not
Registered with the Ministry of Justice of the Russian Federation dated July 9, 2012, No. 24852

**MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION**

**ORDER**
**dated June 6, 2012, No. 4n**

**ON APPROVAL OF THE MEDICAL PRODUCT NOMENCLATURE CLASSIFICATION**

Pursuant to Part 2, Article 38, Federal Law dated November 21, 2011, No. 323-FZ, *On Fundamentals of Public Health Protection in the Russian Federation* (Collection of Laws of the Russian Federation, 2011, No. 48, Article 6724), and the Decree of the Russian Federation President dated May 21, 2012, No. 636, *Concerning the Structure of Federal Executive Bodies* (The Rossiyskaya Gazeta, 2012, No. 114), I order:

To approve of:

Medical product nomenclature classification by types according to Appendix 1;

Medical product nomenclature classification by categories, depending on the potential risk of their application, according to Appendix 2.

Minister
V.I. SKVORTSOVA

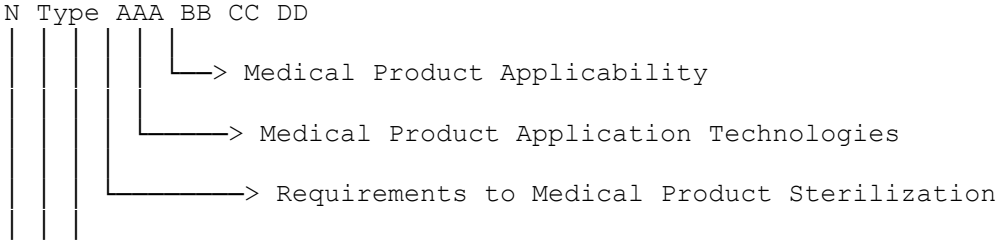
Appendix 1
to Order of the Ministry of Health of the Russian Federation
dated June 6, 2012, No. 4n

**MEDICAL PRODUCT NOMENCLATURE CLASSIFICATION BY TYPES**

The medical product nomenclature classification (hereinafter 'the Classification') by types contains the numerical designation (number) of the medical product type, the medical product type name as well as nine-digit numerical codes (AAA BB CC DD) used for defining the medical product types.

In classification, the first position is the numerical designation (six-digit number) of the medical product type (N), the second position, the medical product type name (Type), the third, three-digit numerical codes (AAA 00 00 00) by the Medical Product Purpose classification attribute (Table 1), the fourth position, two-digit numerical codes (000 BB 00 00) by the Requirements to Medical Product Sterilization classification attribute (Table 2), the fifth position, two-digit numerical codes (000 00 CC 00) by the Medical Product Application Technologies classification attribute (Table 3), the sixth position, two-digit numerical codes (000 00 00 GG) by the Medical Product Applicability classification attribute (Table 4).

The encoding algorithm applied for medical product classification by types is shown in the pattern below:



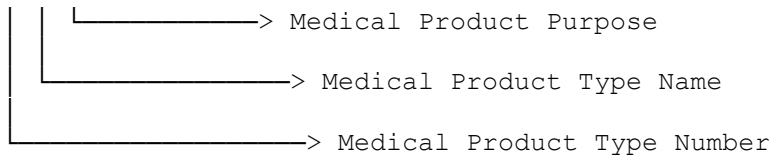



Table 1. Medical Product Purpose by Classification Attribute (AAA)

| s/r No. | Medical product purpose | Identifier |
|---|---|---|
| 1 | Disease prevention | 100 |
| 2 | Diagnosis of diseases, conditions and clinical situations | 200 |
| 3 | Cardiography | 201 |
| 4 | Encephalography | 202 |
| 5 | Radioscopy, radiography | 203 |
| 6 | Vasogrpahy | 204 |
| 7 | CT | 205 |
| 8 | Magnetic resonance imaging | 206 |
| 9 | Position emission tomography | 207 |
| 10 | Ultra-sound diagnosis | 208 |
| 11 | In-vitro diagnosis | 209 |
| 12 | Histo- and cyto-diagnosis | 210 |
| 13 | Genetic diagnosis | 211 |
| 14 | Endoscopy | 212 |
| 15 | Study of blood gases, external respiration parameters, composition of inhaled and exhaled air and gas exchange | 213 |
| 16 | Measurement of medical parameters and values | 214 |
| 17 | Self-testing | 215 |
| 18 | Human body state monitoring | 216 |
| 19 | Pathological studies | 217 |
| 20 | Forensic investigation | 218 |
| 21 | Treatment and medical recovery | 300 |
| 22 | Therapy | 301 |
| 23 | Physiotherapy | 302 |
| 24 | Radiotherapy | 303 |
| 25 | Anesthesia and resuscitation | 400 |
| 26 | Surgery | 500 |
| 27 | Abdominal surgery | 501 |
| 28 | Thoracic surgery | 502 |
| 29 | Brain surgery | 503 |
| 30 | Cardiovascular surgery | 504 |
| 31 | Organ and tissue transplantation | 505 |
| 32 | Combustiology | 506 |
| 33 | Maxillofacial surgery | 507 |
| 34 | Dental surgery | 508 |
| 35 | Plastic surgery | 509 |
| 36 | Restoration, replacement and modification of the anatomy or physiological functions of the body | 600 |
| 37 | Physical impairment or disability compensation | 700 |
| 38 | Pregnancy prevention and termination, conception control | 800 |
| 39 | Intrahospital equipment, including medical products not intended for application for diagnostic and treatment purposes or for medical studies and not directly affecting the clinical assessment of a patient’s condition, study findings or treatment progress | 900 |

Table 2. Requirements to Medical Product Sterilization by Classification Attribute (BB)

| s/r No. | Name | Identifier |
|---|---|---|
| 1 | Non-sterile disposable medical products | 01 |
| 2 | Sterile disposable medical products | 02 |
| 3 | Sterile reusable medical products sterilized in the first application and each subsequent application using the appropriate sterilization methods | 03 |
| 4 | Non-sterile reusable medical products | 04 |
| 5 | Medical product sterilizing equipment | 05 |

Table 3. Medical Product Application Technologies by Classification Attribute (BB)

| s/r No. | Name | Identifier |
|---|---|---|
| 1 | Non-active medical products that operate without a power source, except for the power generated by a human body or gravitation | 01 |
| 2 | Active medical products that operate from a power source, other than the power generated by a human body or gravitation | 02 |
| 3 | Non-active implanted medical products | 03 |
| 4 | Active implanted medical products | 04 |
| 5 | Biomedical products that include such materials as cellular technology and tissue engineering products, bioimplants, self-degrading polymers, tissue glues and surgical sutures | 05 |
| 6 | Surgical tools intended for surgical intervention (cutting, drilling, sawing, scratching, scraping, anchoring, separation, shearing, piercing) | 06 |
| 7 | Prosthetic and orthopaedic devices | 07 |
| 8 | Recovery devices for the disabled | 08 |

Table 4. Medical Product Medical Applicability by Classification Attribute (DD)

| s/r No. | Medical applicability | Identifier |
|---|---|---|
| 1 | Obstetrics and gynaecology | 01 |
| 2 | Allergology and immunology | 02 |
| 3 | Angiology | 03 |
| 4 | Balneology and water treatment | 04 |
| 5 | Gastroenterology | 05 |
| 6 | Haematology | 06 |
| 7 | Genetics | 07 |
| 8 | Hypurgia | 08 |
| 9 | Dermato-venereology | 09 |
| 10 | Desmurgy | 10 |
| 11 | Diabetology | 11 |
| 12 | Infectious diseases | 12 |
| 13 | Cardiology | 13 |
| 14 | Coloproctology | 14 |
| 15 | Exercise treatment and sports medicine | 15 |
| 16 | Narcology | 16 |
| 17 | Neurology | 17 |
| 18 | Neonatology | 18 |
| 19 | Renal medicine | 19 |
| 20 | Cancer medicine | 20 |

| | | |
|---|---|---|
| 21 | Otorhinolaryngology | 21 |
| 22 | Ophthalmology (including optics) | 22 |
| 23 | Pediatrics | 23 |
| 24 | Psychiatry | 24 |
| 25 | Pulmonology | 25 |
| 26 | Rheumatology | 27 |
| 27 | Dentistry | 28 |
| 28 | Audiology | 29 |
| 29 | Traumatic surgery and orthopedics | 30 |
| 30 | Transfusion medicine | 31 |
| 31 | Urology | 31 |
| 3 | Broad application | 32 |

Appendix 2
to Order of the Ministry of Health
of the Russian Federation
dated June 6, 2012, No. 4n

**MEDICAL PRODUCT NOMENCLATURE CLASSIFICATION BY CATEGORIES DEPENDING ON THE POTENTIAL RISK OF THEIR APPLICATION**

1. Medical products are divided into four categories in the medical product nomenclature classification by categories depending on their potential application risk (hereinafter 'the Medical Product Classification'). The categories are designated 1, 2a, 2b and 3.

I. Medical Product Classification (except for medical products for in vitro diagnosis)

2. In medical product classification, each medical product can be referred to one category only:
Category 1 – low-risk medical products
Category 2a – medium-risk medical products
Category 2b – high-risk medical products
Category 3 – very high risk medical products
3. When medical products are classified, their functional purpose and application conditions as well as the following criteria are taken into account:
Duration of medical product application
Invasiveness of medical product application
Exposure of the human body to the medical products or their relationships
Introduction of medical products into a human body (through body cavities or surgically);
Application of medical products for vital organs and systems (heart, the central circulation system, the central nervous system); and
Application of power sources.
4. The following provisions should be taken into account when classifying medical products by their potential risk:
4.1. Non-invasive medical products fall in category 1, unless any of the provisions set forth below is applicable, except for the provisions in Section 4.4.1.
4.2. Non-invasive medical products intended for handling or storage of blood, liquids or body tissues, liquids and gases for subsequent infusion, transfusion or injection into the body fall in category 2a.
4.3. Category 2b comprises non-invasive medical products intended for changing the biological or chemical composition of the blood, other body liquids or liquids intended for infusion into the body. However, when therapeutic intervention consists in filtration, centrifugation, gas exchange or heat exchange for modification of the biological or chemical composition of the blood, other body liquids or liquids intended for infusion into the body, medical products fall in category 2a.
4.4. Non-invasive medical products that touch upon injured skin:
4.4.1. fall in category 1, if they are used as mechanical obstruction or for compression;
4.4.2. fall in category 2b, if they are used for wounds curable via secondary healing only;
4.4.3. fall in category 2a, if they are used in all other cases (including medical products largely intended to influence wound micro-environment).
4.5. Invasive medical products (except for surgical invasive products), application of which is associated with human body cavities and which are not intended for connection to an active medical product:
4.5.1. fall in category 1, if these are short-term medical products (for continuous use for max. 60 minutes);
4.5.2. fall in category 2a, if these are temporary medical products (for continuous use for max. 30 days); however, where these medical products are temporarily applied in the oral cavity down to the throat, in the auditory passage up to the ear-drum or in the nasal cavity, they fall in category 1;

4.5.3. fall in category 2b, if these are long-term medical products (for continuous use for more than 30 days); however, where these medical products are applied for a long term in the oral cavity down to the throat, in the auditory passage up to the ear-drum or in the nasal cavity and cannot be re-absorbed by the mucous membrane, they fall in category 2a;

4.5.4. all invasive medical products (except for surgical invasive products) applied in connection with body cavities and intended for connection to an active medical product of category 2a and higher, fall in category 2a.

4.6. Surgical invasive medical products of short-term application fall in category 2a, if they are:

4.6.1. intended for diagnosis, observation, control or correction of defects in the heart, the central circulation system or the central nervous system in direct contact with organs or parts of these systems, they fall in category 3;

4.6.2. reusable surgical instruments, they fall in category 1;

4.6.3. intended for energy transfer as ionizing radiation, they fall in category 2b;

4.6.4. intended for causing biological effect and for re-absorption to the fullest or significant extent, fall in category 2b;

4.6.5. designed for drug injection via a dosage system using a potentially hazardous injection method, they fall in category 2b.

4.7. Surgical invasive medical products for temporary application fall in category 2a; however, if they are:

4.7.1. intended for diagnosis, observation, control or correction of defects in the heart, the central circulation system or the central nervous system in direct contact with organs or parts of these systems, they fall in category 3;

4.7.2. in direct contact with the central nervous system, they fall in category 3;

4.7.3. intended for energy transfer as ionizing radiation, they fall in category 2b;

4.7.4. intended for causing biological effect and for re-absorption to the fullest or significant extent, fall in category 3;

4.7.5. subject to chemical changes in the body or inject drugs, they fall in category 2b (except for medical products implanted in teeth).

4.8. Implanted medical products as well as surgical invasive medical products of long-term application fall in category 2b, if they are:

4.8.1. intended for implantation in teeth, they fall in category 2a;

4.8.2. in direct contact with the heart, the central circulation system or the central nervous system, they fall in category 3;

4.8.3. intended for causing biological effect and for re-absorption to the fullest or significant extent, fall in category 3;

4.8.4. subject to chemical changes in the body or inject drugs into a patient’s body, they fall in category 3 (except for the medical products implanted in teeth).

4.9. Active therapeutic medical products:

4.9.1. active medical products intended for energy transfer or exchange fall in category 2a. However, if energy transfer to, or exchange with, a human body poses potential hazard due to some particular features of the medical products, taking into account their impact on body parts, to which the energy is applied (including active medical products intended for creating ionizing irradiation or X-ray therapy), they fall in category 2b;

4.9.2. active medical products intended for control of active therapeutic medical products of category 2b fall in category 2b.

4.10. Active diagnostic medical products fall in category 2a, if they are intended for:

4.10.1. transferring the energy absorbed by the human body; however, if the medical product is designed for illuminating a patient’s body in the visible light spectrum, they fall in category 1;

4.10.2. distributing radiopharmaceuticals introduced into a patient’s body;

4.10.3. direct diagnosis or control of vital body functions; however, if they are intended for control of vital physiological parameters, changes in which could pose immediate danger to a patient (e.g. change in the heart function, respiration or the central nervous system activity), they fall in category 2b;

4.10.4. control of active diagnostic medical products of category 2b, they fall in category 2b.

4.11. Active medical products intended for introduction/ clearance of drugs, physiological liquids

or other substances to/from the human body, fall in category 2a. However, if the introduction/clearance method poses a potential hazard, taking into account the type of the respective substances, the body part and the application method, they fall in category 2b.

4.12. Other active medical products fall in category 1.

4.13. The medical products that contain a substance representing a drug or another biologically active substance and influencing the human body together with the medical product fall in category 3.

4.14. Medical products intended for conception control or for STD prevention fall in category 2b; however, if they are implantable or invasive medical products for long-term application, they fall in category 3.

4.15. Medical products intended for disinfection of medical products fall in category 2a; however, if they are intended for contact lens clearing, washing and disinfection, they fall in category 2b.

4.16. Non-active medical products used for obtaining diagnostic X-ray images fall in category 2a.

4.17. Medical products produced with animal skin necrosis or derivative issues fall in category 3; however, if they are intended for contact with uninjured skin only, they fall in category 1.

4.18. Containers for blood, blood preparations and substitutes fall in category 2b.

5. If a medical product is intended for use in combination with other medical products, the categories shall be established for each medical product.

6. If different provisions can be applied to a medical product during classification, the provisions that lead to establishing of the medical product category corresponding to the highest potential risk shall apply.

7. For special software that is an independent product and is used with a medical product the category will be the same as for the medical product.

## II. Medical Product Classification for In Vitro Diagnosis

8. When classifying medical products for in vitro diagnosis (hereinafter 'the Medical Products'), each medical product may only be included into one category:

Category 1 – medical products with low individual risk and low public health risk

Category 2a – medical products with moderate individual risk and/or low public health risk

Category 2b – medical products with high individual risk and/or moderate public health risk

Category 3 – medical products with high individual risk and/or high public health risk.

9. When medical products are categorized by their potential application risk, the following provisions should be taken into account:

9.1. Medical products intended to detect infectious agents in blood, blood components, blood derivatives, cells, tissues or organs to estimate the possibility of their transfusion or transplantation, medical products intended for detecting the infectious agents that may cause life-threatening diseases that are highly contagious and provide the decisive information for establishing the correct diagnosis fall in category 3.

9.2. Medical products used for determining blood groups or tissue types in order to guarantee immunological compatibility of the blood, blood components, cells, tissues or organs, intended for transfusion or transplantation fall in category 2b, except for the ABO system, rhesus system (C, c, D, E, e), Kell system, Kidd system and Duffy system, fall in category 3.

9.3. Medical products fall in category 2b, if they are intended for:

9.3.1. detecting STD infectious agents;

Detection of moderately contagious infectious agents in the spinal fluid or blood, which provide decisive information for establishing a correct diagnosis;

9.3.2. detecting infectious agents when there is a significant risk of erroneous result leading to death or disability of the patient or the fetus;

9.3.3. screening pregnant women to determine their immune status to infections;

9.3.4. determining the infectious disease status or the immune status, if there is a risk of erroneous result leading to a therapeutic solution posing inevitable threat to the patient's life;

9.3.5. screening to select patients for selective treatment or for diagnosis (e.g. cancer diagnosis);

9.3.6. genetic testing, when a test result leads to significant intervention in a human life;

9.3.7. control of drug, substance or biological component levels, when there is a risk of erroneous

result leading to a therapeutic solution that causes a life-threatening situation for a patient;

9.3.8. treatment of patients suffering from a life-threatening infectious disease;

9.3.9. screening of congenital fetal diseases.

9.4. Medical products intended for sample study and self-control fall in category 2b, except for those medical products, analysis of which does not have the critical medical status or is preliminary or necessitates comparison with the respective laboratory tests, fall in category 2a.

9.5. Medical products without any measurement function, that can be applied for general laboratory purposes due to their properties but have special features that allow the manufacturer to recommend them for use for in vitro diagnosis (without indicating any specific types of laboratory tests /analytes), fall in category 1.

9.6. The medical products not covered in Sections 9.1 to 9.5 fall in category 2a, including:

9.6.1. medical products with a measurement function (analyzers) with a variable set of performed laboratory tests, which depends on the applied sets of reagents (test systems). The interdependence of the analyzer and the reagents in use does not normally allow estimating the analyzer separately but this does not change its category 2a classification;

9.6.2. medical products, in application of which therapeutic decision should be made after subsequent studies;

9.6.3. medical products used for cancer monitoring and treatment.

10. Where a medical product is intended for use in combination with other medical products, the categories are established for each medical product.

11. Calibration and control materials with quantitatively and qualitatively preset values fall in the same category as the medical products they are intended to control.

12. For special software that is an independent product and is used with a medical product the category will be the same as for the medical product.