© Aluna Publishing ACTA BALNEOLOGICA, VOLUME LXVI, ISSUE 5, SEPTEMBER-OCTOBER 2024

REVIEW ARTICLE

# National classifier of medical devices nс 024:2023 as a standard and methodological basis for providing the rehabilitation system with medical devices

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#### ABSTRACT

**Aim:** To present methodological approaches to the classification of medical devices in the National Classifier of Medical Devices of Ukraine NC 024: 2023 for providing the rehabilitation system with medical devices for their practical application in the development of the rehabilitation system in the country.

**Materials and Methods:** international and domestic legal documents on the classification of medical devices and the development of the rehabilitation system. bibliosemantic, of systemic approach and of structural-and-logical analysis.

**Conclusions:** methodological approaches to providing the rehabilitation system with medical devices with the use of the National Classifier of Medical Devices NC 024:2023 are presented.

**KEY WORDS:** National Classifier of Medical Devices, rehabilitation system, application

Acta Balneol. 2024;66(5):359-362. doi: 10.36740/ABAL202405109

### INTRODUCTION

The rehabilitation system is actively developing in Ukraine. The directions of development of the rehabilitation system are defined at the legislative level [1,2]. The efficiency of the system depends to some extent on the availability of medical devices.

In Ukraine, the classification of medical devices has been harmonized with the international nomenclature of medical devices Global Medical Device Nomenclature (hereinafter referred to as GMDN) [3], which is currently used in most countries of the European Union and the United States [4- 7]. GMDN is a system of globally recognized international descriptors used to identify medical devices; a product naming system used for diagnosing, prevention, monitoring, treatment, or relieving human illness and injuries. The GMDN nomenclature is recommended for practical use by the International Forum of Medical Device Regulators (IMDRF) and is the only platform for identifying medical devices and the basis for international industry information exchange [8]. Harmonization was carried out through the approval of the National Classifier of Medical Devices (hereinafter

referred to as NC 024:2023) [9].

The National Classifier of Medical Devices was adopted in order to unify technical and economic information and identification of medical devices in accordance with the system of generally accepted international descriptors.

The National Classifier NC 024:2023 should be used in the public procurement process to describe the subject of public

procurement in agreements (contracts), ensure transparency of procurement procedures for medical devices for budget funds, create an effective competitive environment in the field of public procurement, and facilitate the entry into the world market of domestically produced medical devices.

### AIM

To present methodological approaches to the classification of medical devices in the National Classifier of Medical Devices of Ukraine NC 024: 2023 for providing the rehabilitation system with medical devices for their practical application in the development of the rehabilitation system in the country.

### MATERIALS AND METHODS

MATERIALS

International and domestic legal documents on the classification of medical devices and the development of the rehabilitation system.

METHODS

bibliosemantic, of systemic approach and of structural- and-logical analysis.

### REWIEV AND DISCUSSION

The National Classifier of Medical Devices NC 024:2023 is designed to identify instruments, apparatus, devices, materials or other medical equipment. It is an adapted

translation of the list of medical devices included in the GMDN nomenclature, as well as supplemented with medical devices that are not included in the GMDN nomenclature, but are used in Ukraine.

Taking into account the above noted, the compliance of the terminology used in the national classifier of medical devices NC 024: 2023 was analyzed. In the course of the undertaken analysis, the full compliance of the terms used in the national classifier of medical devices NC 024: 2023 with the GMDN system was established. The GMDN system and NC 024:2023 define a medical device as any instrument, apparatuses, device, software, material or other product used both separately and in combination with each other (including software provided by the manufacturer to use specifically for diagnostic and/or therapeutic purposes and necessary for the proper functioning of the medical device) intended by the manufacturer for use in order to provide diagnostics, prevention, monitoring, treatment

or alleviation of the course of the patient’s illness in case of disease, diagnostics, monitoring, treatment, alleviation of the patient’s condition in case of injury or disability or their compensation, research, replacement, modification or maintenance of the anatomy or physiological process, control of the fertilization process and the main intended effect in or on the human body which is not achieved by means of pharmacological, immunological or metabolic agents, but the functioning of which such agents may contribute.

The national classifier of medical devices NC 024:2023 includes 65352 medical devices, 720 of which are used exclusively in the rehabilitation system. When developing the classifier, the following methodological approaches were used: hierarchical, ordinal, five-digit.

Each item of the classifier consists of five parts. These are: code, name of the medical device in Ukrainian, description of the medical device in Ukrainian, name of the medical device

**Table 1.** Fragment of the National Classifier of Medical Devices of Ukraine “Classifier of Medical Devices NC 024:2023”: rehabilitation

|  |  |  |
| --- | --- | --- |
| **Code** | **English name** | **English description** |
| 63362 | Ambulatory posturo- graph | A body-worn device intended to measure and graphically record ambulatory body movements related to posture and balance to assist with the diagnosis and treatment of balance disorders caused by a variety of conditions (e.g., neurological, vestibular). It consists of sensors that detect degree of body sway/tilt, and may in addition include vibratory stimulators which provide feedback to the patient for balance/ posture improvement; it may be connected to an off-the-shelf computer for device control and graphical recording analysis/display. The device is intended to be operated by a healthcare professional in a clinical setting. |
| 38064 | Ankle continuous passive motion exerciser | A mains electricity (AC-powered) device designed to continuously move the ankle joint (e.g., flexion, inversion/eversion) without patient assistance during continuous passive motion (CPM) exercise therapy usually following surgery or trauma to the joint. The device typically consists of a motorized carriage with straps to hold and move the leg/ankle, and an electrical control unit for the healthcare professional to set the variable range of motion and motion speed; digital displays, manual/automated safety capabilities, and other features may also be included. CPM is believed to stimulate articular tissues and circulation of synovial fluid, and to reduce joint oedema. |
| 36678 | Arm ergometer | A device used to provide a quantitative measurement of the rate at which work (energy) is performed by a muscle or group of muscles under controlled conditions. It is operated by a person using their arms, usually the patient, undergoing assessment, treatment, training, or rehabilitation and measures this related muscle activity at defined workloads. |
| 58911 | Arthritis transcutaneous electrical joint stimulation system | An assembly of battery-powered devices intended to be used as adjunctive therapy in reducing the level of pain and stiffness associated with rheumatoid arthritis or osteoarthritis by electrically stimulating arthritic tissue in a joint across the skin (transcutaneously); it is not intended for neurostimulation.It typically consists of an external electric current generator and electrodes (leads) that are placed on the skin with conductive patches to deliver pulsed electrical fields to the painful arthritic tissue. It is intended for routine home-use to treat symptoms of rheumatoid arthritis (RA) of the hands and osteoarthritis of the knee. |
| 48071 | Assistive dynamic arm support system | An assembly of mechanical devices designed to bear the weight of a weak or paralyzed arm providing gravity-compensating support for the functional use and/or rehabilitation of the arm/wrist/hand.It is used to support activities of daily life (ADL) such as feeding, self care, computer use, as well as therapeutical training and prevention of complaints of neck and/or shoulder (CANS). It consistsof a main column anchored to a surface or wheelchair and a suspended sling or a set of components which take the weight bearing through a set of axes, joints, and a splint underneath the user’s arm. Gravity compensation works via a counterweight or spring mechanism and a power-assistive electromotor. |

Hennadiy Slabkiy et al.

in English, description of the medical device in English. It should be noted that digital information about a medical device included in the national classifier is presented in the form of a five-digit numerical code GMDN (Code), and it is cross-referenced with the exact wording of the term (Term Name) and description (Definition).

We carry out a specific example of a medical device intended for rehabilitation:

Code: 61543

Term Name: Mobile gait rehabilitation system, pneumatic- support

Definition: A mobile assembly of battery-powered devices designed to assist a patient with a walking disability (neurogenic, muscular, or osseous in origin) to regain lost motor function, which may include rising from sitting to standing and/or ambulation. It consists of a mobile rigid framework on electronically-controlled wheels which includes: patient-worn inflatable trousers intended to stabilize and support the weight of the patient during ambulation; a pneumatic pump to inflate the trousers; handgrips; and an electronic control unit. It is intended to be used in a clinical setting (e.g., gait lab, rehabilitation center, nursing home) under healthcare professional supervision. A fragment of the National Classifier of Medical Devices of Ukraine, which presents data on medical devices intended

for rehabilitation, is presented in the Table 1.

It should be noted that in the process of procurement of medical devices, the classifier NC 024:2023 is used alongside with the national classifier of Ukraine SC 021:2015 “Unified Procurement Dictionary”[10]. At the same time, the practical use of the National Classifier NC 024:2023 is provided by the computer program “System of on-line access to the classifier of medical devices”. It provides continuous on-line access of the representatives of health care institutions, establishments, organizations and enterprises to the information of the classifier.

In order to organize the provision of rehabilitation assistance, the Ministry of Health of Ukraine approved an approximate list of material-and-technical equipment of inpatient rehabilitation departments, units of health care institutions that provide rehabilitation assistance to adults in the post-acute rehabilitation period [11]. The approved sample list of material-and-technical equipment includes a list of medical devices, their quantity and description for rehabilitation units of health care institutions.

In the context of the implementation of state guarantees of the provision of free medical care [12], the requirements for equipping institutions (units) for the provision of rehabilitation services with medical devices are determined at the state level [13].

The analysis of these documents and NC 024:2023 as a standard for providing the rehabilitation system with medical devices indicates certain discrepancies in the terminology and description of the medical devices specified in them. This situation requires full harmonization of these regulatory documents on the basis of NC 024:2023.

### CONCLUSIONS

The National Classifier of Medical Devices NC 024:2023 is designed to identify instruments, apparatuses, devices, materials belonging to medical devices, is the relevant national standard and, using the computer program “System of on-line access to the classifier of medical devices”, contributes to the provision of the rehabilitation system with medical devices available in Ukraine. At the same time, it is necessary to fully harmonize the sample list of material-and-technical equipment of inpatient rehabilitation departments, units of health care institutions that provide rehabilitation assistance to adults in the post- acute rehabilitation period and the conditions for the purchase of medical services (requirements for the list of equipment) with NC 024: 2023.

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#### CONFLICT OF INTEREST

The Authors declare no conflict of interest

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–Work concept and design, – Data collection and analysis, – Responsibility for statistical analysis, –Writing the article, – Critical review, – Final approval of the article

**RECEIVED:** 11.06.2024

**ACCEPTED:** 03.09.2024 CREATIVE COMMONS 4.0