LABELING OF MEDICAL DEVICES INTENDED FOR SHOWING, DEMONSTRATIONS AT THE PLACE OF FAIRS, EXHIBITIONS

On a modern market economy, for manufacturers of medical devices and their representatives, it is relevant to use all possible legal methods that allow them to better sell their goods, having previously evaluated the offers and needs for a particular type of product with the least investment in this process. An integral part of such an assessment is the advertising of a product, the formation of demand for it and the popularization of the latest achievements of science and technology. Since at various fairs and exhibitions there is a real opportunity to establish commercial collaboration with a wide range of manufacturers, consumers and intermediaries, it is advisable for them to determine the demand for new medical devices before starting their mass production. Whereas such products have not carry out the conformity assessment procedure, they cannot be properly labeled. Unfortunately, there are no clear labeling requirements for such products in Ukraine that would allow them to be identified immediately.

Recently, market surveillance has significantly strengthened monitoring of products displayed at fairs and exhibitions. Therefore, medical devices that were not planned for sale at the time of the exhibition, but presented at it, may cause some misunderstandings, complaints and comments to representatives of products and goods during possible inspections by regulatory authorities.

According to Ukrainian legislation in the field of technical regulation, certain provisions and requirements are established for such products. Since July 1st, 2015, technical regulations in the field of medical devices have become mandatory:

- Technical Regulations on Medical Devices, approved by resolution of the Cabinet of Ministers of Ukraine No. 753 dated October 2nd, 2013 [1];

- Technical Regulation on Medical Devices for In Vitro Diagnostics, approved by the Cabinet of Ministers of Ukraine No. 754 dated October 2nd, 2013 [2];

- Technical Regulation on Implantable Active Medical Devices, approved by the Cabinet of Ministers of Ukraine No. 755 dated October 2nd, 2013 [3].

The above technical regulations are developed on the basis of the relevant Council of the EU: Directive 93/42/EEC, Directive 98/79/EEC and Directive 90/385/EEC.

In accordance with the specified technical regulations, the putting into circulation and/or operation of products on the territory of Ukraine is allowed only if they fully comply with the requirements of the technical regulation in which they fall, as a result of which a labeling must be affixed with a conformity mark to technical regulations. At the same time, the technical regulation provides a provision regarding the labeling of medical devices that will not be used for their intended purpose, but are intended only for display, demonstration at the place of the fair, exhibition.

Clause 10 of the Technical Regulations on medical devices states that equipment that is presented at the place of a fair, exhibition, display or is displayed in a different way and does not meet the requirements of this technical regulation should be accompanied by a visible mark that indicates that such equipment cannot be introduced into circulation or into operation without bringing it into line with the requirements of the Technical Regulations. Demonstration of the operation of such equipment is possible only if appropriate measures are taken to prevent electromagnetic interference.

Clause 9 of the Technical Regulation on in vitro diagnostic medical devices states that it is allowed to exhibit at trade fairs, exhibitions, demonstrations of products that have not passed the conformity assessment procedure with the requirements of this Technical Regulation, provided that they are not used for sample analysis and the manufacturer has made clear designation with information that such products are not to be put into circulation or operation until they are brought into compliance with the requirements of the Technical Regulations.

According to paragraph 9, paragraph 3 of the Technical Regulations for active medical devices that implant, it is indicated that labeling with the mark of compliance with technical regulations is NOT applied to products that are displayed at fairs, exhibitions, presentations and the like.

Thus, taking into account the above provisions of technical regulations, in order to avoid misunderstandings between representatives of products at exhibitions, fairs, shows and representatives of regulatory authorities, we recommend developing a label for medical devices used for demonstration, which will clearly indicate that the product is not intended for the putting into circulation and/or operation. An example of labeling for such medical devices is given in fig. 1:

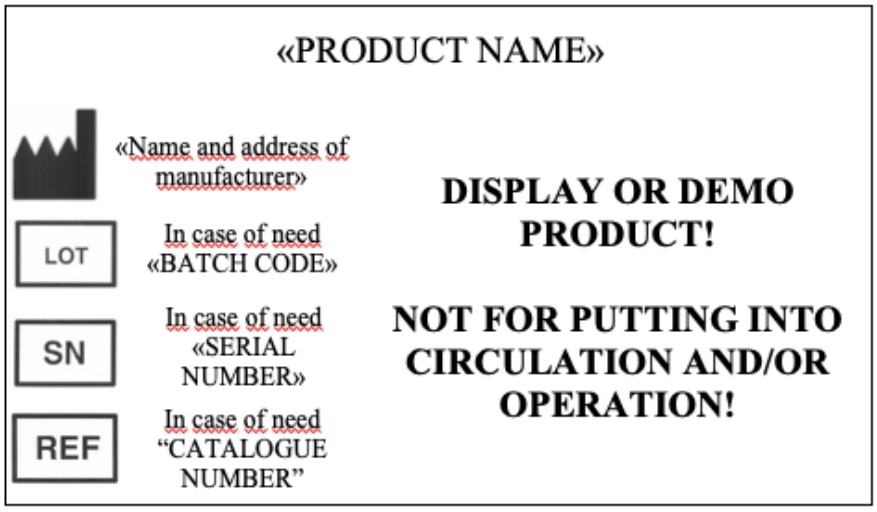

Fig.1. Example of possible labeling

At the stage of preparation for the exhibition, it is advisable for representatives of the manufacturer of medical devices to obtain official confirmation of their participation from the organizers of the exhibition/fair, which will contain: contact information about the place of the event; date and time; the name of the organization as a participant of the event and the list of medical devices that will participate in the demonstration.

We also recommend that you make a request to the designated conformity assessment body in order to receive an official letter explaining the labeling of products for demonstration, as such, which cannot be put into operation or commissioned without bringing them into line with the requirements of the Technical Regulations.

You can contact the designated conformity assessment body of UNI-CERT, LLC for the further information.

References

1. Технічний регламент щодо медичних виробів, затверджений постановою Кабінету Міністрів України №753 від 02.10.2013.

Доступно на: https://zakon.rada.gov.ua/laws/show/753-2013-%D0%BF

2. Технічний регламент щодо медичних виробів для діагностики in vitro, затверджений постановою Кабінету Міністрів України №754 від 02.10.2013.

Доступно на: https://zakon.rada.gov.ua/laws/show/754-2013-%D0%BF

3. Технічний регламент щодо активних медичних виробів, які імплантують, затверджений постановою Кабінету Міністрів України №755 від 02.10.2013.

Доступно на: https://zakon.rada.gov.ua/laws/show/755-2013-%D0%BF

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