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CHECKLISTS FOR CHECKING COMPLIANCE OF UKRAINAN MEDICAL DEVICES MARKET

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According to the reforms in medical field of Ukraine the topical issue is using medical devices with the proper quality. One of the ways for checking compliance and usage control is labeling.

Package labeling (American English) or labelling (British English) is any written, electronic, or graphic communication on the package or on a separate but associated label [1]. It helps to spread awareness among the customers about the item they are consuming and labeling also helps to mention ingredients [2].

During last year some specialists from the Kyiv National University of Technology and Design in cooperation with the Ukrainian Scientific Institute of Certification developed the checklists for active medical devices («in vitro» diagnostics) for the purpose of evaluation information provided by the manufacturer on the standard basis of the packages labeling for transportation. The ultimate goal was to propose a draft protocol for the laboratory test results.

We found out that as part of the conformity assessment procedure, the manufacturer must prove that the medical device meets the basic requirements of the technical regulations for medical devices. This requirement is duplicated by the EU Directives. The international name is Essential Requirements Checklist (check-list).

By analogy with the profile European directives, Ukrainian technical regulations establish the requirements for proving compliance by filling such a check list. This document is often drawn up in the form of a table that is well known to a foreign producer. The checklist is a kind of summary excerpt from the whole mass of technical documentation of the manufacturer.

This documentation is necessary for proving compliance with the requirements of technical regulations.

The development of the checklist requires a lot of patience, care and knowledge of normative documentation in the form of standards.

The meaning of some of these characters is obvious. Some are already widely known and well-known for healthcare professionals. The symbols proposed by DSTU EN 980: 2007 «Graphic symbols for use in the labeling of medical devices» which are used not only by healthcare professionals, may require additional explanations in the national language of the country (where the medical device is exported). Explanations of the used symbols should be given in the instructions for the medical devices.

Most of the proposed characters have been introduced for the first time. They are unfamiliar to manufacturers and users; therefore, this standard requires

explanation of the meaning of these new characters in the documentation accompanying the medical product.

Over time, the requirement to explain the meaning of the symbols will be reduced. We cannot always enter universal characters to express information about a particular product. Not all characters are appropriate for all types of medical products. The probability of information that is expressed by symbols can be influenced by various actions. For example, damage to the package may affect the sterility of the product [3].

Here is an extract from the table 1 that we have created for the laboratory test results [4, 5].

Table 1 - Labeling checklists for medical devices based on the DSTU EN 980: 2007

№	Criteria	Symbol	Description
1	2	3	4
1	**Name/ Trade Name of the device**	Symbol	Name/Trade Name of the device
2	**The Name and Address of manufacturer**		This symbol must be accompanied by the name and address of the manufacturer who is responsible for the product. The address is not necessary for the symbol directly on the container, as defined in EN 375 and EN 378, except when the container is also an external container. **Note.** The symbol № 5.2 DSTU EN 980: 2007 corresponds to this symbol.
3	**Authorised Representative in the European community**		This symbol must be accompanied by the name and address of the authorized representative in the European Union, in the adjacent symbol. The address does not require a symbol directly on the container, as defined in EN 375 and EN 376, except when the container is also an external container. **Note.** The symbol № 5.3 DSTU EN 980: 2007 corresponds to this symbol.
4	**Operating instruction / Instruction for use, where appropriate**		«Introduction to operating instructions». **Note 1.** This symbol is given in ISO 7000/1641 and as the symbol number 3.31 ISO 15223. **Note 2.** The symbol № 5.8 DSTU EN 980: 2007 corresponds to this symbol.
5	**Lot / batch no**		«Lot Number». This symbol must be accompanied by the manufacturer's party code. This code will be adjacent to the symbol. **Note 1.** The symbol number 3.14 ISO 15223 corresponds to this symbol. **Note 2.** The symbol № 4.4 DSTU EN 980: 2007 corresponds to this symbol.

Continuation of Table 1

1	2	3	4
6.	**Serial number**	**SN**	This symbol must be accompanied by the registration number of the manufacturer. The manufacturer's registration number must be placed after or below the symbol. **Note 1.** The symbol number 3.16 ISO 15223 corresponds to this symbol. **Note 2.** The symbol № 4.5 DSTU EN 980: 2007 corresponds to this symbol.
7.	**Catalogue number**	**REF**	«Reference number», «serial number». The manufacturer's directory number should be located after or below the symbol adjacent to it. **Note 1.** The symbol number 3.15 ISO 15223 corresponds to this symbol. **Note 2.** The symbol № 4.9 DSTU EN 980: 2007 corresponds to this symbol.

Conclusion. A draft protocol for the laboratory test results of medical devices has been created within this research. According to the subject of the paper specific normative documentation, standards and other current resources have been used. The draft had been approved and used on a par with other enterprise checklists by Medical Devices Conformity Assessment Notified Body «Ukrainian Scientific Institute of Certification». This development is expected to simplify the obtaining and organizing information about new medical devices.

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