MINISTRY OF HEALTH OF UKRAINE

State enterprise “Ukrainian Medical Center of Certification”

Procedure for State Registration of Medical Equipment and Medical Devices

Kyiv

21.05.2012

Documents that Regulate Registration and Use of Medical Devices in Ukraine:

- "Procedure for the State Registration of Medical Equipment and Medical Devices" approved by the decision of the Cabinet of Ministers of Ukraine as of November 9, 2004 No. 1497.
- National Standard of Ukraine "Medical Devices. Development and Production. Terms. State Standard of Ukraine 3627:2005" refers to national devices.
- National Standard of Ukraine "Medical Devices. Classification Based on Potential Risk of Application. General Requirements. State Standard of Ukraine 4388:2005."
- National Standard of Ukraine "Graphic Symbols for Medical Devices Marking (EN 980:2003, IDT) State Standard of Ukraine EN 980:2007."
- Law of Ukraine "On General Safety of Non-Food."
- Technical Regulations for Medical Devices, Active Implantable Medical Devices, Medical Devices for in vitro Diagnostics.

- **“Procedure of the State Registration of Medical Equipment and Medical Devices”** approved by the decision of the Cabinet of Ministers of Ukraine as of November 9, 2004 No. 1497 and defines the mechanism of the state registration of medical equipment and medical devices (hereinafter referred to as the Medical Devices).

- Ukrainian and imported medical devices on the list that is determined by the State Service for Drugs and Medical Devices (hereinafter referred to as the Service) are subject to the State registration.

- Import into the customs territory, sale and use of medical devices in Ukraine is allowed only after their state registration, except the instances specified by the Ministry of Health of Ukraine in the established order.

2. **Procedure defines definition of the terms:**

- medical devices
- component parts
- medical devices modification
- registration materials
- harm
- medical devices safety
- danger
- medical devices risk of use
- applicant
- expert institution
- medical devices examination
- test
- medical devices classification
- advisory body

3. The state registration of medical devices shall be done by the State Administration of Ukraine on Medical Products on the basis of examination and if necessary test conducted by expert institutions.

4. The state registration of medical devices shall be done on the basis of the application and respective documents submitted to the State Administration of Ukraine on Medical Products by the applicant who is responsible for production, safety, quality, and effectiveness of medical devices.

The application should contain the following information:

- ***name of medical devices*** *(in Ukrainian and English), number according to the catalogue;*

- ***name of an applicant*** *(applicant's country of registration, address, telephone, fax, email).* ***If an applicant is not a producer,*** a document should be submitted together with an application confirming his right for the state registration on behalf of the producer stating name of a recipient of the certificate of state registration and its owner;

- ***name of the producer*** *(producer's country of registration, address, telephone, fax, email)*;

- ***safety class of medical devices*** depending on the degree of a potential risk of use;

- ***code under UC FEAG (the Ukrainian classification of foreign economic activity goods)***

5. The following documents should be submitted together with the application:

1) Medical devices usage guide (instruction);
2) Certificate of origin of medical devices;
3) Certificate of compliance of medical devices with quality and safety requirements for human health;
4) Copies of legal documents, information on standards, regulatory database on the basis of which medical devices are produced;
5) Materials to determine safety class of medical devices depending on the degree of a potential risk of use as well as materials of their preclinical and clinical studies and/or testing;
6) Catalogue of medical devices;
7) Report on the results of the state metrological certification for measuring instruments;
8) Label or labeling sample of medical devices;
9) Copy of a document about the applicant's registration;
10) Confirmation of payment of a registration fee.

All the documents (originals and copies certified by a notary or an authority which issued the original document) shall be translated into Ukrainian. Three copies of all the documents (copies certified by an applicant) shall be submitted to the expert institutions.

Applicant bears the responsibility for accuracy of the information presented in the materials.

6. The Service considers the submitted documents in the established by the Ministry of Health of Ukraine order, within the period of not more than 90 days.

The Service involves expert institutions to conduct necessary examination and tests of medical devices and issues appropriate directions to the applicant.

The applicant chooses expert institutions with regard to their profile and the list, approved by the Service.

7. Expert institution enters the results of the examination into the protocol (record, conclusion), that is sent to the Service or given to the applicant.

8. In the course of examination, in order to obtain additional data on the safety, quality and effectiveness of a medical device, expert institution, if necessary, may require that the applicant submit additional documents.

9. On the basis of the report of expert institutions the Service assigns test of the medical device.

10. The scope and content of examination (test) depend on the degree of potential risk of use of medical devices in medical practice.

- Four safety classes are established: I, IIa, IIb and III.
- Safety class of medical devices is declared by the applicant (based on producer's documents) and confirmed by the results of technical examination.

11. Based on the examination (test) results and the recommendations of the advisory body of the state registration the Service decides on the registration of medical devices or refuse registration.

- Decision on the refusal of state registration is made provided the safety, quality and effectiveness of the device are not confirmed.

- The Service informs the applicant in written form on such decision in the period of 10 days.

14. **Re-registration of medical devices is carried out in the following cases:**

- Expiry of the certificate;
- Change of the name and address of the owner (producer, developer);
- Transfer of the right to manufacture medical devices to another producer;
- Changes in the description of medical devices;
- Use of new materials that contact with the human body in the process of medical devices production.
- Changes in medical devices usage guide (instruction);
- Changes in the legal document regarding medical devices;
- Identification of contraindications and limitations of use of medical devices;

15. Application for re-registration of medical devices is submitted to the Service in the period no earlier than 120 and no later that 90 calendar days before certificate expiry.

16. Re-registration of medical devices is carried out in the established order for state registration.

19. The Service based on the recommendations of advisory body may decide to **cancel state registration or terminate certificate for a specified period** in case of receiving the following information:

- previously unknown adverse properties of medical devices, found in the process of production and/or use;
- inconsistencies in marking;
- threat for human health or life;
- absence or lack of quality and effectiveness compared to previously declared.

As a result: prohibition (temporary prohibition) of the use of medical devices, about which the Service makes a special mark in the Register and informs the applicant in written form in the period of ten days.

After elimination of identified negative properties of medical devices the Service, based on the recommendations of advisory body may decide on the renewal of certificate.

20. The decision to cancel state registration or terminating of the certificate may be appealed by the applicant in the established by the legislation order.

21. **During the term of certificate applicant is responsible for:**

- quality and safety of the registered medical devices,
- timely notification on any changes to the registration documents for this period,
- providing comprehensive information of the reason of such changes and their impact on safety, quality and effectiveness of the device.

Requirement for Medical Devices Marking

National Standard of Ukraine EN 980:2007 “Graphic symbols for Medical Devices Marking (EN 980:2003, IDT)“

Law of Ukraine “On General Safety of Non-Food” as of January 2, 2010. Article 8 of the Law says:

“Producers are required: 1) to indicate on the product or its package name and address of the producer"

Sample of medical device marking
Surgical latex gloves

Powdered sterile surgical latex gloves (size 7.5)

Date of production
xx. xx. 2011

Date of expiry
xx.xx.2013

Upper limit storage temperature 30 C
www.vogt-medical.com

CE
0123

Vogt GmbH
Bauerstr, 9, Haus C, 76137, Karlsruhe, Germany
Tel.:+497721313647. e-mail: vm@vogt.com
изготовитель:
TG Medical SDN. BHD
Lot 5040, Batu 18, Off Jalan Meru, 50050 Klang, Jalan Teratai., Malaysia

CP	**xxxx/2012**
xx.xx.2012	

THANK YOU FOR ATTENTION!

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CHANGES
IN THE ORDER OF CIRCULATION OF MEDICAL PRODUCTS ON THE MARKET

PROCEDURE OF THE CONFIRMATION OF CORRESPONDENCE IN THE AREA REGULATED BY LAW.

- Law of Ukraine "**On confirmation of correspondence**" (2001):
- **Article 9.** Confirmation of correspondence in the area regulated by law
- The procedure of the confirmation of correspondence in the area, regulated by law for specific products that could be dangerous for life and health of the human, animals, plants, as well as for property and the environmental security, is introduced by technical regulations.

  With the introduction of technical regulations, the central executive body officially publishes the List of national standards. The voluntary application of these standards may be considered as a proof of the production correspondence to requirements of technical regulations. Manufacturer or supplier has also the right to confirm the production correspondence to requirements of technical regulations by other ways than the correspondence to standards, provided be these regulations.

Certification in the area regulated by Law

- **Article 11. Certification in the area regulated by Law is implemented in accordance with technical regulations.**
- **According to results of the certification implementation in case of positive decision of the appointed body on the assessment of correspondence, the applicant receives a certificate of correspondence. The sample of that certificate is approved by the central executive body on correspondence assessment issues**

OBLIGATIONS OF PRODUCERS AND SUPPLIERS OF THE PRODUCTION THAT IS SUBJECT TO CONFIRMATION OF CORRESPONDENCE IN THE AREA REGULATED BY LAW

- **Article 13**. Manufacturer is obliged: to assist to all confirmation assessment procedures set for specific production; to put on production the national mark of correspondance in the area regulated by Law;

  To give the information about certification to the provider by means of indicating registration numbers of certificates of correspondence in documents, according to which the appropriate production is transferred;

  To give information about the declaration of correspondence to the provider if this is established by technical regulations for the appropriate production type, by specifying the registration numbers of declaration of correspondence in the documents according to which the appropriate production is transferred;

MARK OF CORRESPONDENCE

TECHNICAL REGULATIONS

- Technical regulations for medical products are approved by the Cabinet of Ministers of Ukraine on June 11, 2008, № 536

Procedure of medical products circulation on market

- Registration - according to "Procedure for state registration of medical equipment and products of medical destination" approved by the Cabinet of Ministers of Ukraine on 09.11.2004, № 1497 (for the date of 12.04.2011) *Certificate of state registration*
- Certification - according to appropriate technical regulations. *Certificate of correspondence*. Simultaneously the certification according the Order of ”Derzhspozhyvstandard” (State Inspectorate of Ukraine on Consumer Protection) № 28 is canceled
- Declaration of Correspondence according to appropriate technical regulations

Declaration of correspondence

- **National standard of Ukraine ISO/IEC 17050-1:2006**.

Assessment of correspondence. Declaration of the provider about the correspondence. Part 1. General requirements (ISO / IEC 17050-1:2004, IDT)

National standard of Ukraine ISO/IEC 17050-2:2006

Declaration of the provider about the correspondence. Part 2. Supporting documentation (ISO/IEC 17050-2:2004, IDT)

Purpose of correspondence declaration

- The purpose of the manufacturer's declaration is confirmation that the appropriate product meets the requirements that are referred in the declaration, with a clear indication of the person responsible for this correspondence and declaration
- Declaration of Correspondence can be used separately or jointly with another correspondence assessment procedure for technical regulations or for other purposes

General requirements

- Organization, that issues the declaration of correspondence, is responsible for issuing, updating, distribution, renewal, action suspension or abrogation for the declaration of correspondence of the object to specified requirements

- Declaration of Correspondence shall be based on results of specific activity according to the assessment of correspondence (for example on tests, measurement, auditing, control or surveillance) made by one or more parties: by the first, the second or the third. Correspondence assessment bodies, involved in these activities, where possible, should refer to relevant international standards, guidelines and other regulations documents

- Declaration of correspondence adopted for a group of homogeneous production, shall apply to each specific unit of the group. Declaration of correspondence adopted for production similar to already provided production for any past period of time, shall cover each unit, which is provided again.

Contents of Declaration of correspondence

Party that issued a declaration of correspondence, shall guarantee that the declaration contains sufficient information for the purpose that the recipient of Declaration of Correspondence could identify the provider that received the declaration, the object of declaration, standards or other specified requirements, according to which the declaration of correspondence is adopted , as well as the person who signed the declaration on behalf and on the order of the organization that issues a declaration of correspondence.

Declaration of correspondence shall contain at least the following:

a) unique identification of the declaration of correspondence;
b) name and contact address of the party that adopted the declaration of correspondence;
c) designation of the object of the correspondence declaration (e.g., name, type, date of production or production model number, description of process, management system, person or body and / or other additional information related to the case);
d) statement of correspondence;

- e) full and clear list of standards and other specified requirements, and chosen variants, if any;
f) date and place of Declaration of correspondence issue ;
g) the signature (or equivalent proof of confirmation), name and post of authorized person(s) acting on behalf of the applicant;
h) any restrictions on the legal force of Declaration of correspondence.

Additional information

Correlation of Declaration of Correspondence to the results of assessment of correspondence, on which the present declaration is based, for example:

a) name and address of the body for assessment of correspondence (e.g., testing laboratory, supervisory body, certification body);
b) references to the reports on correspondence assessment and date of reports;
c) references to any used management system ;

- d) references to the documents on the accreditation of bodies for correspondence assessment, if their area of accreditation refers to the Declaration of correspondence;
e) a reference to the availability of appropriate supporting documentation;
f) additional information concerning these received certificates, certificates of registration or marks;
- g) other activities or programs of the body for assessment of correspondence (e.g., group membership agreement)

Example of declaration of correspondence

№ _____

Name of the applicant: _____

Address of the applicant: _____

Object of declaration: _____

Object of declaration, described above, that meets the requirements of the following documents:

documents № name, issue, date of issue

- Additional information:
- Signed on behalf and on the order of:

(Place and date of issue)

(Name, post)

(Signature or equivalent of the signature of the person authorized by the applicant)

Classes of potential risk of application

Medical products according to a potential risk of application are divided into classes: I, IIa, IIb and III. Attribution of medical products to a particular class is based on the vulnerability of the human body, taking into account potential risks associated with the development and manufacture of these products

- State Standard of Ukraine (DSTU) 4388:2005 "Medical products. Classification based on potential risk of application. General requirements"
- It is assumed that any potential risks that may be associated with the application of medical products, are acceptable if compared to the useful effect for the patient and if combined with a high level of protection of life and health.

Procedures of confirmation of correspondence

- For the class of potential risk - a producer (his representative in Ukraine) is preparing documentation that confirms the correspondence of production technical requirements, issues declaration of correspondence, applying the mark of correspondence
- For other risk classes - producer (his representative in Ukraine) is preparing documentation that confirms the correspondence of production to technical requirements, receives confirmation (certificates) of the correspondence of the quality management system according to the requirements of State Standards of Ukraine (DSTU) ISO13485, products - technical requirements, issues the declaration of correspondence (with reference to the certificates), applying the mark of correspondence with the code of the body

Register of appointed bodies for assessment of correspondence(on the date of 01.05.2012)

UA.TR. 001	State enterprise “Ukrmetrteststandard" Of the State Inspectorate of Ukraine on Consumer Protection (Derjspozhivstandart of Ukraine) 03680, Kyiv, 4, Metrologitchna str.	09.12.2010 Order of the State Inspectorate of Ukraine on Consumer Protection (Derjspozhivstandart of Ukraine) № 559
UA.TR. 002	State enterprise “Charkivstandardmetrology” Of the State Inspectorate of Ukraine on Consumer Protection (Derjspozhivstandart of Ukraine) 61002, Harkiv, 36, Mironositska str.	10.07.2009 Order of the State Inspectorate of Ukraine on Consumer Protection (Derjspozhivstandart of Ukraine) № 244
UA.TR. 039	State enterprise “Ukrainian medical centre for certification" Ministry of Health of Ukraine 02160, Kyiv, 18, Tchigorina str.	08.12.2010 Order of the State Inspectorate of Ukraine on Consumer Protection (Derjspozhivstandart of Ukraine) № 550
UA.TR. 067	State enterprise “State medical centre for certification" Ministry of Health of Ukraine 02660, Kyiv, 2a, Tchervonogvardiysky bystreet	16.02.2012 Order of the Ministry for economical development and Trade of Ukraine № 209

List of bodies on certification of management systems accredited for the correspondence to requirements of ISO / IEC 17021:2006

Body on quality systems certification State Enterprise “Ukrainian medical center for certification" Ministry of Health of Ukraine	02042, 02160, Kyiv, 18, Tchigorina str.	(044) 285-83-83, 490-27-41	8O018	12.04.2010-11.04.2013
Body on certification State Enterprise “State medical center on certification" Ministry of Health of Ukraine	02660, Kyiv, 2a, Tchervonogvardiysky bystreet	(044) 296-70-45, 296-10-11	8O044	02.06.2011-01.06.2014

Market surveillance

- Products that have passed all authorization procedures and are on the market, are subject to market surveillance according to the Laws:
- “On state market surveillance and control of non-food production" and “On common security of non-food production"
- By the Cabinet of Ministers of Ukraine Decree from 01.06.2011 № 573 "On approving the list of state market survey and areas of their responsibility“, State Service of Ukraine for drugs is determined as the body of state of market surveillance in the area of responsibility for medical products

Thank’s for your attention!

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