

Implementation of the classification of medical devices of Ukraine in international approaches

Gennadiy O. Slabkiy¹, Victoria J. Bilak-Lukyanchuk¹, Rostislav L. Kartavtsev², Vitalii Kondratskyi³

¹ UZHHOROD NATIONAL UNIVERSITY, UZHHOROD, UKRAINE

² STATE UKRAINIAN ASSOCIATION "POLYTECHMED", KYIV, UKRAINE

³ CARDINAL STEFAN WYSZYNSKI UNIVERSITY, WARSZAWA, POLAND


ABSTRACT

Aim: To study the level of compliance of the National Classifier of Ukraine «Classifier of Medical Devices of Ukraine NC 024: 2023» with international approaches to the classification and use of medical devices.

Materials and Methods: National Classifier of Ukraine «Classifier of Medical Devices of Ukraine NC 024: 2023» and the international nomenclature of medical devices Global Medical Device Nomenclature. Methods: bibliosemantic, of content analysis and of structural-and-logical analysis.

Conclusions: In the course of the study, full compliance of the national classifier of medical devices of Ukraine NC 024: 2023 with the GMDN system was established.

KEY WORDS: Ukraine, medical devices, classification, international approaches, compliance.

Wiad Lek. 2024;77(2):345-347. doi: 10.36740/WLek202402123 

INTRODUCTION

In Ukraine, planned work is underway to implement the classification of medical devices in accordance with international approaches. Thus, on the basis of the relevant Directives of the European Union [1,2], the Cabinet of Ministers of Ukraine approved the Technical Regulations on Medical Devices [3], the Technical Regulations on Medical Devices for in vitro Diagnostics [4], the Technical Regulations on Active Implantable Medical Devices [5], which became mandatory for use in the country on July 1, 2015. In order to put medical devices into circulation and/or operation on the territory of Ukraine, it is necessary to undergo a conformity assessment procedure for these devices and affix a national mark of conformity. In particular, the circulation and use of medical devices in Ukraine is allowed in case of confirmation of their compliance with one of the three specified medical technical regulations.

The first national classifier of medical devices in Ukraine was approved in 2019. Subsequently, it was improved and the classifier NC 024:2023 is currently in force [6].

Taking into account that the purpose of implementing the classifier of medical devices at the national level is the effective application of the European approach to the identification of medical devices in Ukraine, which is a step towards the European integration of the health care system of Ukraine and will simplify the entry of Ukrainian medical devices into foreign markets, we

analyzed the compliance of methodological approaches and terminology used in the national classifier of medical devices NC 024: 2023 of Ukraine and GMDN.

GMDN – is a system of universally recognized international descriptors used for the identification of medical devices; a system of product names used for diagnosing, prevention, monitoring, treatment, or alleviation of human illnesses and injuries [7].

AIM

The aim was to study the level of compliance of the National Classifier of Ukraine "Classifier of Medical Devices of Ukraine NC 024: 2023" with international approaches to the classification and use of medical devices.

MATERIALS AND METHODS

MATERIALS

National Classifier of Ukraine "Classifier of Medical Devices of Ukraine NC 024: 2023" and the international nomenclature of medical devices Global Medical Device Nomenclature.

METHODS

Bibliosemantic, of content analysis and of structural-and-logical analysis.

Table 1. A fragment of the National Classifier of Medical Devices of Ukraine «Classifier of Medical Devices NK 024:2023»

Code	English name	Definition in English
34175	Acupuncture needle, single-use	A sterile, long, slender, sharply-pointed instrument used to stimulate peripheral nerves in order to produce surgical anaesthesia, relieve pain, and to promote other therapeutic effects. It is widely used in complementary therapy. This is a single-use device.
34178	Invasive breast implant sizer, single-use	A sterile surgical instrument intended to be placed intraoperatively in a surgically-prepared mammary pocket to provide a volume measurement for the appropriate selection of a breast implant (mammary prosthesis). The device is typically a balloon-like elastomer pouch with tubing that is placed in the pocket, filled to an optimal volume, and then removed. This is a single-use device.
35362	Chemical/physical sterilization process indicator	A sterilization indicator designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. This is a single-use device.
35368	Auditory stimulator	A mains electricity (AC-powered) device that applies sound stimuli (e.g., pure tones, speech) to a patient's acoustic system. It is typically used as a component of several types of devices such as audiometers, auditory evoked-potential recording systems, and auditory function screening devices.
35380	Tendon stripper	A hand-held manual surgical instrument designed to excise a length of ligament, tendon or fascia for use as a living graft. It typically consists of a handle and a semicircular shaped trough that terminates in a sharp cutting edge. It is typically made of high-grade stainless steel. This is a reusable device.

For the application of these materials and methods during the study, permission was obtained from the ethical commission of Uzhhorod National University. Protocol dated 08.02. 2023 № 6/2.

REVIEW AND DISCUSSION

In the course of the study, it was found that the National Classifier of Ukraine “Classifier of Medical Devices NC 024: 2023” is designed to identify instruments, apparatus, devices, gadgets, materials or other products related to medical devices. It should be noted that the Classifier of Medical Devices NC 024:2023 is an adapted translation of part of the list of medical devices included in the GMDN nomenclature and supplemented with medical devices that are not included in the GMDN nomenclature, but are used in Ukraine.

When creating the national classifier of Ukraine “Classifier of medical devices NC 024: 2023”, hierarchical, ordinal, five-digit classification methods were used. Information about a medical device in the national classifier is presented in the form of a 5-digit numerical code GMDN (Code) is cross-referenced with the exact wording of the term (Term Name) and Definition (Definition). This can be seen in the following example: “Code (GMDN Code): 10729. Term (GMDN Term Name): «Central venous catheter». Definition: (GMDN Definition): “A sterile, flexible tube intended to be introduced into a neck or thoracic vein and often advanced into the superior vena cava for various infusion/aspiration procedures (i.e., non-dedicated) including the intravenous administration of nutrients, fluids, chemotherapeutic agents or other drugs, and blood sampling or delivery; it may also be used to monitor venous pressure. The proximal end of this central venous catheter (CVC) is typically fixed to the patient for

long-term use. It may include supportive devices associated with introduction (e.g., guidewire, introducer); it is not primarily intended for extracorporeal blood therapies such as haemodialysis. This is a single-use device”.

Each of the items of the classifier on a medical device consists of five parts: code, name of the device in Ukrainian, description of the device in Ukrainian, name of the device in English, description of the device in English.

A fragment of the National Classifier of Medical Devices of Ukraine is presented in the table 1. It should be noted that when determining the subject of procurement, the National Classifier NC 024:2023 is used together with the National Classifier of Ukraine SC 021:2015 “Unified Procurement Dictionary” [8].

In the course of the study by comparison, it was found that the National Classifier of Ukraine “Classifier of Medical Devices of Ukraine NC 024: 2023” [6] is harmonized with the international nomenclature of medical devices Global Medical Device Nomenclature [7], which is used in 70 countries of the world, in particular, in most countries of Europe and the United States. Currently, the nomenclature is used by about 7500 manufacturers, it includes about a million items [9]. The GMDN nomenclature is recommended for use by the International Forum of Medical Device Regulators (IMDRF) and is actually the only platform for identifying medical devices and international industry information exchange [9].

CONCLUSIONS

In the course of the study, the full compliance of the methodological approaches, structure and terminology used in the development of the National Classifier of Ukraine “Classifier of Medical Devices of Ukraine NC 024: 2023” with those of the GMDN system was established.

REFERENCES

1. Dyrektyva 93/42/YEES vid 14.06.1993 Shchodo pytannya medychnoho obladdnannya [Regarding medical equipment, Directive 93/42/EEC of the European Parliament and of the Council]. 1993. https://online.budstandart.com/ua/catalog/doc-page.html?id_doc=67838 [Accessed 27 November 2023] (Ukrainian)
2. Regarding medical devices for in vitro diagnostic, Directive 98/79/EC of the European Parliament and of the Council]. 1998. <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A31998L0079> [Accessed 27 November 2023]
3. CABINET OF MINISTERS OF UKRAINE RESOLUTION of October 2, 2013 No. 753 [On the approval of the Technical Regulation on medical devices Technical Regulation on Medical Devices, Resolution of the Cabinet of Ministers of Ukraine №753]. 2013. <https://zakon.rada.gov.ua/laws/show/753-2013-%D0%BF#Text> [Accessed 27 November 2023] (Ukrainian)
4. Postanova vid 2 zhovtnya 2013 r. № 754 Pro zatverdzhennya Tekhnichnoho rehlamentu shchodo medychnykh vyrobiv dlya diahnostyky in vitro [Technical Regulation on In Vitro Diagnostic Medical Devices, Resolution of the Cabinet of Ministers of Ukraine №754]. 2013. <https://www.kmu.gov.ua/npas/246787748> [Accessed 27 November 2023] (Ukrainian)
5. Kabinet Ministriv Ukrayiny. Postanova vid 2 zhovtnya 2013 r. № 755 Pro zatverdzhennya Tekhnichnoho rehlamentu shchodo aktyvnykh medychnykh vyrobiv, yaki implantuyut' [Technical Regulation on Active Implantable Medical Devices, Resolution of the Cabinet of Ministers of Ukraine №755]. 2013. <https://zakon.rada.gov.ua/laws/show/755-2013-%D0%BF#Text> [Accessed 27 November 2023] (Ukrainian)
6. Ministerstvo Ekonomiky Ukrayiny. Nakaz 24.05.2023 № 4139 Pro zatverdzhennya natsional'noho klasyfikatora NK 024:2023 ta skasuvannya natsional'noho klasyfikatora NK 024:2019 [On the approval of the national classifier NC 024:2023 and the repeal of the national classifier NC 024:2019, Order of the Ministry of Economy of Ukraine №4139]. 2023. <https://zakon.rada.gov.ua/rada/show/v4139930-23#Text> [Accessed 27 November 2023] (Ukrainian)
7. GMDN. Global Medical Device Nomenclature. <https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-inclusion-process/what-kind-medical-device-it/introduction-global-medical-device-nomenclature-gmdn> [Accessed 27 November 2023]
8. Ministerstvo Ekonomichnoho Rozvytku i Torhivli Ukrayiny. Nakaz 23.12.2015 № 1749 Pro zatverdzhennya natsional'noho klasyfikatora Ukrayiny DK 021:2015 ta skasuvannya natsional'noho klasyfikatora Ukrayiny DK 021:2007 [On the approval of the national classifier of Ukraine DK 021:2015 and the cancellation of the national classifier of Ukraine DK 021:2007. Order of the Ministry of Economic Development and Trade of Ukraine № 174]. 2015. <https://zakon.rada.gov.ua/rada/show/v1749731-15> [Accessed 27 November 2023] (Ukrainian)
9. International Medical Device Regulators Forum. International Medical Device Regulators Forum (IMDRF). <http://www.imdrf.org> [Accessed 27 November 2023]

CONFLICT OF INTEREST

The Authors declare no conflict of interest

CORRESPONDING AUTHOR

Gennadiy O. Slabkiy

Uzhhorod National University

14 University St, 88000 Uzhhorod, Ukraine

e-mail: gennadiy.slabkiy@uzhnu.edu.ua

ORCID AND CONTRIBUTIONSHIP

Gennadiy O. Slabkiy: 0000-0003-2308-7869 **A** **F**

Victoria J. Bilak-Lukyanchuk: 0000-0003-3020-316X **A**

Rostislav L. Kartavtsev: 0000-0002-2634-0017 **B** **D**

Vitalii Kondratskiy: 0000-0002-2413-0198 **E** **F**

A – Work concept and design, **B** – Data collection and analysis, **C** – Responsibility for statistical analysis, **D** – Writing the article, **E** – Critical review, **F** – Final approval of the article

RECEIVED: 17.10.2023

ACCEPTED: 11.02.2024

