

New Requirements for Placing of Medical Devices on the Market: Conformity Assessment to the Technical Regulations

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This summer the medical device circulation reform became one of the most discussed topics in the medical community. Particular attention was drawn to the transition from state registration of medical devices to assessment of their conformity to the Technical Regulations starting from 1 July 2015. Here we tried to present a brief and simple overview of the key innovations resulting from the implementation of the Technical Regulations, drawing a comparison between these two procedures where possible.


Alterations in the system of technical regulation are not a novelty in Ukraine as various groups of products, e.g. personal protective equipment, lifts, hot-water heaters, have been undergoing conformity assessment in accordance with the relevant technical regulations for years. Technical regulations on medical devices were first approved in 2008, but their mandatory application was postponed over and over again. The Technical Regulations were amended and Resolutions No. 753, No. 754 and No. 755 of the Cabinet of Ministers of Ukraine of 2 October 2013 approved the latest revisions. **On 1 July 2015, the Technical Regulations became mandatory for all medical devices, with the exception of those already registered in accordance with the legislation that was in force until 1 July 2015 and approved for being placed on the market and put into service without regard to the new requirements.**

The Technical Regulations do not apply to already registered devices:

- until 1 July 2017 in the case of devices whose registration certificate has no expiry date or expires after 1 July 2017;
- until the expiry date of the registration certificate in the case of devices whose registration certificate expires before 1 July 2017.

These medical devices can be sold and used until their use-by date without undergoing any conformity assessment procedures and being labelled with the national conformity symbol, which gives the possibility to build up the stocks and gradually satisfy the new legislative requirements.

It is no longer possible to extend or amend the registration certificate. In such case, as with all medical devices or equipment that is placed on the market for the first time, conformity assessment is required.

CP	12345/2012 01.01.2012	<p>It should be emphasized that the device labelling cannot bear both symbols at the same time. Devices can be placed on the market if they either have the state registration certificate or have been assessed for conformity and are accompanied by the declaration of conformity.</p>	 National conformity symbol
Symbol of state registration			

It is important to note that even when the devices with affixed CE mark and are accompanied by documents certifying that they comply with the European Directives concerning medical devices and are approved for placing on the EU market, they are nevertheless not allowed to be placed on the Ukrainian market unless they have undergone the national conformity assessment procedure. Moreover, the previous registration does not facilitate this process, and the results of technical, preclinical and clinical evaluations cannot be considered as proof of conformity to the Technical Regulations.

However, for devices bearing the CE marking, the EC declaration of conformity suggests the choice of the procedure, applicable standards and decisions adopted. The same approach can be useful for simplifying the national conformity assessment procedure.

The procedures for conformity assessment and for state registration are so cardinaly different that it is impossible to present the changes in the “before/after” format. The essential differences, in our opinion, are:

- Change of status of the certain products, which are no longer can be considered as medical devices;
- Changes in the documentation that must accompany devices when they are imported and placed on the market;
- Change of the bodies designated to carry out the procedure;
- Requirement to designate the authorized representative of the manufacturer in Ukraine;
- New classification of medical devices;
- Non-linear nature of the conformity assessment procedure, absence of a unified list of documents;
- Considerably simplified access to the market for the lowest-risk products;
- Inspection at the manufacturing site as part of some procedures;
- New requirements for device labelling and instructions for use (user manual);
- Market surveillance of device circulation.

Products that are no longer medical devices. In accordance with the amended legislation regarding circulation of medical devices, personal hygiene products cannot be considered to be medical devices, as defined in the Technical Regulation (Resolution No. 753). The examples of such products are:

- Feminine hygiene products, e.g. tampons, sanitary pads;
- Baby hygiene products, e.g. diapers and napkins;
- Other products such as cotton disks, cotton swabs, etc.

These products are governed by the Laws of Ukraine “On public health and sanitary safety”, “On general safety of non-food products”, “On principles of the state language policy” and the relevant by-laws. Manufacturing, importation and placing of hygiene products on the market must conform to the regulatory requirements of the Sanitary and Epidemiological Service of the MOH.

Authorization documents. Medical devices for which the relevant procedures for assessment of conformity to the Technical Regulations have been carried out can be placed on the market provided that they are accompanied by a **declaration of conformity** issued by the manufacturer or his authorised representative in Ukraine:

“Declaration of conformity is the procedure whereby the manufacturer or his authorised person (hereinafter referred to as the ‘manufacturer’) on his sole responsibility ensures and declares that the products concerned meet the legislative requirements” - the Law of Ukraine “On verification of conformity”

The declaration must cover one or more medical devices manufactured, clearly identified by means of product name, code or other unambiguous reference.

The declaration of conformity must accompany the device when it is placed on the market and sold. The Laws of Ukraine “On state market surveillance and control of non-food products” and “On general safety of non-food products” prescribe that financial penalties shall be imposed if, for example, in the course of inspection the national market surveillance authority reveals that the declaration of conformity is missing or contains inadequate information.

Change of authorities. The state registration was a centralised procedure carried out by the State Administration of Ukraine on Medicinal Products (SAUMP). Conformity assessment involves other authorities, the so-called designated or notified bodies (the counterparts of the EU notified bodies). By the time this overview was being written, 10 state-owned and private bodies had been designated; the list of these bodies is made available on the web-site of the Ministry for Economic Development and Trade of Ukraine.

The SAUMP is engaged in the market surveillance for devices that has been assessed for conformity, controlling the products placed on the market (in pharmacy networks, warehouses of the importers and distributors, etc.).

An essential requirement of the Technical Regulations that applies to all classes of devices and all types of conformity assessment procedures is for the manufacturer which is not a resident of Ukraine to appoint his **authorized representative**. The definition is given in the Technical Regulations:

"authorised representative" means any legal person or sole proprietor being a resident of Ukraine or registered in accordance with the laws of Ukraine, 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'

Designation of the authorised representative in Ukraine

The authorised representative is the liaison between Ukraine (notified bodies, market surveillance authorities, inland revenue bodies, consumers, etc.) and the manufacturer; he performs post-marketing surveillance. The authorised representative acts under the power of attorney or the agreement made between him and the manufacturer. The agreement is more preferable for determining the rights and obligations of both parties, the responsibilities of the authorised representative with regard to quality and safety, communication timing, procedures for handling complaints and adverse reaction reports, and many other aspects.

The authorised representative must keep the documentation at the disposal of the national authorities and/or the notified body for a period of at least 5 years (in the case of implantable devices at least 15 years).

The name and address of the authorized representative must be indicated on the packaging of each medical device or in the instructions for use. Each medical device (type / version) must be linked to only one authorised representative. The manufacturer may appoint a distributor, the representative office, or a third party as his authorised representative.

It should be noted that if the manufacturer chooses to appoint the representative office as his authorised representative, it may entail the serious risk of non-compliance with the current legislation, which prohibits representative offices to conduct business: carrying out regulatory activities in relation to the products manufactured at the other sites of the holding or by contract manufacturers may be regarded as rendering of services to third parties, which is a commercial activity.

Medical device classification. According to the field of use, medical devices are governed by one of the three following Technical Regulations:

- Technical Regulation on Medical Devices;
- Technical Regulation on In Vitro Diagnostic Medical Devices;
- Technical Regulation on Active Implantable Medical Devices.

Medical devices other than in vitro diagnostic devices and active implantable medical devices are classified in Classes I, II a, IIb and III. In vitro diagnostic devices are classified into devices in Lists A and B, devices for self-testing, devices for performance evaluation, and other devices.

Non-linear procedure. Unlike the state registration procedure, assessment of conformity to the Technical Regulations can be carried out in a number of ways, depending on the class/category of the device concerned, which give the possibility to choose the extent of evaluation, i.e. to decide whether the procedure will involve on-site inspection or product testing.

The class of the medical device determines whether a notified body has to be involved: for the lowest-risk products self-declaration is enough.

In the case of other medical devices, either documentation review and on-site inspection have to be carried out, whereafter the manufacturer is issued with a certificate valid for 5 years, or the product has to be assessed for conformity batch-by-batch, whereafter the certificate is granted for the batch assessed.

Self-declaration. The access to the market has been simplified for Class I medical devices (non-sterile, without a measuring function), analysers, reagents and other IVD devices that are not included in List A or List B of the Technical Regulation on In Vitro Diagnostic Medical Devices and not intended for self-testing.

For these devices, no submission or evaluation is required, except notification of the State Administration of Ukraine on Medicinal Products. To ensure compliance of these devices with the relevant Technical Regulations, it is necessary to:

- Designate the authorised representative in Ukraine and complete all relevant legal formalities;
- Compile the technical documentation, translate the necessary parts thereof, and assemble it in conformity with the relevant Technical Regulation and procedure;
- Draw up and sign the Declaration of conformity;
- Submit the address of the authorised representative, list and description of the devices concerned to the SAUMP;
- Affix the conformity mark to the device labelling, ensure that the labelling requirements and instructions for use (user manual) comply with the requirements of the relevant Technical Regulation and the applicable legislation.

When self-declaring the conformity to the relevant Technical Regulations, particular attention should be paid to fulfilment of all requirements and formalities imposed on the authorised representative, since devices become subject to market surveillance from the moment of their admission into the customs territory of Ukraine. The authorised representative must retain documentation and provide it to the market surveillance authorities upon request.

Conformity assessment with the involvement of a notified body

A notified body must be involved in the conformity assessment procedure for the following classes of medical devices:

- Class I sterile devices, Class I devices with a measuring function; all devices falling into Classes IIa, IIb and III;
- In-vitro diagnostic devices: devices for self-testing, reagents, calibrators and control materials in List A and List B;
- All active implantable medical devices.

The application and supporting documents shall be submitted to one of the notified bodies together with a written declaration that no application has been lodged with any other notified body.

The notified bodies may considerably differ in terms of the scope of accreditation or the experts and inspectors employed, which may significantly influence the timing and other aspects of the conformity assessment procedure. The choice of the notified body is extremely important as it can predetermine the

course of the entire procedure. It is not recommended to change the notified body because in this case some procedures will have to be re-initiated and once more be paid for.

There are two options for carrying out conformity assessment with the involvement of a notified body:

1. **Assessment of the quality management system at the manufacturing site (on-site inspection)**, whereafter the manufacturer is issued with the certificate of the device conformity for a period of five years.
2. **Batch-by-batch conformity assessment**, which implies issuing the certificate for the certain batch (shipment) of medical devices after examination of documents and testing of product samples.

The on-site inspection is more comprehensive, time-consuming and expensive than the batch assessment. However, the costs for the fourth or fifth batch-by-batch assessment may already exceed those for the manufacturing site inspection.

In order to obtain the conformity certificate **valid for 5 years**, it is necessary to:

- Designate the authorized representative in Ukraine and complete all relevant legal formalities;
- Select the appropriate procedure according to the class of the device concerned, the manufacturer's documentation, and other aspects;
- Compile the technical documentation, translate the necessary parts thereof, and assemble it in conformity with the relevant Technical Regulation and procedure; prepare the Application and the check-list;
- Choose the notified body, submit the documents, pay the fees;
- Undergo examination of documentation and respond to findings (if any);
- Agree the dates and plan of inspection;
- Receive the notified body's decision on approval of the quality management system at the site and the certificate of the device conformity to the requirements of the Technical Regulation;
- Draw up and sign the Declaration of conformity;
- Affix the conformity mark and the identification number of the notified body to the device labelling; ensure that the other requirements for the labelling and instructions for use (user manual) comply with the requirements of the relevant Technical Regulation and the applicable legislation.

Batch certificate would be useful for rapid placing of devices on the market, for rarely (in single quantities) imported devices and equipment, or when the manufacturer refuses to undergo on-site inspection. However, it should be emphasized that batch-by-batch assessment is not applicable to sterile medical devices.

In order to obtain a **batch certificate**, it is necessary to:

- Designate the authorized representative in Ukraine and complete all relevant legal formalities;
- Compile the technical documentation, translate the necessary parts thereof, and assemble it in conformity with the relevant Technical Regulation and procedure;
- Choose the notified body, submit the documents, pay the fees;
- Undergo examination of documentation and testing of the product samples;
- Receive the certificate of the batch conformity to the requirements of the Technical Regulation;
- Draw up and sign the declaration of conformity;
- Affix the conformity mark and the identification number of the notified body to the device labelling, ensure that the other requirements for the labelling and instructions for use (user manual) comply with the requirements of the relevant Technical Regulation and the applicable legislation.

The declaration of conformity issued following the conformity assessment actually substitutes for a registration certificate at the customs clearance. A copy of the declaration must accompany the product placed on the market.

Inspection of the site can cover wide range of products and thus considerably reduce the future costs for placing the new products on the market.

The manufacturer must inform the notified body of any plan for substantial changes to the product range or safety, or to the quality management system. The notified body is the authority that shall decide on measures necessary to approve such changes.



Requirements for labelling and instructions for use. Affixing of the national conformity mark, indication of the name and address of the authorised representative in Ukraine are essential modifications to the labelling of the medical devices that have been assessed for conformity. General description the conformity mark and the application rules were approved by Resolution No. 1184 of the Cabinet of Ministers of Ukraine of 30 December 2015, and the requirements for the mark size are specified in the Technical Regulations. Where the conformity assessment has involved a notified body, the identification number of that body must be indicated next to the conformity mark.

A few modifications have been also added to the instructions for use; these are listed in the Technical Regulations and must be taken into account when devices are prepared for placing on the market.

Information on the device label and in the instructions for use must be presented in accordance with the Law of Ukraine “On principles of the state language policy” and may be additionally translated into other languages.

Market Surveillance. The authority responsible for market surveillance of devices that have been assessed for conformity is the State Administration of Ukraine on Medicinal Products.

In accordance with Article 15 of the Law of Ukraine “On state market surveillance and control of non-food products”, the officials from the market surveillance authorities have the right to examine documentation and inspect product samples, take product samples and have them tested, and must be granted free access to:

- α) commercial and storage premises;
- β) places of the product use during their assembling and/or putting into service;
- χ) locations where the products are exhibited or demonstrated;
- δ) bonded warehouses where the products whose clearance is suspended as a result of control measures are stored.

The changes made to the technical regulation system not only introduce new rules for placing the devices on the market, but also describe the subsequent market surveillance procedures. It is of utmost importance for the manufacturer, his authorized representative in Ukraine, and all subjects of the distribution network to understand and comply with the new requirements that came into force on 1 July 2015.

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