

On approval of the Rules for the formation and maintenance of the nomenclature of medical devices of the Republic of Kazakhstan

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated October 12, 2020 No. ҚР ДСМ-127/2020. Registered with the Ministry of Justice on October 14, 2020 No. 21431

Unofficial translation

In accordance with clause 4 of article 258 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and Health Care System", I HEREBY ORDER:

1. To approve the attached Rules for the formation and maintenance of the nomenclature of medical devices of the Republic of Kazakhstan.

2. To recognize as invalid the order Minister of Healthcare of the Republic of Kazakhstan dated May 16, 2019 No. ҚР ДСМ-78 "On approval of the Rules for the formation and maintenance of the nomenclature of medical devices of the Republic of Kazakhstan " (registered with the Register of State Registration of Regulatory Legal Acts as No. 18703, published on May 29, 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

3. Committee for Quality Control and Safety of Goods and Services of the Ministry of Healthcare of the Republic of Kazakhstan in accordance with the procedure, established by the legislation of the Republic of Kazakhstan, shall ensure:

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

2) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

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

4. Control over execution of this order shall be entrusted to the supervising Vice Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall come into force upon expiry of ten calendar days after the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Approved by the order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated October 12, 2020
No. ҚР ДСМ-127/2020

Rules for formation and maintenance of the nomenclature of medical devices of the Republic of Kazakhstan

Chapter 1. General Provisions

1. These Rules for formation and maintenance of the nomenclature of medical devices of the Republic of Kazakhstan (hereinafter referred to as the Rules) have been developed in accordance with clause 4 of article 258 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and Health Care System" (hereinafter referred to as the Code) and shall determine the procedure for formation and maintenance of the nomenclature of medical devices of the Republic of Kazakhstan.

2. In these Rules, the following basic concepts are used:

- 1) Agency for the Global Medical Device Nomenclature – organization, responsible for formation and maintenance of the Global Medical Device Nomenclature;
- 2) Global Medical Device Nomenclature, GMDN – systematized nomenclature classifier of types of medical devices used to identify medical devices;
- 3) classification attribute – the term used to describe the characteristics and characteristics of a type of medical device;
- 4) the nomenclature of medical devices of the Republic of Kazakhstan - a systematized nomenclature classifier of types of medical devices, harmonized with the Global Medical Device Nomenclature (GMDN) and used in the Republic of Kazakhstan;
- 5) type of medical devices – a group of medical devices with a similar purpose, similar application technologies, design features and a common digital designation in the nomenclature of medical devices of the Republic of Kazakhstan;
- 6) code of the type of a medical device – a system of digital symbols used to represent and (or) transmit data.

Chapter 2. Procedure for formation and maintenance of the Nomenclature

3. The nomenclature is formed and maintained by the state expert organization in the field of circulation of medicines and medical devices (hereinafter referred to as the state expert organization) in electronic form and posted on the official website of the state expert organization.

4. The nomenclature is formed on the basis of the Global Medical Device Nomenclature, GMDN, by decoding of a GMDN code to a Nomenclature code.

5. The nomenclature contains the list of medical devices with indication of names, codes and descriptions of the types of medical devices, as well as the list of classification attributes.

An example of recording the type of medical device, assigning the type of medical device to the classification criteria is presented in the appendix to these Rules.

6. Name, description of the type of medical devices, classification attributes of the Nomenclature conform with the name, description of the type of medical devices, classification attributes of the GMDN.

7. The state expert organization shall carry out:

1) the provision of translation to the Kazakh and Russian languages of names and descriptions of the types of medical devices, included to the GMDN;

2) the provision of translation to the Kazakh and Russian languages of names and descriptions of new types of medical devices, as well as information about amendments made to the names and descriptions of types of medical devices, included to the GMDN, received from the Agency of GMDN and making the corresponding amendments in the Nomenclature;

3) ensuring the exclusion of types from the Nomenclature, based on information received from the GMDN Agency on the exclusion of certain types of medical devices from the GMDN;

4) making entries in the State Register of Medicines and Medical Devices by types of medical devices Nomenclature by example in accordance with the appendix to these rules;

5) analysis and generalization of comments and suggestions from users of the Nomenclature on its structure and content.

8. The state expert organization, when carrying out the examination of medical devices, performed in accordance with the procedure prescribed by clause 4 of Article 23 of the Code, shall evaluate the declared Nomenclature code for compliance with the type of medical device

Appendix
to the Rules for formation and
maintenance of the nomenclature
of medical devices

Sample of a record of a type of medical device

Code	Name	Description
254333	Suture 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 attributes

Код	Classification attributes
1)	S u r g i c a l
2)	D e n t i s t r y
3)	O t o l a r y n g o l o g y
4)	G a s t r o e n t e r o l o g y
5)	U r o l o g y
6)	N e u r o l o g y
7)	Obstetrics and gynecology
8)	O p h t h a l m o l o g y
9)	O r t h o p e d i c s

254333	1 0)	P l a s t i c	s u r g e r y
	1 1)		C a r d i o l o g y
	1 2)		B l a d e s
	1 3)	M i l l s	a n d a c c e s s o r i e s
	1 4)	Equipment for the regeneration and processing of body tissues	
	1 5)		P l a s t i c
	1 6)		s u r g i c a l
	1 7)	T o o l s	f o r s t i c h i n g f a b r i c s
	1 8)		I n o r g a n i c m a t e r i a l s
	1 9)		M a n u a l
	2 0)		S t e r i l i z a b l e
	2 1)	S y n t h e t i c	p o l y m e r s
	2 2)		M e t a l s
	23)	Suture materials and accessories	