Legalization of import products for the Ukrainian market of medical products

After the events of 2014, Ukraine took the path of development, oriented towards the European Union. On September 1st, 2017, the Association Agreement between Ukraine and the EU entered into force. Ukraine assumed the responsibility to follow the path of harmonization with EU legislation and, as a result, some changes took place in the regulatory documents of the health sector. It should be noted that affixed CE mark at the product, as well as availability documents, which confirm compliance to the European Directives on medical devices, does not authorize placement of the product on the Ukrainian market without passing the national conformity procedure.

Since July 1st, 2017 the new legislative requirements regarding import and sales of medical devices were established since Technical regulations, developed on the base of relevant EU Directives, came into force.

Technical regulation on medical devices, approved by Resolution of Cabinet of Ministers of Ukraine №753 dated 02.10.2013	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
Technical regulation on medical devices for in vitro diagnostic, approved by Resolution of Cabinet of Ministers of Ukraine №754 dated 02.10.2013	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
Technical regulation on active implantable medical devices, approved by Resolution of Cabinet of Ministers of Ukraine №755 dated 02.10.2013	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

Because these directives have already been updated in the EU, a similar update will take place in Ukraine in the next few years.

In order to determine whether the product belongs to the category of medical devices or not, the national conformity assessment body will use the relevant terms in the technical regulations and, as recommendations, the relevant European documents. The major one is «Manual on borderline and classification in the Community regulatory framework for medical devices. Version 1.19 of April 2018». In addition to it, there are few documents, which complement the action of the main one.

To import medical devices to Ukraine, primary it is necessary to pass the procedure of conformity assessment to Technical Regulations requirements and obtain a Certificate of Conformity. Depending on the risk class of the medical device and some other factors, there are 4 routes of conformity assessment:


СЕРТИФІКАТ ВІДПОВІДНОСТІ

1. **Self-declaration**
2. **Batch examination of medical devices**
3. **Audit of the quality management system**
4. **Recognition of EU Certificates**

The rules that define the class of potential risk of medical devices are specified in the Technical Regulations, but the decision to classify products as "medical" devices is made by the manufacturer on the basis of current local legislation. Then a dossier on the product should be drawn up. In the event of disputes regarding the determination of the status of the product, the manufacturer or his Authorised representative may apply to the Ukrainian conformity assessment body to receive a clarification letter regarding belonging to the category of medical device.

1. Self-declaration

The procedure of self-declaration applies to such medical devices:

- I-class medical devices (non-sterile, without measuring functions) according to requirements of Technical regulation on medical devices, approved by Resolution of Cabinet of Ministers of Ukraine №753 dated 02.10.2013;
- Medical devices for in vitro diagnostic, which not belong to List 'A' or 'B' as well as non-intended for self-control and/or clinical evaluation of Technical regulation on medical devices for in vitro diagnostic, approved by Resolution of Cabinet of Ministers of Ukraine №754 dated 02.10.2013.

For the devices listed above, it is not required to submit documents and to pass examinations in any conformity assessment body, except submission of information to the State Service of Ukraine on Medicines and Drugs Control. In order to comply with the requirements of the Technical Regulations of such medical devices, it is necessary:

- Appoint Authorised representative of manufacturer on the territory of Ukraine, perform all legal formalities associated with this;
- Draw up a Technical documentation (further –Technical file) in accordance with the requirements of the relevant Technical regulation and conformity assessment procedure; make the necessary translations;
- Draw up a Declaration of Conformity to the requirements of the Technical Regulations;
- Submit information about the location of the manufacturer/ Authorised representative in Ukraine, a list and description of the devices to the to the State Service of Ukraine on Medicines and Drugs Control;
- Affix mark of conformity on the label; ensure that requirements on labeling and instruction for use (user manual) comply with requirements of Technical regulation and current legislation.

For specified devices, a declaration of conformity is a document that confirms their compliance with the requirements of the Technical regulations and, therefore, is the basis for their placement on the Ukrainian market. Particular attention when declaring compliance with the Technical Regulations should be given to the fulfillment of all requirements and formalities, including those entrusted to the Authorised representative, since from the moment of customs clearance in Ukraine, medical devices become the object of market surveillance.

2. Batch examination of medical devices

The procedure of conformity assessment through batch examination of medical devices involves issuing a certificate for a particular batch of products (lot), or for a medical device with a certain serial number. In this case, it is necessary to review the documentation and examine the products in an accredited testing laboratory. This procedure is suitable for large, expensive equipment, for infrequently used products, for fast product's placing on the market or in the case of a manufacturer's refusal to grant access for inspection of production sites.

The procedure of conformity assessment through batch examination of medical devices does not involve inspection of production and therefore is not applied when assessing the conformity of sterile products!

This procedure can be used for:

- Non-sterile medical devices, according to requirements of Technical regulation on medical devices (Decree of CMU no. 753);
- Medical devices for in vitro diagnostic, specified in List B of Annex 2 of Technical regulation on medical devices for in vitro diagnostic (Decree of CMU no. 753), as well as medical devices for in vitro diagnostic, intended for self-testing;
- Medical devices subject to the Technical regulation on active implantable medical devices (Decree of CMU no. 755).

To obtain certificate for the batch of devices you need:

- Appoint Authorised representative of manufacturer on the territory of Ukraine, perform all legal formalities associated with this;
- Draw up a Technical file in accordance with the requirements of the relevant regulations and related legislation;
- Submit an Application and an accompanying dossier of documentation for the procedure to the designated conformity assessment body;
- Complete the procedure of examination of documentation as well as examination of the products in an accredited testing laboratory;
- Obtain a certificate of conformity to Technical regulations requirements for a batch of medical devices or medical device with a certain serial number;
- Draw up Declaration of conformity to Technical regulation requirements;

- Affix mark of conformity and identification number of conformity assessment body on the label and instruction for use of medical device.

3. Audit of the quality management system

Audit of the quality management system (QMS) is the main and most frequently used route of passing the conformity assessment procedure of medical devices regardless of their classification.

After passing the conformity assessment through audit of manufacturing sites with the involvement of the conformity assessment body, a certificate of conformity of the implemented QMS for the production of medical devices with the requirements of the Technical Regulations for a period of 5 years is issued. To obtain the mentioned certificate you need:

- Appoint Authorised representative of manufacturer on the territory of Ukraine, perform all legal formalities associated with this;
- Draw up a Technical file in accordance with the requirements of the relevant regulations and related legislation;
- Submit an Application and an accompanying dossier of documentation for the procedure, which also depends on the classification of the product, to the designated conformity assessment body;
- Complete the procedure of examination of documentation (stage 1), respond to comments (if any);
- Accept the objects, dates and audit plan of the production (the 2nd stage of audit);
- Organize a visit of auditors to the production (minimum 2 persons);
- Eliminate the inconsistencies detected at the second stage of audit (if applicable);
- Receive a report on the conducted audit and a certificate of conformity of the implemented QMS for the production of medical devices to the requirements of the Technical Regulations from the conformity assessment body;
- Draw up Declaration of conformity to Technical regulation requirements;
- Affix mark of conformity and identification number of conformity assessment body on the label and instruction for use of medical device.

It is important to note that during the validity of the certificate of conformity issued by the procedure through the audit, it is necessary to conduct surveillance audits that, in accordance with the requirements of 9.1.3.3 DSTU ISO / IEC 17021-1: 2015 should be carried out annually. Manufacturer have to inform conformity assessment body on each planned significant changes in the QMS or in the sphere of the certificate of conformity (product list, list of production sites). The decision on the necessary actions to approve such changes is made by the conformity assessment body on the basis of the analysis of the submitted information.

4. Recognition of EU Certificates

Special interest among importers who have EU certificates on their devices is caused by the last scheme, because it allows to save considerably time and finance, in comparison with on-site audit of production. However, for its use there are a number of limitations that not all notified bodies can overcome.

For international recognition of documents (that is, the recognition of certificates, protocols, reports, certificates, etc.), an international agreement between Ukraine and another country is required on mutual recognition of works on conformity assessment.

There are currently no such Agreements in the field of medical devices, and in the long term mutual recognition of the results with the EU is possible by signing the Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) regarding medical devices, which is one of the components of the Association Agreement between Ukraine and the European Union.

At the moment, the Ukrainian legislation allows the the recognition of the results of the work on assessing the conformity of European bodies with Ukrainian designated conformity assessment bodies under its responsibility, on the basis of signed recognition agreements with foreign accredited bodies (subject to the same requirements for accreditation) and the conduct of a

national procedure or part thereof.

To recognize the results of conformity assessment unilaterally, the following conditions must be met:

- The Ukrainian designated conformity assessment body has a signed Agreement on the recognition of the results of works with a foreign notified body;
- The foreign notified body has proper accreditation;
- The foreign notified body has an appointment for the relevant Directives;
- An application for the recognition procedure and a necessary dossier of documents was submitted to the Ukrainian designated body.

The Ukrainian Scientific Institute of Certification has the largest experience in Ukraine on the procedure for the recognition of EU certificates for medical devices and, accordingly, has signed agreements with leading European notified bodies. In the event that the EU certificate is issued by one of these notified bodies, it is possible to carry out procedure of recognition, which will facilitate and accelerate the initial audit, annual supervision and extension of the scope of the certificate (adding new products, sites). Examination of documents is carried out in English, German, Ukrainian and Russian.

Appointment of Authorised representative of manufacturer on the territory of Ukraine

Appointment of the Authorised Representative of the manufacturer in Ukraine is a mandatory requirement of the Technical Regulations for all types of conformity assessment procedures and classes of medical devices if the manufacturer is not a resident of Ukraine. The definition of an authorised representative is given in Technical regulation on medical devices (Resolution of Cabinet of Ministers of Ukraine №753 dated 02.10.2013, item 2.13 of General part):

> *'authorised representative means any legal person or sole proprietor who is a resident in Ukraine or is registered in accordance with Ukrainian legislation, or a representative office of a foreign business entity, that is duly authorised by the manufacturer to act on his behalf with regard to the obligations of the manufacturer under this Technical Regulation'*

The authorized representative in Ukraine serves as a liaison between Ukraine (conformity assessment bodies, market supervision bodies, revenue bodies, consumers etc.) and the manufacturer and performs post-marketing surveillance.

The authorized representative in Ukraine acts in accordance with the Power of Attorney or Manufacturer's Representative Agreement. The agreement is preferable for assigning rights and obligations of both parties, as well as responsibilities of the authorized representative concerning quality and safety, communication timing, reaction to complaints and reports of adverse events and many other activities.

The authorised representative must keep all documentary records for at least 5 years (for implantable medical devices the term is not less than 15 years) in order to provide access to them upon the request of public authorities and / or conformity assessment bodies.

The package labeling and/ or in the instruction for use of the medical device shall contain the name and the address of the Authorised representative. At the same time, each medical device (type/ model) must be linked to only one authorized representative. At the manufacturer's discretion, distributor, representative office or a third party may be Authorised as the representative.

The appointment of the Representative Office of the manufacturer in Ukraine as an Authorised Representative carries with it serious risks of violating the requirements of the current legislation regarding the prohibition on conducting economic activities. The implementation of regulatory actions in respect of products produced at other holding plants, or at contract plants, can be regarded as rendering services to third parties, which is commercial activity.

Requirements regarding the labeling and instructions for use

The affixing of a national mark of conformity, the specification of an Authorised representative in Ukraine, are important requirements for the labeling of medical devices that have passed the conformity assessment procedure. Description of mark of conformity is given in Resolution of Cabinet of Ministers of Ukraine №1184 dated 30.12.2015. In addition, Technical regulations states the requirements for the size of the mark of conformity. If the conformity assessment was conducted with the involvement of a designated conformity assessment body, its number should be indicated next to the mark of conformity.

The name of the medical device, the name and address of the manufacturer must be identical in the declaration of conformity, instructions for the use of the product, labeling and the Certificate of Conformity!

Information on the labeling and instructions for the use of a medical device is recommended to be provided in Ukrainian, while other languages may be included.

Market surveillance

State Service of Ukraine on Medicines and Drugs Control is the market surveillance body for medical devices that have passed the conformity assessment procedure in Ukraine.

According to Article 15 of Law of Ukraine 'On State Market Surveillance and Control of Non-food Products' officials of the market surveillance authority to carry out checking of documents and examination of product samples, sampling and testing have the right to visit without hindrance:

- Trading and storage facilities;
- Places of use of the product during its installation and/ or putting into service;
- Places of exhibitions or demonstrations of products;
- Places of customs storage of products, registration of which is suspended as a result of control.

There is an Sectoral plan for state market surveillance for 2019. In addition, unscheduled inspections related to the non-conformity of medical devices can also be conducted. The objects of such checks at distributors of products are:

- the presence of the technical regulations conformity mark on the products (including the identification number of the designated body for conformity assessment) and compliance with the rules of rules of its application and affixing;
- the presence of supplied documentation, which must be attached to the relevant products (in particular, instructions for use of products), labels, marking, other marks and their compliance with the established requirements;
- availability of a declaration of conformity;
- examination of samples of relevant products and identification of the manufacturer of the products;
- sampling and examination (testing) of product samples (in case there is reason to believe that the product is dangerous, presents a risk and/or does not comply with the established requirements).

Failure to provide documents for the purchase of products in the event that questions arise about product safety and the manufacturer or importer fails to establish, threatens the business entity with penalties as the person who placed such unsafe products on the market!

The system of technical regulation in Ukraine provides requirements not only for the admission of medical devices to the market, but also for their surveillance during subsequent circulation. Therefore, it is extremely important for all subjects of the commodity distribution chain, and especially for the manufacturer and his authorised representative in Ukraine, to understand and fulfill these requirements.

The Ukrainian Scientific Institute of Certification conducts the conformity assessment procedure, relying solely on the obtained objective evidence and being completely independent and impartial in its decisions, fulfilling all aspects of Ukrainian legislation and guided by EU legislation. We have the best knowledge and experience in Ukraine for carrying out such a procedure and we carry out expert examination of documents and conduct audits in English, German, Ukrainian and Russian.

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