

## Recognition of EC certificates for medical devices in Ukraine

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*Procedure of national conformity of medical devices with partial recognition of EC certificates exists in Ukraine more than three years. During this period we have faced a lot of particularities and pitfalls, deeply studied national and European legislation, obtained clarifications at competent authorities, held many seminars and gathered enormous experience. In this article we would like to share our expertise and answer the most common questions. We are convinced that the recognition procedure is an important part of pro-European development vector of Ukraine.*



### Background

The Ukraine–European Union Association Agreement determined that one of the main aims of the association is to establish conditions for enhanced economic and trade relations leading towards Ukraine's gradual integration in the EU Internal Market.

According to Article 55 of the Agreement access to existing markets is facilitated through cooperation in the field of technical regulations, standards, metrology, market surveillance, accreditation and conformity assessment procedures; establishing regulatory dialogues at both horizontal and sectoral levels; and in particular - promoting and encouraging cooperation between their respective organisations, public or private, responsible for metrology, standardisation, testing, market surveillance, certification and accreditation.

In accordance with the provisions of the Agreement, Ukraine shall take the necessary measures in order to gradually achieve conformity with EU technical regulations and EU standardisation, metrology, accreditation, conformity assessment procedures and the market surveillance system, and undertakes to follow the principles and practices laid down in relevant EU Decisions and Regulations.

The development and approval of technical regulations in Ukraine is regulated by the Law of Ukraine “On Technical Regulations and Conformity Assessment.” It is important to note here that if the technical regulation is developed on the basis of the legislative act of the European Union, the content, form and structure of such technical regulation should fully and accurately correspond to the content, form and structure of the relevant act of legislation of the European Union, considering specific national legal acts that regulate public relations.

Harmonisation of technical regulations in Ukraine and the EU in the long term perspective should eliminate technical barriers in trade and bring the requirements of the EU and Ukraine as close as possible.

One of the important and key points in the field of harmonisation of legislation in healthcare industry is the adoption of Technical Regulations, which contain requirements for the efficacy and safety of medical devices. Whereas relevant EU Directives for medical devices have been taken as the basis for their development.

Three Technical Regulations on medical devices became mandatory in Ukraine on July 1, 2015:

- Resolution of the Cabinet of Ministers No. 753 "On Approval of Technical Regulations for Medical Devices";

- Resolution of the Cabinet of Ministers No. 754 "On Approval of Technical Regulations for In Vitro Diagnostics Medical Devices”;
- Resolution of the Cabinet of Ministers No. 755 "On Approval of Technical Regulations for Implantable Active Medical Devices".

These Regulations apply to all medical devices and their accessories, establish the conditions for placing on the market, put into the service and describe the conformity assessment procedures.

The adoption of Technical Regulations on medical devices allows to determine the best way to demonstrate national conformity with the essential requirements based on the classification of medical devices. **It is important that the main goal of adopting Technical Regulations based on EU Directives is to bring the requirements for products in Ukraine in line with EU standards.**

Despite the Technical regulations of Ukraine are based on EU Directives and relevant harmonisation of standards, for some period there was no simplified route of national conformity for those manufacturers who have already proven conformity of products in Europe.

**Foreign manufacturers of medical devices faced a lot of significant problems with regulatory access of products to the Ukrainian market, while political and economic situation was the most unfavorable for business: the cumulative drop in GDP by more than 16% in 2014-2015, devaluation of the local currency (hryvnia) by more than 300%, the antiterrorist operation in Eastern Ukraine, decrease of public procurements, bankruptcy of several national distributors of medical devices. Overall situation was also influenced with the skepticism of manufacturers related to the de facto expiry of unlimited state registration certificates for medical devices.**

Thus, the introduction of national Technical Regulations on medical devices, even based on the European legislation, was perceived extremely negatively. Many international manufacturers have not accept the fact that, despite the presence of an ISO 13485 certificate, another audit became necessary.

### **What is the problem of hosting the audit?**

Conducting of any audit is extremely stressful and costly for the manufacturer. Much more stressful and costly than it might seem at first glance.

Auditors are always accompanied by a team of several site employees, while several other employees of the regulatory and quality departments promptly provide documentation, and managers of various levels are always involved in the process. Before the audit, preparatory meetings are held, after the audit - questions and comments are analyzed. If necessary, translators and other staff are also involved. On average, about 25 employees are involved in the audit from the side of the manufacturer, some of whom have to arrive from the head office or other production sites.

Before the audit “general preparation” takes place: detailed discussion of the audit plan, roles and responsibilities of team members. Production processes may be forced to stop to allow auditors to enter the production facilities.

The largest and most technologically advanced manufacturers most often use multiply production sites in different countries that have a single multi-site manufacturing system. According to the requirements of ISO/IEC 17021, at least 70% of such a system must be audited on site, which requires many weeks of work for the auditors and employees involved, and enormous direct and indirect costs.

During the first steps of conformity assessment we faced with the fact that some auditors considered as their duty to make at least a few findings to the manufacturer at all costs – otherwise what’s the purpose of visiting? Such observations are documented and drafted in the form of a protocol of non-compliance, and

the manufacturer must take corrective actions on each finding. This is an integral part of the quality management system, and even the most controversial comments must be taken into account, managed anyhow and relevant careful and weighted answer must be given. It should be noted that the level of competence and ethical conduct of auditors has grown significantly in recent years, and we practically do not encounter such problems at present.

Manufacturer receives national certificate of conformity valid up to 5 years after the certification audit and responding to findings. However, according to the requirements of ISO/IEC 17021 supervisory audits must be carried out every 12 months, and according to the provisions of IAF MD 5 such inspections must cover at least 1/3 of the system.

**Thus, conducting of one audit lead to significant expenses for the manufacturer, and directly impacts the final cost of the medical device in Ukraine.** Considering the economic and political problems of the country – the decision of the manufacturer to enter the Ukrainian market can be also affected.

As a result of the difficulties described above and many of those already forgotten, the medical device market operators have not applied for conformity assessment since the adoption of the regulations in 2013, whereas the transition to the European system of technical regulation of medical devices has been postponed several times.

### **The recognition**

Law of Ukraine “On Technical Regulations and Conformity Assessment” came into force on February 10, 2016, seven months after Technical Regulations on medical devices became mandatory. Section VIII “Recognition of conformity assessment results” of the Law determined the possibility of recognition.

**- Technical Regulations do not contain any other information on the recognition route except for those medical devices, intended for purchase by specialized procurement organizations.**

Content, form and structure of Technical regulations on medical devices should correspond as close as possible with EU Medical Device Directives, which do not include any description of the recognition procedure. Thus, such route should be established by another legal act with equal or higher force as Resolutions of the Cabinet of Ministers.

Article 45 “Recognition of the results of conformity assessment conducted outside Ukraine” of the Law defines options and requirements of the recognition. Article has been slightly amended at July 3, 2019 by the Law “On Amending Certain Legislative Acts of Ukraine Regarding the Implementation of Acts of the European Union Legislation in the Field of Technical Regulation”. Text of the article is brief but sufficient for establishment of the recognition route:

**The first part of Article 45** describes the general requirements to systems of technical regulation in Ukraine and in the reference country:

*1. The results of conformity assessment to the requirements of Technical regulations performed in another country are recognised and accepted in Ukraine in case if conformity assessment procedures (even if they differ from Ukrainian procedures) assure the same or higher level of conformity to the requirements of relevant technical regulations, as Ukrainian conformity assessment procedures.*

In simple words: product requirements in the referent country must be similar as or higher then in Ukraine.

According to Article 56 of the Ukraine–European Union Association Agreement, Ukraine shall take the necessary measures in order to gradually achieve conformity with EU technical regulations and EU standardisation, metrology, accreditation, conformity assessment procedures and the market surveillance

system, and undertakes to follow the principles and practices laid down in relevant EU Decisions and Regulations.

The introductory part of each Ukrainian Technical Regulation for medical devices contains direct reference on the parent EU Directive:

- Technical Regulation on medical devices (Resolution No. 753): *this Technical Regulation is developed on the basis of the EU Council Directive of June 14, 1993 No. 93/42/EC regarding medical devices.*
- Technical Regulation for *in vitro* diagnostics medical devices (Resolution No. 754): *this Technical Regulation is developed on the basis of the Directive of the European Parliament and the EU Council dated October 27, 1998 No. 98/79/EC.*
- Technical Regulation for implantable active medical devices (Resolution No. 753): *this Technical Regulation is developed on the basis of EU Council Directive No. 90/385/EC dated June 20, 1990 to approximate the legislation of the member states regarding implantable active medical devices.*

Thus requirements of the first part of the Article 45 of the Law of Ukraine “On Technical Regulations and Conformity Assessment” for medical devices are fulfilled (requirements are identical). However that narrows the recognition process to the EU Directives only: it is unlikely that Ukrainian conformity assessment bodies will manage to recognise conformity assessment results from the USA, Canada, Japan, China or other countries. In general that comes align with Ukrainian intention to achieve national product requirements with EU standards.

**- There are no Technical Regulations in the EU, but there are Directives.**

Paragraph 5 of Article 10 of the Law of Ukraine “On Technical Regulations and Conformity Assessment” provides clear definition of the wording “Technical Regulations”:

*A regulatory act having the characteristics of a technical regulation defined by this Law shall be considered a technical regulation regardless of the use of the definition of "technical regulation" in the title.*

**The second part of Article 45** describes the possibility of **unconditional recognition** of conformity documents at the interstate level when signing a mutual agreement between Ukraine and another state.

Currently mutual recognition of conformity assessment results (certificates and Declarations, trial protocols) is not conducted between Ukraine and any other country. In perspective such mutual recognition is achievable by signing the Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) in the field of medical devices, which is one of the components of the Association Agreement between Ukraine and the European Union.

The ACAA is a type of Mutual Recognition Agreement (MRA) referred to in the second part of the Article 45 of the Law of Ukraine “On Technical Regulations and Conformity Assessment”. Such an agreement will allow unconditional recognition of conformity assessment documents issued by notified bodies of Ukraine and EU member states. The ACCA is concluded across industrial sectors, and it is primarily planned to sign the agreement regarding low-voltage equipment, electromagnetic compatibility, machinery and equipment operating under pressure. Medical devices and *in-vitro* diagnostic medical devices are identified as the next priority product sectors.

Signing of the Mutual Recognition Agreement will enable Ukrainian conformity assessment bodies to apply for EU notification, i.e. the right to perform conformity assessment with the requirements of the European Directives. Currently the EU has signed such agreements with Australia, Canada, Japan, Switzerland and the

United States; the competent authorities of these countries have the status of notified bodies in the EU Nando system.

The third part of Article 45 describes the possibility of **conditional and partial recognition** of the results of conformity assessment:

3. *Conformity assessment bodies have the right to recognize and accept the conformity assessment results (testing protocols, documents on conformity, etc.) to the requirements of technical regulations carried out by foreign accredited conformity assessment bodies on the basis of agreements on recognition signed with such bodies, under the following conditions:*

- *national accreditation bodies, which accredit conformity assessment bodies both in Ukraine and in another state, are members of an international or regional accreditation organization and/or have entered into a mutual recognition agreement with such organization regarding relevant types of conformity assessment activities;*
- *the conformity assessment body on the basis of conformity assessment results (testing protocols, conformity documents, etc.) carried out by a foreign accredited conformity assessment body, applies the conformity assessment procedure or part of it and issues a conformity document foreseen by that procedure, on its own responsibility.*

This part of the article describes a set of conditions and requirements:

1. A foreign conformity assessment body (= notified body) that issued conformity assessment results have relevant accreditation to the relevant procedures (Directives) in the EU. The register of notified bodies is presented in the Nando (New Approach Notified and Designated Organizations) system on the EU Government website.
2. A Ukrainian conformity assessment body must have a signed Recognition Agreement with a foreign body. It is important to note that the requirement for the **Mutual Recognition Agreement is not indicated**, as specified in the second part of Article 45. Thus, recognition can be one one-sided, which is quite logical for the relatively young system of technical regulation of Ukraine and taking into account the fact that it is Ukraine, according to the Agreement, should harmonise it's legislation in the field of technical regulation towards the EU legislation. Agreement between the Ukrainian and European bodies can include specific requirements and additional conditions except those described above and below.
3. The National Accreditation Agency of Ukraine (NAAU) is an associate member of the European co-operation for Accreditation (EA) and a signatory to the EA Bilateral Agreement (EA BLA) in the areas of accreditation of testing and calibration laboratories, product certification bodies, certification bodies for management systems, personnel certification bodies and inspection bodies. NAAU is also a full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory to the Mutual Recognition Agreement (ILAC MRA) in the areas of accreditation of testing and calibration laboratories and inspection bodies.
4. The basis for the recognition procedure is a conformity document, that is a EU certificate issued by the European notified body. The Ukrainian conformity assessment body shall receive a copy of the EU certificate and a reference to that certificate in the Application form.
5. The Ukrainian conformity assessment body shall apply the conformity assessment procedure, or a part of that procedure, described in the relevant Technical Regulations. This requirement accurately describes that the Ukrainian body does not have the right to unconditionally (fully) recognize the EU certificate, and obliged to carry out at least national specific requirements set in the relevant Annex to the Technical Regulation. Accordingly, the Application for conformity assessment should include a reference to the corresponding Annex (procedure, module). The Ukrainian conformity assessment body shall evaluate national requirements that differ from

European ones (including language and labeling requirements), designation of the Authorized Representative, actions taken to perform the post-marketing surveillance in Ukraine etc. Scope of other assessment works within the recognition procedure remain at the discretion of the body and the provisions of the Recognition Agreement between EU and UA bodies.

6. The result of the recognition procedure is a Ukrainian certificate of conformity, and for high classes of potential risk, also a design examination/type verification certificate.

**- According to Article 41 of the Law, the designated bodies must conduct conformity assessment according to the procedures of the Technical Regulations, where the recognition procedure is not described.**

The bodies in fact should conduct only those procedures that are defined by Technical Regulations. According to Article 45 of the Law, part of the conformity assessment work must be performed by the national conformity assessment body, and the other part of the work can be recognized. Accordingly, the Application for conformity assessment should include reference to the exact procedure (Annex) and the Ukrainian body should carry out that part of assessment works. Recognition is not a separate independent route of conformity assessment, but the way to consider some results of works that have been already accomplished in EU.

Thus, all necessary conditions for **partial recognition** have been established on the state level. Then national conformity assessment bodies should take the initiative: to study relevant European legislation, apply for additional training, develop and implement the appropriate procedure, establish cooperation with the European notified body and sign the Recognition Agreements.

At the moment we completed that article, the Nando database includes 57 notified bodies designated for conformity assessment under Directive 93/42/EEC. According to our information, the Ukrainian conformity assessment bodies have signed recognition agreements with 30 notified bodies, namely:

- 0123 TÜV SÜD Product Service GmbH
- 0197 TÜV Rheinland LGA Products GmbH
- 2274 TÜV NORD Polska Sp. z o.o
- 0044 TÜV NORD CERT GmbH
- 0086 BSI Assurance UK Limited
- 0344 DEKRA Certification B.V.
- 0124 DEKRA Certification GmbH
- 0297 DQS Medizinprodukte GmbH
- 0426 ITALCERT S.r.l.
- 0476 Kiwa Cermet Italia S.p.a.
- 1984 Kiwa Belgelendirme Hizmetleri A.Ş.
- 0088 Lloyd's Register Quality Assurance – LRQA
- 0477 Eurofins product testing Italy S.r.l.
- 0413 Intertek Semko AB
- 0318 Agencia Española de Medicamentos y Productos Sanitarios – AEMPS
- 1014 Elektrotechnický zkušební ústav, s.p. – EZÚ
- 0459 LNE/G-MED
- 0494 SLG Prüf- und Zertifizierungs GmbH
- 0543 Presafe Denmark A/S
- 1370 Bureau Veritas Italia S.P.A.
- 2195 Szutest Uygunluk Değerlendirme A.Ş.
- 0051 IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.
- 0843 UL INTERNATIONAL (UK) LTD
- 0482 MEDCERT GmbH

0653 NATIONAL EVALUATION CENTER OF QUALITY & TECHNOLOGY IN HEALTH SA – EKAPTY SA

1304 SIQ – Slovenian Institute of Quality and Metrology

0483 MDC medical device certification GmbH

2460 DNV GL Presafe AS

0402 RISE Research Institutes of Sweden AB

2797 BSI The Netherlands B.V.

1434 Polish Centre for Testing and Certification

0425 ICIM S.p.A.

2409 CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.

This means that at least **every second medical device** that meets the EU requirements can follow a national conformity assessment procedure without duplicating part of the previously performed certification works. From our point of view, it is logical and efficient to recognise quality management system audit as the most expensive and complicated part of conformity assessment procedure.

At the same time the Ukrainian conformity assessment body is obliged to verify compliance with all national requirements: language and labeling requirements, the proper designation of the Authorized Representative of the manufacturer in Ukraine, post-marketing issues etc.

The partial recognition procedure is collegial conformity route, where Ukrainian body considers results of assessment performed by EU notified body. If the EU notified body had reason to believe that the products do not fully meet the requirements for efficacy and safety, then the Ukrainian body will not be able to apply the recognition procedure.

The procedure also promotes cooperation between Ukrainian and European bodies, ensures constant communication and exchange of experience, understanding and establishing European practices in the national system of technical regulation of medical devices and leads to the fulfillment of the goals specified in the Association Agreement between Ukraine and the European Community.

For example, the partial recognition procedure has been supported by many EU designated bodies. One of the largest European bodies [TUV SUD published an article regarding the support of the recognition procedure](#), and offered Ukrainian conformity assessment bodies to sign the recognition agreements.

### Important aspects

The partial recognition procedure of conformity assessment results is not an absolute panacea for medical devices admitted to the EU market, as it imposes a number of significant restrictions, having evaluated which, the manufacturer can decide in favor of the “classical” procedure involving audit.

1. Any restrictions of the EU certificate, on the basis of which recognition is carried out, should also apply to the Ukrainian certificate. For example, the validity of the Ukrainian certificate should not exceed the expiration date of the EU certificate.

The second significant example of the restriction is the list of products for conformity assessment by partial recognition cannot be wider than in the European certificate. If medical devices are not intended for the EU market, they have not passed conformity assessment in the notification body, they cannot be declared as part of the recognition procedure.

2. Some notified bodies issue an invoice to the manufacturer for providing the protocols and letters necessary for the Ukrainian body to carry out the procedure. For manufacturers located in EU countries, the need to receive and pay for the letter can offset the economic benefits of the recognition procedure.

3. The basis for recognition is the EU certificate, which does not allow grouping products of the same manufacturer, released under different certificates, and can also affect the total cost of the entire project. This situation is especially applicable for class III products, for which, in addition to the certificate of conformity, a design examination certificate must also be issued for a single product or a small group.

4. The partial recognition procedure in no way exempts from the requirements of ISO/IEC 17021 standard with respect to annual supervision. Thus, each year it is necessary to carry out supervision procedure, in which the results of the inspection carried out by the EU notified body can also be partially recognised.

5. Any changes and restrictions that occur with the EU certificate should be reflected in the national certificate of conformity. If the manufacturer stops producing products for the EU market and is excluded from the European certificate, such changes should be immediately carried out with respect to the Ukrainian certificate.

If the EU certificate is suspended or canceled (for example, for safety reasons), the Ukrainian conformity assessment body must terminate the Ukrainian certificate.

6. The presence of a positive assessment of the EU notified body does not absolutely guarantees the issuance of a Ukrainian certificate of conformity if the documentation that is submitted with the Application does not meet the requirements of the Technical Regulations (for example, if the Ukrainian body has any comments on the functions of the Authorized Representative, product labeling or instructions for use, incorrect Declaration of Conformity etc.).

7. The partial recognition procedure does not exempt the manufacturer and its Authorized Representative from national requirements regarding the efficacy and safety of medical devices, conducting post-marketing surveillance, maintaining a quality management system, and fulfilling the national part of Essential Requirements. The Authorized Representative of the manufacturer must keep all the necessary documents for submission at the request of the competent authorities in accordance with the requirements of the Technical Regulations and other legislative acts.

Manufacturer must carefully consider the pros and cons before making decision towards recognition procedure, examine the financial and organizational aspects.

## Conclusion

Having completed more than 500 projects on conformity assessment for medical devices and medical devices for *in-vitro* diagnostic using the partial recognition route, we are convinced that this procedure is a transparent, fast and economical way of a national conformity assessment for medical devices approved for the EU market.

This procedure is sufficiently regulated in the national legislation but requires a deep understanding, both from the designated conformity assessment body and from the manufacturer. There are many particularities and limitations that should be assessed before the start of certification, and taken into account throughout the entire circulation of products on the Ukrainian market.

In addition to the economic and other benefits for the patient (consumer), distributor and manufacturer, this route of conformity assessment develops international cooperation in technical regulation and enables national bodies to establish contractual relations with EU authorities. **We are convinced that this procedure is an important component of the pro-European vector of the development of Ukraine.**

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