On approval of the Rules for formation and maintenance of the Medical Device Nomenclature of the Republic of Kazakhstan

Invalidated Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated May 16, 2019 № ҚР ДСМ-78. Registered with the Ministry of Justice of the Republic of Kazakhstan on May 21, 2019 № 18703. Abrogated by Order of the Minister of Health of the Republic of Kazakhstan dated 12.10.2020 № KR DSM-127/2020.

Unofficial translation

The footnote. Abrogated by Order of the Minister of Health of the Republic of Kazakhstan dated 12.10.2020 № KR DSM-127/2020 (effective ten calendar days after the date of its first official publication).

In accordance with clause 4 of article 83 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On public health and health care system" **I HEREBY ORDER**:

1. To approve the attached Rules for formation and maintenance of the Medical Device Nomenclature of the Republic of Kazakhstan.

2. The Committee of Pharmacy of the Ministry of Health of the Republic of Kazakhstan in accordance with the procedure established by the laws of the Republic of Kazakhstan shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) within ten calendar days from the date of state registration of this order, direction of its copy in paper and electronic form in the Kazakh and Russian languages to the Republican State Enterprise on the Right of Economic Management "Republican Center of Legal Information" of the Ministry of Justice of the Republic of Kazakhstan for official publication and inclusion to the Reference Control Bank of Normative Legal Acts of the Republic of Kazakhstan;

3) placement of this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication.

4) within ten working days after state registration of this order, submission to the Department of Legal Service of the Ministry of Health of the Republic of Kazakhstan of information about implementation of the measures, stipulated by subclauses 1), 2) and 3) of this clause.

3. Control over execution of this order shall be entrusted to the Vice-Minister of Health of the Republic of Kazakhstan Nadyrov K.T.

4. This order shall come into force upon expiry of ten calendar days after its official publication.

Approved
by the order
dated May 16, 2019
no. ҚР ДСМ-78

Rules
for formation and maintenance of the Medical Device Nomenclature
of the Republic of Kazakhstan
Chapter 1. General provisions

1. These Rules for formation and maintenance of the Medical Device Nomenclature of the Republic of Kazakhstan (hereinafter referred to as the Rules) shall determine the procedure of formation and maintenance of the Nomenclature of medical devices of the Republic of Kazakhstan.

2. In these Rules the following main definitions shall be used:

1) a type of medical device - a group of medical devices having similar purpose, similar application technologies, design features and a general digital designation in the nomenclature of medical products of the Republic of Kazakhstan

2) Global Medical Device Nomenclature (Global Medical Device Nomenclature, GMDN) – systematic nomenclature classifier of types of medical devices used to identify medical devices;

3) Medical Device Nomenclature of the Republic of Kazakhstan (hereinafter referred to as the MDNRK) - systematized nomenclature classifier of types of medical devices, harmonized with GMDN and used in the Republic of Kazakhstan;

4) code of a type of medical device – a system of digital characters used to represent and / or transmit data;

5) classification attribute – a term used to determine attributes and characteristics of a type of medical device

6) Agency for the Global Medical Devices Nomenclature - organization responsible for formation and maintenance of the Global Medical Device Nomenclature.

Chapter 2. Procedure of formation and maintenance of MDNRK

1. MDNRK is formed and maintained by the state expert organization in the sphere of circulation of medicines and medical devices (hereinafter referred to as the state expert organization) in an electronic form and shall be posted on the official website of the state expert organization.

2. MDNRK is formed on the basis of the Global Medical Device Nomenclature (GMDN) by transcoding the GMDN code to the MDNRK code.

3. MDNRK contains a list of types of medical devices with names, codes and descriptions of types of medical devices, as well as a list of classification features.

4. The name, description of the type of medical device, the classification features of MDNRK correspond to the name, description of the type of device and the classification features of GMDN.

5. State expert organization shall:

1) ensure the translation into Kazakh and Russian of the names and descriptions of the types of medical devices included in GMDN;

2) ensure the translation into Kazakh and Russian of the names and descriptions of new types of medical devices received from GMDN Agency, as well as information on changes made to the names and descriptions of types of medical devices included in GMDN and making appropriate changes to MDNRK;

3) ensure the exclusion of species from MDNRK, based on information received from the GMDN Agency on the exclusion from GMDN of certain types of medical devices;

4) enter to the State Register of medicines and medical devices of records by types of medical devices MDNRK based on the sample, according to annex to these Rules;

5) perform the analysis and generalization of comments and proposals of MDNRK users concerning its structure and content.

6. The state expert organization, in performance of expertise of medical devices in accordance with the order of the Minister of Health of the Republic of Kazakhstan dated November 18, 2009 no. 736 "On approval of the Rules for the expertise of medicines and medical devices" (registered with the Register of state registration of regulatory acts of the Republic of Kazakhstan under No. 5926, published in 2010 in the Collection of acts of central executive and other central government bodies of the Republic of Kazakhstan No. 5), shall evaluate the declared MDNRK code for compliance with generic pertinence of the medical device.

Annex
to the Rules for formation and
maintenance of the
Medical Device
Nomenclature of the
Republic of Kazakhstan

Sample of a record of a type of medical device

Code	Name	Description
254333	Sutural knife	Special hand-held surgical instrument for cutting suture materials to remove them. It can be a single scalpel blade with protection or a scissor structure. The device is reusable.

Sample of assigning the type of medical device to classification features

Code	Classification features
254333	1) Surgical 2) Dentistry 3) Otolaryngology 4) Gastroenterology 5) Urology 6) Neurology 7) Obstetrics and gynecology 8) Ophthalmology 9) Orthopedics 10) Plastic surgery 11) Cardiology 12) Blades 13) Mills and accessories 14) Equipment for the regeneration and processing of body tissues 15) Plastic 16) Manual, surgical 17) Tools for stitching fabrics 18) Inorganic materials 19) Manual 20) Sterilizable 21) Synthetic polymers 22) Metals 23) Suture materials and accessories