technical regulations conducted by foreign accredited conformity assessment bodies on the basis of agreements with such conformity assessment bodies, provided that:

national accreditation bodies accrediting conformity assessment bodies, both in Ukraine and in another State, are members of an international or regional accreditation organization and/or have concluded a mutual recognition agreement with such an organization with respect to the relevant types of conformity assessment activities;

the designated body shall, on the basis of the document of conformity issued by a foreign conformity assessment body, apply the conformity assessment procedure or part thereof and issue the conformity document provided for in this procedure, on its own responsibility."

European cooperation for Accreditation (EA) is the main organization within which European accreditation bodies cooperate. The EA is an association of national accreditation bodies in Europe formally approved by the authorities of their respective countries for the accreditation of organizations providing conformity assessment services such as certification, verification, inspection, testing and calibration.

The EA has been formally designated as the authority to perform these activities in accordance with Article 14 of Regulation (EC) No. 765/2008 of the European Parliament and of the Council laying down the requirements for accreditation and market surveillance concerning the sale of products since July 9, 2008.

The purpose of the EA is to coordinate and manage the European accreditation infrastructure to ensure that the results of conformity assessment services provided in one country are recognized in another country without further inspections, which contributes to the development of the European Community and the global economy.

The EA membership is divided into full membership and associate membership. The EA includes 36 full members and 13 associate members. Associate members are national accreditation bodies officially designated by a country that is a potential candidate for membership or subject to the European Neighborhood Policy (ENP).

In Ukraine, accreditation of conformity assessment bodies is carried out by the National Accreditation Agency of Ukraine (NAAU), which performs its functions based on the Law of Ukraine "On Accreditation of Conformity Assessment Bodies". In November 2011, the National Accreditation Agency of Ukraine signed an Associate Membership Agreement with the EA in the following areas:

- accreditation of bodies operating certification of persons (standard ISO/IEC 17024);

- accreditation of bodies providing audit and certification of management systems (standard ISO/IEC 17021);

- accreditation of calibration laboratories (standard ISO/IEC 17025);

- accreditation of testing laboratories (standard ISO/IEC 17025);

- accreditation of inspection bodies (standard ISO/IEC 17020);

- accreditation of bodies certifying products (standard ISO/IEC 17065).

The recognition by the EA means that NAAU's activities are fully equivalent to those of any other accreditation body, a member of the EA, which in turn demonstrates the similar level of competence of the conformity assessment bodies accredited by such accreditation bodies for compliance with the specified standards and application of the same algorithms of work.

Thus, the requirements set out in the second paragraph of Clause 3 of the Article have been fulfilled.

With regard to the requirements set out in the third paragraph of the Article, today the conformity assessment body 'UNI-CERT' LLC has concluded twenty-seven agreements with the notified bodies, namely:

- TÜV SÜD Product Service GmbH (0123)
- TÜV Rheinland LGA Products GmbH (0197)
- TÜV NORD Polska Sp. z o.o (2274)
- TÜV NORD CERT GmbH (0044)
- BSI Assurance UK Limited (0086)
- BSI Group The Netherlands B.V. (2797)
- DEKRA Certification B.V. (0344)
- DEKRA Certification GmbH (0124)
- DQS Medizinprodukte GmbH (0297)
- ITALCERT S.r.l. (0426)
- Kiwa Cermet Italia S.p.a. (0476)
- Kiwa Belgelendirme Hizmetleri A.§. (1984)
- Lloyd's Register Quality Assurance - LRQA (0088)
- Eurofins product testing Italy S.r.l. (0477)
- Intertek Semko AB (0413)
- Agencia Espanola de Medicamentos y Productos Sanitarios - AEMPS (0318)
- Elektrotechnický zkušební ústav, s.p. - EZÜ (1014)
- GMED (0459)
- SLG Prüf - und Zertifizierungs GmbH (0494)
- Presafe Denmark A/S (0543)
- Bureau Veritas Italia S.P.A. (1370)
- Szutest Uygunluk Değerlendirme A.Ş. (2195)
- IMQ Istituto Italiano Del Marchio Di Qualitä S.P.A. (0051)
- UL INTERNATIONAL (UK) LTD (0843)

- RISE Research Institutes of Sweden AB (0402)
- ICIM S.p.A. (0425)
- CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. (2409)

All the above-mentioned bodies are accredited by the relevant national accreditation bodies that are full members of the EA.

Thus, the requirements set out in the first paragraph of Clause 3 of the Article are fulfilled as well.

We began working on the conclusion of Agreements on recognition of conformity assessment more than two years ago, almost immediately after the Law of Ukraine "On Technical Regulations and Conformity Assessment" had entered into force. The conclusion of each agreement is a long-term process, which requires a lot of effort. This means many hours of negotiations and correspondence with European colleagues, a detailed analysis of national and European legislation and painstaking joint work on the text.

However, I am convinced that cooperation with the EU notified bodies is very important. First of all, it significantly simplifies access to the Ukrainian market for quality, advanced and technological medical devices and reduces the cost of the regulatory procedure, which in turn reduces the cost of the products for patients. Secondly, it gives us the opportunity to exchange information and experience with the authoritative and competent bodies of the European Community.

Currently, 'UNI-CERT' LLC has concluded twenty-seven agreements with the notified bodies, whose certificates of conformity have become possible to be recognized in Ukraine. We continue negotiations with more than twenty others and hope to conduct every second conformity assessment procedure through recognition of results in the near future.

Roman Mykhalko,

Director of the Designated Conformity Assessment Body of the Ukrainian Scientific Institute of Certification (UNI-CERT LLC)

Since there is a confirmation of compliance with all the requirements set out in the Article and which are necessary for the appliance to the recognition procedure when conducting the conformity assessment, we consider it necessary to review some nuances directly in the conduction of this procedure.

The conformity assessment procedure by recognition begins with the submission of the application, together with the documentation dossier as indicated in the relevant Annex to the Technical Regulation for which the procedure is being carried out.

1) Since the requirements of Clause 3 of the Article provide for the recognition of the results of the conformity assessment carried out, and the results of such assessment are evidenced by a report and/or decision drawn up under a procedure carried out by a notified body, it is necessary to obtain the report and/or decision of the notified body which became the basis for the issue of the EU certificate to grant a certificate of conformity under the procedure with the recognition of the conformity assessment body.

2) The national designated conformity assessment body *applies the conformity assessment procedure or part thereof,* which requires an individual approach to the recognition procedure. Thus, based upon decision of the body, recognition can be applied to the quality management system

assessment that will allow refraining from audit. Recognition may also be applied to the design examination procedure, which will allow the manufacturer not to provide the confidential part of the technical documentation, such as the design documentation.

3) *Validity and scope of the certificate.* Since according to paragraph 3, Clause 3 of the Article, the recognition procedure is carried out on the basis of a document of conformity issued by a foreign conformity assessment body, certificate of conformity is in focus of procedure, the national Ukrainian certificate of conformity obtained as a result of such procedure must contain a similar validity, list of products, production sites, a list of conditions for surveillance audits and other restrictions. Accordingly, the certificate of conformity under the recognition procedure is issued for the same validity as the EU one, which is recognized, and contains the same or reduced scope.

It should be noted that after the expiration of the validity of the Ukrainian certificate of conformity, which was issued by recognition of the EU certificate, it is possible to carry out re-certification. The recertification procedure is usually faster and cheaper than the initial certification procedure.

4) *Surveillance audits.* When conducting products conformity assessment using an audit procedure, the national designated conformity assessment body, as well as the notified body, must comply with the requirements of ISO/IEC 17021 standard. This standard provides requirements for annual surveillance audits, as well as re-certification audits in the last year of the certification cycle. Given this, the Ukrainian designated conformity assessment body should verify the validity of the certificate, which is recognized through obtaining the relevant confirmation from the EU notified body in the same manner as mentioned above.

5) *Extension of the scope.* Under the condition, that the EU certificates scope is not recognized in full in the framework of initial procedure or the amendments to the EU certificate are made, the applicant may need to extend the scope or change the certificate of conformity issued in accordance with the requirements of the Technical regulation. In such case, the applicant must inform the national conformity assessment body on his/her intention, and in turn, national conformity assessment will contact the notified body for confirmation again. When extension the scope to new product groups takes place, it is also necessary to submit a new part of documentation regarding such products.

Thus, Article 45 of the Law of Ukraine "On Technical Regulations and Conformity Assessment" describes the working mechanism for the recognition of results, based on concluding of direct agreements between national designated conformity assessment bodies and European notified bodies. Following the recognition procedure, it is possible to achieve:

- Significant cost and time saving in conduction of the initial conformity assessment procedure, surveillance audits, extension of scope and re-certification procedures;

- Absence of the need to provide confidential documentation (such as design documentation) when carrying out the design examination procedure;

- Carrying out conformity assessment procedures in relation to procedures that have not been regulated yet, for example, conformity assessment of a medical device containing components of a medicinal product or biological material and which have an auxiliary role.

Anna Telpiakova
Roman Mykhalko