Translation of the document

Original text in Ukrainian: http://zakon2.rada.gov.ua/laws/show/753-2013-%D0%BF

CABINET OF MINISTERS OF UKRAINE
RESOLUTION
No. 753 of 2 October 2013
Kyiv
On Approval of the Technical Regulation on Medical Devices

{As amended by the CMU Resolutions
No. 181 of 27 May 2014
No. 215 of 1 July 2014}

In accordance with Article 14 of the Law of Ukraine 'On standards, technical regulations and conformity assessment procedures', the Cabinet of Minister of Ukraine has decided as follows:

1. The Technical Regulation on Medical Devices and the action plan for its application attached hereto are hereby approved.

2. The State Administration of Ukraine on Medicinal Products shall ensure application of the Technical Regulation approved by this Resolution.

2^1. The Technical Regulation approved by this Resolution shall not apply to the medical devices that have been registered with the state, entered into the State Register of Medical Equipment and Medical Devices and approved for use within the territory of Ukraine and for placing on the market and/or putting into service without undergoing conformity assessment procedures and being marked with the national conformity mark:

until 1 July 2016 – for medical devices whose state registration certificate has no expiry date or expires after 1 July 2016;

until the end of the validity period of the state registration certificate – for medical devices whose state registration certificate expires before 1 July 2016;

These medical devices are allowed for sale and use within the territory of Ukraine until the end of their lifetime, without undergoing a conformity assessment procedure and being marked with the national conformity mark.

{The Resolution is amended by adding clause 2^1 in accordance with Resolution No. 181 of the CMU of 27 May 2014; the amendment comes into force on 1 July 2015}

3. The Resolutions of the Cabinet of Ministers of Ukraine in the list attached hereto are hereby revoked.

4. This Resolution shall enter into force in six months from the date of publication, excluding points 1, 3 to 6, 8, 9 and 11 of the list of the revoked Resolutions of the Cabinet of Ministers of Ukraine, as approved by this Resolution, which shall come into force on 1 July 2015.

{Clause 4 as amended by Resolution No. 215 of the CMU of 1 July 2014}

Prime Minister of Ukraine **M. AZAROV**

ID 70

APPROVED
by Resolution No. 753 of the Cabinet of Ministers of Ukraine
of 2 October 2013

TECHNICAL REGULATION
on Medical Devices

{Regarding coming into force of the Technical Regulation and amendments thereto refer to Section III of Law 3164-IV of 1 December 2005}

General

1. This Technical Regulation shall apply to medical devices and their accessories (hereinafter referred to as 'medical devices'). For the purposes of this Technical Regulation, accessories shall be treated as medical devices.
This Technical Regulation has been developed on the basis of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
2. For this Technical Regulation, the following definitions shall apply:
1) 'putting into service' means the stage at which a device has been made available to the final user and/or consumer as being ready for use for the first time for its intended purpose;
2) 'placing on the market' means the first making available of a device other than a device intended for clinical investigation or performance evaluation, with a view to distribution and/or use on the Ukrainian market, regardless of whether it is new or fully refurbished;
3) 'custom-made device' means any device specifically made in accordance with a written prescription of a medical practitioner or a duly qualified person, which gives specific design characteristics of such device intended for the sole use of a particular consumer.
Mass-produced devices that are adapted to meet the individual requirements of a medical practitioner or any other professional user shall not be considered to be custom-made devices;
4) 'manufacturer' means the legal person or the sole proprietor responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or by a third party authorised to act on his behalf.
The obligations of the manufacturers also apply to the legal persons or sole proprietors who assemble, package, fully refurbish and/or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market under their own name, excluding the persons who assemble or adapt devices already on the market to the requirements of an individual consumer;
5) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with its intended use;
6) 'generic device group' means a set of devices having the same or similar intended uses or commonality of technology;
7) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling and/or in the instructions for use;
8) 'clinical data' means the data pertaining to the safety and/or performance of a device when used as intended. The sources of clinical data include:
clinical investigation(s) of the device concerned;
clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated;
published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;

9) 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination (including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for the proper functioning of the medical device), intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, of diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement, modification or support of the anatomy or of a physiological process, for control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

10) 'device intended for clinical investigation' means any device (with the exception of *in vitro* diagnostic devices) intended for use by a duly qualified medical practitioner when conducting clinical investigations;

11) 'single use device' means a device intended to be used once only for a single patient.

12) 'device subcategory' means a set of devices having common areas of intended use or common technology;

13) 'authorised representative' means any legal person or sole proprietor who is a resident in Ukraine or is registered in accordance with Ukrainian legislation, or a representative office of a foreign business entity, that is duly authorised by the manufacturer to act on his behalf with regard to the obligations of the manufacturer under this Technical Regulation;

For the purpose of this Technical Regulation, 'national standards' shall have the meaning defined in the Law of Ukraine 'On standardisation'; 'declaration of conformity', 'supplier' shall have the meanings defined in the Law of Ukraine 'On verification of conformity'; 'conformity assessment body', 'risk', 'technical regulations' shall have the meanings defined in the Law of Ukraine 'On standards, technical regulations, and conformity assessment procedures'; and 'medicinal products' shall have the meaning defined in the Law of Ukraine 'On medicines'.

3. Where a device is intended to administer a medicinal product to a human body, that device shall be governed by this Technical Regulation.

If such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by the Law of Ukraine 'On medicines'. The requirements for medical devices set out in Annex 1 hereto shall apply only to the safety and performance-related device characteristics.

4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and whose action on the human body is ancillary to that of the device, that device shall be assessed for conformity and placed on the market in accordance with this Technical Regulation.

Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma and whose action on the human body is ancillary to that of the device, that device shall be assessed for conformity and placed on the market as a medical device in accordance with this Technical Regulation.

5. This Technical Regulation shall not apply to:

1) *in vitro* diagnostic medical devices;

2) active implantable medical devices;

3) medicinal products covered by the Law of Ukraine 'On medicines'. In deciding whether a product is a medicinal product or a medical device, the main criterion is the principal mode of action of the product;

4) cosmetic products;

5) human blood, products derived from blood, plasma or blood cells of human origin, devices that incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of devices referred to in the second paragraph of clause 4 of this Technical Regulation;

6) anatomical materials of human origin and medical devices incorporating or derived from anatomical materials of human origin, with the exception of devices referred to in the second paragraph of clause 4 of this Technical Regulation;

7) anatomical materials of animal origin, unless a device is manufactured utilizing non-viable animal tissues or products derived from non-viable animal tissues.

6. Where a device is intended by the manufacturer to be used as a personal protective equipment, that medical device must also meet the relevant occupational safety and health requirements laid down in the Technical Regulation on Personal Protective Equipment, as approved by Resolution No. 761 of the Cabinets of Ministers of Ukraine of 27 August 2008 (*Ofitsiinyi Visnyk Ukraiiny* [Official Gazette of Ukraine] 2008, No. 66, Art. 2216).

7. The Technical Regulation on Electromagnetic Compatibility of Equipment, as approved by Resolution No. 785 of the Cabinets of Ministers of Ukraine of 29 July 2009 (*Ofitsiinyi Visnyk Ukraiiny,* 2009, No. 58, Art. 2028), shall not apply to devices governed by this Technical Regulation.

8. This Technical Regulation shall not affect the application of the Technical Regulation on Sealed Sources of Ionizing Radiation, as approved by Resolution No. 1382 of the Cabinets of Ministers of Ukraine of 5 December 2007 (*Ofitsiinyi Visnyk Ukraiiny,* 2007, No. 93, Art. 3408).

Placing on the market and putting into service

9. Medical devices may be placed on the market and/or put into service only if they fully comply with the requirements laid down in this Technical Regulation when duly supplied and properly installed, maintained and used in accordance with their intended purpose.

Medical devices that conform to the national standards included in the list of national standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of compliance with the requirements of this Technical Regulation shall be presumed to conform to the requirements of this Technical Regulation.

The national standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of the conformity of devices with the requirements of this Technical Regulation include monographs of the State Pharmacopoeia of Ukraine, in particular those on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products.

10. The equipment which is shown at trade fairs, exhibitions, demonstrations, or demonstrated in any other way, and does not conform to this Technical Regulation must be accompanied by a visible sign indicating that such equipment cannot be placed on the market or put into service until it is has been brought into compliance with this Technical Regulation. Demonstration of performance of such equipment is allowed only if the adequate actions have been taken to prevent electromagnetic interference.

Requirements for medical devices

11. The devices must meet the requirements set out in Annex 1 which apply to them, taking account of the intended purpose of the devices concerned.

12. The devices that are also machinery within the meaning of the Technical Regulation on Safety of Machinery, as approved by Resolution No. 62 of the Cabinet of Ministers of Ukraine of 30 January 2013 (*Ofitsiinyi Visnyk Ukraiiny*, 2013, No. 9, Art. 344), must meet the essential health and safety requirements set out in Annex 1 to the Technical Regulation on Safety of Machinery to the extent to which those requirements are more specific than the requirements set out in Annex 1 to this Technical Regulation.

Language of the information provided to the user or consumer

13. Information that shall be provided to the user/consumer in accordance with the section 'Information supplied by the manufacturer' of Annex 1 must be in conformity with the Law of Ukraine 'On principles of the state language policy'.

Classification

14. Medical devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with the criteria set out in Annex 2.

Conformity assessment procedures

15. In order to affix the national conformity mark to medical devices falling within Class III (other than custom-made devices or those intended for clinical investigations), the manufacturer shall follow the procedure set out in Annex 3,

or the procedure set out in Annex 4, coupled with either the procedure set out in Annex 5 or the procedure set out in Annex 6.

16. In order to affix the national conformity mark to medical devices falling within Class IIa (other than custom-made devices or those intended for clinical investigations), the manufacturer shall follow the procedure set out in Annex 8, coupled with the procedure set out in Annex 5, or with the procedure set out in Annex 6, or with the procedure set out in Annex 7.

Instead of applying the above procedures, the manufacturer may also follow the procedure referred to in Annex 3 (in which case the section 'Examination of the design of the device' of Annex 3 is not applicable).

17. In order to affix the national conformity mark to medical devices falling within Class IIb (other than custom-made devices or those intended for clinical investigations), the manufacturer shall follow the procedure set out in Annex 3 (in which case the section 'Examination of the design of the device' of Annex 3 is not applicable), or the procedure set out in Annex 4, coupled with the procedure set out in Annex 5, or with the procedure set out in Annex 6, or with the procedure set out in Annex 7.

18. In order to affix the national conformity mark to medical devices falling within Class I (other than custom-made devices or those intended for clinical investigations), the manufacturer shall follow the procedure set out in Annex 8 and draw up the declaration of conformity required for placing the device on the market.

19. Before placing a custom-made device on the market, the manufacturer shall perform the procedure set out in Annex 9 and submit the statement set out in Annex 9.

20. During the conformity assessment procedure, the manufacturer and the conformity assessment body (if involved) shall take account of the results of any assessments and verifications that have been carried out in accordance with this Technical Regulation before, during and after the manufacture.

21. The manufacturer may instruct his authorised representative to initiate the procedures provided for in Annexes 4, 5, 8 and 9.

22. Where the conformity assessment procedure involves a conformity assessment body, the manufacturer or his authorised representative may apply to such body of their choice within the framework of the tasks for which the body has been designated.

23. The conformity assessment body may require (where duly justified) the manufacturer or his authorised representative to provide any information or data necessary for establishing or verifying the conformity with this Technical Regulation in view of the chosen conformity assessment procedure.

24. Decisions taken by the conformity assessment bodies in accordance with Annexes 3, 4, 6 and 7 shall be valid for five years. They may be extended for a further period of five years upon application submitted at a time agreed in the contract signed by both parties.

25. The records and correspondence relating to the procedures referred to in clauses 15 to 19 of this Technical Regulation shall be maintained in line with the Law of Ukraine 'On principles of the state language policy'.

26. For individual devices that do not conform to clauses 15 to 19 of this Technical Regulation but the use of which is in the interest of protection of health and life of a specific person, the procedures for placing on the market and putting into service shall be established by the MOH.

Particular procedure for systems and procedure packs and procedure for sterilization

27. This section shall apply to the systems of medical devices (hereinafter referred to as 'systems') and procedure packs.

28. Any legal person or sole proprietor who assembles devices bearing the national conformity mark in order to place them on the market as a system or procedure pack shall draw up a declaration by which he states that:

he has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out all manufacturing operations in accordance with these instructions;

he has assembled the system or procedure pack and provided all relevant information for users, including relevant instructions from the manufacturers; and the whole manufacturing process has been subjected to appropriate methods of internal control and inspection.

Where the conditions above are not met, or the system or procedure pack incorporates devices that do not bear a national conformity mark, or the chosen combination of devices is not compatible, the system or procedure pack shall be treated as a medical device in its own right and as such be subjected to the relevant procedure set out clauses 15 to 19 of this Technical Regulation.

29. Any legal person or sole proprietor who sterilizes, for the purpose of placing on the market, systems or procedure packs referred to in clause 28 of this Technical Regulation or other medical devices bearing the national conformity mark that are intended by their manufacturers to be sterilised before use, shall, at his choice, follow one of the procedures referred to in Annex 3 or 6. The application of the procedures above and the involvement of the conformity assessment body are limited to the aspects of the procedure relating to the obtaining of sterility. The person shall draw up a declaration stating that sterilization has been carried out in accordance with the manufacturers' instructions.

30. The medical devices referred to clauses 28 and 29 hereof shall not bear an additional national conformity mark, but shall be accompanied by the information referred to in the section 'Information supplied by the manufacturer' of Annex 1, which includes the information provided by the manufacturers of the devices that have been put together. The person who drew up declarations referred to in clauses 28 and 29 hereof shall keep these declarations and make them available to the state market surveillance bodies upon their request.

Registration of persons responsible for placing devices on the market

31. Any manufacturer of Class I medical devices other than custom-made devices or those intended for clinical investigations, any manufacturer of custom-made devices, or any other legal person or sole proprietor engaged in the activities referred to clauses 27 to 30 of this Technical Regulation shall provide the SAUMP with information on the registered place of business and the list and the descriptions of the devices concerned.

Clinical investigations

32. In the case of devices intended for clinical investigations, the manufacturer or his authorised representative registered in Ukraine shall follow the procedure referred to in Annex 9 and notify the SAUMP by submitting the statement referred to in clause 2 of Annex 9.

33. In the case of implantable medical devices falling within Class III and long-term invasive devices falling within Class IIa or IIb, the manufacturer may initiate the relevant clinical investigation at the end of a 60-day period after notifying the SAUMP, unless executive authorities have notified him within that period of a negative decision based on considerations of public health or public policy.

The SAUMP may authorise the manufacturer to initiate the relevant clinical investigations before the expiry of the period of 60 days if the ethics committee has approved (issued a favourable opinion on) the programme of investigation in question.

34. The SAUMP may authorise the manufacturer to initiate the clinical investigations of other medical devices (with the exception of those referred to in clause 33 of this Technical Regulation) immediately after the date of notification, provided that the ethics committee has approved (issued a favourable opinion on) the programme of investigation in question.

35. The clinical investigations must be conducted in accordance with the requirements set out in Annex 10.

36. The SAUMP shall, if necessary, take the appropriate steps to ensure public health, in particular refuse or suspend the clinical investigation in accordance with the procedure approved by the MOH.

37. The manufacturer or his authorised representative shall notify the SAUMP of the end of the clinical investigation, with a justification in case of early termination. The manufacturer or his authorised representative shall keep the report referred to in the eighth paragraph of clause 9 of Annex 10 and make it available to the state market surveillance bodies upon their request.

38. The provisions of clauses 32 and 33 of this Technical Regulation do not apply where the clinical investigations are conducted using devices which are authorized in accordance with clauses 15 to 19 hereof to bear the national conformity mark, unless the aim of these investigations is to use the devices for a purpose other than that provided for by the relevant conformity assessment procedure. The relevant provisions of Annex 10 remain applicable.

Conformity assessment bodies

39. Conformity assessment bodies shall meet the criteria established by law. The conformity assessment bodies that meet the criteria laid down in the national standards that conform to the European harmonised standards shall be presumed to meet the relevant criteria.

40. Where a designated conformity assessment body does not meet the criteria set out in clause 39 of this Technical Regulation, the respective designation shall be withdrawn, with account taken of the requirements of the Law of Ukraine 'On the main principles of the state supervision (control) in the area of economic activity'.

41. The conformity assessment body shall inform the SAUMP of all issued, modified, supplemented, suspended, withdrawn or refused certificates of conformity and the other relevant conformity assessment bodies about certificates suspended, withdrawn or refused and, on request, about certificates issued and refused, and provide other information.

42. Where a conformity assessment body finds that the requirements of this Technical Regulation have not been met or are no longer met by the manufacturer or that a certificate of conformity should not have been issued, it shall suspend or withdraw the certificate issued until compliance with such requirements is ensured by the manufacturer. The conformity assessment body shall inform the SAUMP of such suspension or withdrawal.

National conformity mark

43. Medical devices (other than custom-made devices or devices intended for clinical investigations) considered to meet the requirements referred to in clause 11 of this Technical Regulation must bear the national mark of conformity when they are placed on the market.

{Clause 43 as amended by Resolution No. 181 of the CMU of 27 May 2014}

44. The requirements regarding the national conformity mark are set out in Annex 11. The national conformity mark must appear, as the manufacturer decides, on the medical device or its packaging and on the instructions for use where such instruction is mandatory. The marking must be visible, legible and indelible. The national conformity mark may also appear on the device label.

{The first paragraph of clause 44 as amended by Resolution No. 181 of the CMU of 27 May 2014}

The national conformity mark must be accompanied by the identification number of the conformity assessment body responsible for implementation of the procedures set out in Annexes 3 and 5 to 7 (where applicable).

45. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the national conformity mark. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the national conformity mark is not thereby reduced.

46. Where the SAUMP or inland revenue authorities find out that the national conformity mark has been affixed unduly or is missing in violation of this Technical Regulation, the manufacturer or his authorised representative must bring the devices into compliance with the requirements of this Technical Regulation.

47. Where the non-compliance continues, the SAUMP or the inland revenue authorities shall take actions to restrict or prohibit the placing on the market of the device concerned or to ensure that it is withdrawn from the market in accordance with the procedure prescribed by law.

48. Clauses 46 and 47 of this Technical Regulation shall also apply where the national conformity mark has been affixed in accordance with the procedures set out in this Technical Regulation, but on products that are not covered by this Technical Regulation.

Confidentiality

49. All the parties involved in the application of this Technical Regulation must observe confidentiality with regard to all information obtained in carrying out their tasks.

The state market surveillance bodies or inland revenue authorities shall, while carrying out their tasks, cooperate with the conformity assessment bodies.

Annex 1
to the Technical Regulation

ESSENTIAL REQUIREMENTS
for medical devices
Section I. General Requirements

1. The medical devices must be designed and manufactured in such a way that, when used for the intended purposes and under appropriate conditions, they will not pose a risk to the clinical condition or the safety of consumers, or the health and safety of users or other persons, provided that any potential risks that may be associated with the intended use of such devices are acceptable when weighed against the benefits to the consumers and are compatible with a high level of protection of health and safety.
2. The solutions adopted by the manufacturer for the design and construction of the medical devices must conform to the safety requirements, taking account of the state of the art.
In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:
eliminate or reduce the risks associated with the use of the device (safe design and construction);
take appropriate measures to protect the consumers (including alarms, if necessary, to avoid potential risks that are associated with the use of the device and cannot be eliminated);
inform the users of the potential risks that cannot be eliminated by precautionary measures.
3. The medical devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for the functions intended by the manufacturer, as defined in subclause 7 of clause 2 of the Technical Regulation on Medical Devices.
4. The characteristics and performances of the medical devices as defined in this Annex must not deteriorate to such a degree that the clinical conditions and safety of the consumers or other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to stresses that can occur under normal conditions of use.
5. The medical devices must be designed, manufactured and packaged in such a way that their characteristics and performances will not be adversely affected during transport or storage under conditions intended by the manufacturer.
6. Demonstration of conformity of the medical devices with the relevant requirements must include a clinical evaluation in accordance with Annex 10 to the Technical Regulation on Medical Devices.

Section II. Requirements regarding design and manufacturing

Chemical, physical and biological properties

1. The medical devices must be designed and manufactured in such a way as to guarantee that their characteristics and performances will conform to the requirements set out in Section I of this Annex.
Particular attention must be paid to:
the choice of materials, particularly as regards toxicity and flammability;
compatibility between the materials used and the tissues, cells and body fluids, taking account of the intended purpose of the device;
where necessary, the results of biophysical or modelling research.
2. The medical devices must be designed, manufactured and packaged in such a way as to minimize the risks posed by contaminants to the persons involved in the transport, storage and use of the devices and to the consumers, taking account of the intended purpose of the devices. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.
3. The medical devices must be designed and manufactured in such a way as to ensure that they can be safely used with the materials, substances and gases with which they enter into contact during their intended use. The devices intended to administer medicinal products must be designed and manufactured in such a way as to ensure that they are

compatible with the respective medicinal products in accordance with the provisions and restrictions that apply to them, and that their performance is maintained in accordance with the intended use.

4. Where a medical devices incorporates, as an integral part, a substance that, if used separately, may be considered to be a medicinal product and whose action on the body is ancillary to that of the device, the quality, safety and efficacy of such substance must be verified in accordance with the Law of Ukraine 'On medicines'.

The conformity assessment body shall, having verified the efficacy of the concerned substance as a part of the medical device and taking account of the intended purpose of the device, request from the State Expert Center of the MOH an opinion on the efficacy, safety and quality of the medicinal product, in particular on the benefit/risk profile of the incorporation of the substance into the device. While preparing its opinion, the State Expert Center shall take into account the manufacturing process and the data related to the efficacy of incorporation of the substance into the medical device, as specified by the conformity assessment body.

If the medical device incorporates, as an integral part, a human blood derivative, the conformity assessment body shall, having verified the efficacy of the substance concerned as a part of the medical device and taking account of the intended purpose of the device, request from the State Expert Center of the MOH an opinion on the quality and safety of the derivative, in particular on the benefit/risk profile of the incorporation of such human blood derivative into the medical device. While preparing its opinion, the State Expert Center of the MOH shall take into account the manufacturing process and the data related to the efficacy of incorporation of the human blood derivative into the device, as specified by the conformity assessment body.

If changes are made to an ancillary substance incorporated into a medical device (in particular when the changes are related to the manufacturing process), the conformity assessment body shall be informed of the changes. The conformity assessment body shall consult the State Expert Center of the MOH in order to confirm that the appropriate quality and safety of the ancillary substance are maintained. The State Expert Center shall take into account the data related to the efficacy of incorporation of such substance into the medical device, as specified by the conformity assessment body, in order to ensure that the changes have no adverse effect on the established benefit/risk profile of the incorporation of the substance into the medical device.

If the State Expert Center has obtained information on the ancillary substance that could affect the established benefit/risk profile of incorporation of the substance into the device, it shall provide the conformity assessment body with recommendations on whether such information affects the established benefit/risk profile of incorporation of the substance into the medical device or not. The conformity assessment body shall take this information into account when reconsidering its assessment.

5. The medical devices must be designed and manufactured in such a way as to minimize the risks associated with leakage (emission) of substances from the device. Particular attention must be paid to the substances that are carcinogenic, mutagenic or toxic to reproductive function, in accordance with the legislation.

If parts of a medical device (or the device itself) intended for administration and/or elimination of medicinal products, body fluids or other substances to or from the body, or the devices intended for transport and storage of such biological fluids or substances contain phthalates that are classified as carcinogenic, mutagenic or toxic to reproductive function, an indication that the device contains phthalates must appear on the medical device itself and/or on the packaging of each device or, where appropriate, on the sales packaging of the devices.

If the intended use of such devices includes treatment of children or pregnant or nursing women, the manufacturer must provide justification for the use of such substances in the technical documentation and include the information on the residual risks for these populations and, if applicable, on appropriate precautionary measures in the instructions for use.

6. The medical devices must be designed and manufactured in such a way as to reduce (as mush as possible) the risks associated with unintentional ingress of substances into the device, taking account of the specific features of the device and the nature of the environment in which the device is intended to be used.

Infection and microbial contamination

7. The medical devices and processes of their manufacturing must be designed in such a way as to eliminate or reduce (as much as possible) the risk of infection to the consumers, users and third parties. The design of devices must allow easy handling and, where necessary, minimize contamination of the device by the consumer during use.

8. Tissues of animal origins must be taken from animals that have been subjected to veterinary controls and surveillance.

The conformity assessment bodies must retain the information on the geographical (territorial) origin of such animals.

Processing, preservation, testing and use of tissues, cells and substances of animal origin must be carried out in such a way as to ensure the optimal level of security. In particular, to ensure protection against viruses and other infectious agents, the above actions are to be performed by applying validated methods of eradication or viral inactivation in the course of the manufacturing process.

9. The medical devices that are delivered in a sterile state must be designed, manufactured and packaged in accordance with the procedures that ensure that the devices are sterile when placed on the market and remain sterile, under the indicated conditions of storage and transport, until the protective packaging is damaged or opened.

10. The medical devices that are delivered in a sterile state must be manufactured and properly sterilised by a validated method.

11. The medical devices intended to be sterilised must be manufactured in controlled conditions.

12. The packaging systems for non-sterile medical devices must ensure their storage without deterioration of the established level of cleanliness of such devices and minimize the risk of bacterial contamination if the devices are to be sterilised before use. The selected packaging system must be suitable for use, taking account of the sterilization method indicated by the manufacturer.

13. The packaging and/or label must distinguish between identical or similar medical devices that are delivered in both sterile and non-sterile state.

Construction and environmental properties

14. If the device is intended for use in combination with other devices or equipment, the whole such combination (including the connection system) must be safe and not impair the characteristics of the devices included in the combination. Any restrictions on use of such devices must be indicated on the label or in the instructions for use.

15. The medical devices must be designed and manufactured in such a way as to eliminate or minimize (as far as possible) the following risks:

the risk of injury related to the physical features, in particular the volume/pressure ratio, dimensions and ergonomic characteristics;

the risk related to such environmental factors as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration;

the risk of reciprocal interference with other medical devices used for the investigations or treatment;

the risk related to impossibility of maintenance or calibration (in the event of implants) due to ageing of materials used or decreased accuracy of any measuring or control mechanism.

16. The medical devices must be designed and manufactured in such a way as to minimize the risk of fire or explosion under normal conditions of use and in the event of a single fault.

Particular attention must be paid to the devices whose intended use includes the use of flammable substances or substances that can cause combustion.

Medical devices with a measuring function

17. The medical devices with a measuring function must be designed and manufactured in such a way as to ensure the accuracy of measurements within the appropriate limits of accuracy, taking account of the intended use of the devices. The limits of accuracy must be indicated by the manufacturer.

18. The measurement, monitoring and display scale must be designed in accordance with ergonomic principles, taking account of the intended purpose of the device.

The measurements made by devices with a measurement function must be expressed in standard units (of the International System of Units [SI]) in accordance with the Classification of Codes for Units of Measure and Accounting.

Protection against radiation

General requirements

19. The medical devices with a measuring function must be designed and manufactured in such a way as to prevent (as far as possible) exposure of the consumers, users and other persons to radiation, taking account of the intended purpose while not restricting the levels of radiation necessary to achieve therapeutic and diagnostic purposes.

Intended radiation

20. If the medical device is intended to emit hazardous levels of radiation necessary for specific medical purposes, and the benefit of such emission is considered to outweigh the risks associated with such emission, it must be possible for the user to control the emission. Such medical devices must be designed and manufactured in such a way as to ensure the indicated reproducibility and tolerance of relevant variable parameters.

21. If the medical device is intended to emit potentially hazardous visible and/or invisible radiation, they must be fitted with visual and/or audible warnings of such emissions.

Unintended radiation

22. The medical devices must be designed and manufactured in such a way as to reduce, as far as possible, the exposure of consumers, users and other persons to unintended, scattered or reflected radiation.

Instructions for use

23. Instructions for use of the medical devices emitting radiation must contain detailed information on the nature of the radiation, means of protecting the consumer and the user, and the means of preventing misuse and eliminating the risks caused by the action of such devices.

Ionizing radiation

24. The medical devices emitting ionizing radiation must be designed and manufactured in such a way as to ensure (where possible) regulation and control of quantitative, geometrical and qualitative characteristics of the radiation emitted, taking account of the intended use.

25. The medical devices emitting ionizing radiation that are intended for diagnostic radiology must be designed and manufactured in such a way as to ensure the appropriate image and/or output quality for the intended medical purpose while minimizing the risk of radiation exposure of the consumers and users.

26. The medical devices emitting ionizing radiation that are intended for therapeutic radiology must be designed and manufactured in such a way as to ensure reliable monitoring and control of the optimal dose of radiation, type and power of radiation and, where necessary, the quality of radiation.

Requirements for medical devices connected to or equipped with an energy source

27. The medical devices incorporating electronic programmable systems must be designed in such a way as to ensure the reproducibility, reliability and efficacy of such systems according to the intended use of the device. Such systems must incorporate the means to eliminate or minimize the consequent risks in the event of a single fault.

28. If the medical devices incorporate software or are medical software in themselves, the software must be developed according to the state of the art, taking account of the principles of development cycle, risk management, validation and verification.

29. The medical devices where safety of consumers depends on an internal power supply must be equipped with means of determining the state of such power supply.

30. The medical devices where safety of the consumer depends on an external power supply must be equipped with an alarm system to signal any power failure.

31. The medical devices intended to monitor one or more clinical parameters must be equipped with an alarm system to alert the user of situations that can lead to death or serious deterioration of the consumer's health.

32. The medical devices must be designed and manufactured in such a way as to minimize the risk of creating electromagnetic fields that can impair the performance of other devices or equipment under normal conditions.

Protection against electrical risks

33. The medical devices must be designed and manufactured in such a way as to avoid (as far as possible) the risks of accidental electric shock during normal use, provided that the devices are installed correctly, and in single fault condition.

Protection against mechanical and thermal risks

34. The medical devices must be designed and manufactured in such a way as to protect the consumer and user against mechanical risks.

35. The medical devices must be designed and manufactured in such a way as to minimize possible risks arising from vibrations of medical devices, taking account of technical progress and of the means available for limiting vibrations, in particular at the source, unless such vibrations are part of the intended performance.

36. The medical devices must be designed and manufactured in such a way as to minimize the potential risks arising from noise generated by devices, taking account of technical progress and of the means available to reduce noise, particularly at source, unless such noise is part of the intended performance.

37. Terminals and connectors to electricity, gas, hydraulic or pneumatic power sources that the user has to handle must be designed and manufactured in such a way as to minimize all possible risks.

38. Accessible parts of medical devices (excluding the parts or areas intended to supply heat or reach specified temperatures) and their surroundings must not reach potentially dangerous temperatures under normal use.

Protection against the risks posed by energy supplies and substances delivered by devices

39. The medical devices intended to supply the consumers with energy or substances must be designed and manufactured in such a way that the flow rate can be set and maintained with the accuracy sufficient to guarantee the safety of the consumers and users.

40. The medical devices must be equipped with means of preventing and/or indicating any inadequacies in the flow-rate that could pose a danger.

The medical devices must incorporate the means of preventing (as far as possible) an accidental release of dangerous levels of energy generated from energy and/or substance.

41. The functions of the controls and indicators must be clearly indicated on the medical devices.

Instructions or symbols on the devices that are necessary for the device operation and reflect current and/or adjustable parameters must be understandable to the user and, where appropriate, to the consumer.

Information supplied by the manufacturer

42. Each medical device must be accompanied by the information necessary for its safe and proper use, taking account of the training and qualification of the consumers and users, and for identification of the manufacturer.

This information includes the details on the label and the instructions for use.

As far as possible and applicable, the information necessary to use the device safely must appear on the device itself and/or on the packaging of every unit or, where necessary, on the sales packaging. If individual packaging of each unit is not practicable, the information must be provided in the leaflet supplied with one or more devices.

Instructions for use must be included in the packaging of each medical device. Such instructions for use are not required for Class I or Class IIa devices if such devices can be used safely without any such instructions.

43. Where appropriate, the information accompanying the devices should take the form of symbols. All symbols and identification colours must conform to the harmonized standards. If no such standards exist, the symbols and colours used must be described in the documentation supplied with the devices.

44. The device label must contain the following particulars:

1) the name or trade mark and address of the manufacturer. For medical devices that are imported to be placed on the market, the label, or the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative if the manufacturer is not a resident of Ukraine;

2) the details that are strictly necessary to identify the device, and contents of the packaging;

3) where appropriate, the word 'Sterile';

4) where appropriate, the batch code (following the word 'Lot') or the serial number;

5) where appropriate, the date by which the device can be used safely, expressed as the year and month;

6) where appropriate, an indication that the device is for single use. A manufacturer's indication that the device is for single use must conform to the harmonized standards;
7) for custom-made devices, the words 'custom-made device';
8) for medical devices intended for clinical investigations, the words 'exclusively for clinical investigations';
9) any special conditions of storage and/or handling of the device;
10) any special operating instructions;
11) any precautions and/or warnings;
12) the year of manufacture - for the active devices not covered by subclause 5 of this clause. This information may be included in the batch or serial number;
13) where applicable, method of sterilization;
14) if the device incorporates, as an integral part, a human blood derivative, an indication that the device contains a human blood derivative.
45. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly indicate the purpose on the label and in the instructions for use.
46. Where reasonable and practicable, the medical devices and their detachable components must be identified (where necessary, in terms of the batch numbers) to allow detection of any potential risk posed by the devices and detachable components.
47. Where appropriate, the instructions for use must contain the following:
1) details referred to in clause 44 of this Section (excluding subparagraphs 4 and 5) of this Annex;
2) performances referred to clause 3 of Section I of this Annex and any undesirable side effects;
3) if the medical device must be installed with or connected to other medical devices and/or equipment in order to operate as required for its intended purpose, a detailed description of the device characteristics sufficient to correctly identify such devices and/or equipment in order to obtain a safe combination;
4) all information necessary to verify whether the device is installed correctly and can operate properly and safely as well as the details of the nature and frequency of the maintenance and calibration required to ensure the accurate and safe operation during the whole lifetime of the device;
5) where appropriate, information needed to avoid certain risks related to implantation of the device;
6) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;
7) the necessary instructions in the event of damage to the sterile packaging and, where necessary, information regarding the methods of resterilization;
8) if the device can be reused, information on the respective processes to prepare the device for reuse, in particular cleaning, disinfection, packaging, method of sterilization for devices to be resterilised, and any restrictions on the number of reuses;
If the medical devices have to be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the devices continue to conform to the requirements set out in Section I of this Annex.
If the medical device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused. If in accordance with clause 42 of Section II of this Annex, no instructions for use are needed, the information must be provided upon request of the user;
9) detailed information on any additional treatment needed before the device can be used (e.g. sterilization, final assembly, etc.);
10) for the medical devices emitting radiation for medical purposes, detailed information on the nature, type, intensity and distribution of this radiation.
The instructions for use of medical devices must contain details that allow the medical staff to inform the patient of any contraindications and precautions for use, in particular the following:
precautions to be taken in the event of changes in the device performances;
precautions to be taken with regard to exposure to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

the medicinal product(s) which the device is intended to administer, including any restrictions on the choice of substances to be administered;
precautions to be taken to eliminate any specific, unusual risks related to the disposal of the medical devices;
medicinal products or human blood derivatives incorporated into the device as an integral part;
degree of accuracy claimed for the medical devices with a measuring function;
date of issue or the latest revision of the instructions for use.

Annex 2
to the Technical Regulation
CLASSIFICATION CRITERIA
for medical devices

Definitions

1. For this Annex, the following definitions shall apply:

1) 'active medical device' means any medical device operation of which depends on a source of electrical energy or any source of power (other than that directly generated by the human body or gravity) and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the consumer, without any significant change, are not considered to be active medical devices. Stand alone software is considered to be an active medical device.

2) 'active device for diagnosis' means any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring physiological conditions, states of health, illnesses or congenital deformities and treatment;

3) 'active therapeutic device' means any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap;

4) 'invasive device' means a device which, in whole or in part, penetrates inside the body, either through the surface of the body or a body orifice;

5) 'implantable device' means any device intended to be totally introduced into the human body or to replace an epithelial surface or the surface of the eye by surgical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device;

6) 'body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma;

7) 'surgically invasive device' means any device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation;

8) 'reusable surgical instrument' means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

For the purposes of this Annex, 'central nervous system' means brain, meninges and spinal cord.

For the purposes of this Annex, 'central circulatory system' means the following vessels: pulmonary arteries (arteriae pulmonales), ascending aorta (aorta ascendens), coronary arteries (arteriae coronariae), common carotid artery (arteria carotis communis), external carotid artery (arteria carotis externa), internal carotid artery (arteria carotis interna), vertebral arteries (arteriae cerebrales), brachiocephalic trunk (truncus brachicephalicus), cardiac veins (venae cordis), pulmonary veins (venae pulmonales), superior vena cava (vena cava superior), inferior vena cava (vena cava inferior).

2. According to duration of use, medical devices are divided into following groups:

transient: medical devices that are intended for continuous use for not more than 60 minutes;

short term: medical devices that are intended for continuous use for not more than 30 days;

long term: medical devices that are intended for continuous use for more than 30 days.

Implementing rules

3. Application of the classification criteria shall be governed by the intended purpose of the devices.

4. If the device is intended to be used in combination with another device, the classification criteria shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

5. Software, which drives a device or influences the use of a device, falls in the same class.

6. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

7. If several criteria apply to the same device, based on the performance specified for the device by the manufacturer, such device shall fall into the higher class.
8. In calculating the duration referred to in clause 2 of this Annex, continuous use means an uninterrupted actual use of the device for the intended purpose.

Classification criteria for non-invasive medical devices

9. All non-invasive devices are in Class I, unless one of the provisions set out hereinafter applies.
10. All non-invasive devices intended for channelling or storing blood, body fluids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:
if they may be connected to an active medical device in Class IIa or a higher class;
if they are intended for use for storing or channelling blood or other body fluids or for storing organs, parts of organs or body tissues.
In all other cases these devices are in Class I.
11. All non-invasive devices intended for modifying the biological or chemical composition of blood, other body fluids or other liquids intended for infusion into the body are in Class IIb. If the treatment consists of filtration, centrifugation or exchanges of gas or heat, the devices are in Class IIa.
12. All non-invasive devices that come into contact with injured skin:
are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
are in Class IIb if they are intended to be used principally with wounds, penetrate under the skin and for which the healing is only secondary intent;
are in Class IIa in all other cases (in particular, the devices principally intended to manage the micro-environment of a wound).

Classification criteria for invasive devices

13. All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I:
are in Class I if they are intended for transient use;
are in Class IIa if they are intended for short term use. If devices are intended for use in the oral cavity, the nasopharynx, in an ear canal up to the ear drum or in a nasal cavity, they are in Class I;
in Class IIb if they are intended for long-term use. If such devices are used in the oral cavity, the nasopharynx, in an ear canal up to the ear drum or in a nasal cavity and are not intended to be absorbed by the mucous membrane, they are in Class IIa.
All invasive devices with respect to body orifices (other than surgically invasive devices), intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.
14. All surgically invasive devices intended for transient use are in Class IIa unless they are:
intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III;
reusable surgical instruments, in which case they are in Class I;
intended specifically for use in direct contact with the central nervous system, in which case they are in Class III;
intended to supply energy in the form of ionising radiation, in which case they are in Class IIb;
intended to have a biological effect or to be wholly or partially absorbed, in which case they are in Class IIb;
intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.
15. All surgically invasive devices intended for short-term use are in Class IIa unless they are intended:
specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III;
specifically for use in direct contact with the central nervous system, in which case they are in Class III;
to supply energy in the form of ionising radiation, in which case they are in Class IIb;
to have a biological effect or to be wholly or partially absorbed, in which case they are in Class III;

to produce chemical changes in the body (except when the devices are placed in the teeth), or to administer medicines, in which case they are in Class IIb.

16. All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:

to be placed in the teeth, in which case they are in Class IIa;

to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III;

to have a biological effect or to be wholly or partially absorbed, in which case they are in Class III;

to produce chemical changes in the body (except when the devices are placed in the teeth), or to administer medicines, in which case they are in Class III.

Additional criteria applicable to active devices

17. All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, intensity and the site of application of the energy. In such case the devices are in Class IIb.

All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.

18. Active devices intended for diagnosis are in Class IIa:

if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the consumer's body, in the visible spectrum;

if they are intended to image *in vivo* distribution of radiopharmaceuticals;

if they are intended for direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of energy is such that it could result in immediate danger to the consumer, for instance cause variations in cardiac performance, respiration, CNS activity. In this case the devices are in Class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology, including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

19. All active devices intended to administer and/or remove medicines, body fluids or other substances to and/or from the body are in Class IIa. Where such administration or removal is done in the manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application, such devices are in Class IIb.

20. All other active medical devices are in Class I.

Special rules for device classification

21. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in the Law of Ukraine 'On medicines', and whose action on the human body is ancillary to that of the device, are in Class III.

All devices incorporating, as an integral part, a human blood derivative are in Class III.

22. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb. Implantable or long-term invasive devices used for the above purposes are in Class III.

23. All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb.

All devices intended specifically for disinfecting medical devices are in Class IIa. Medical devices intended specifically for disinfecting invasive devices are in Class IIb.

These requirements do not apply to medical devices intended to clean medical devices (other than contact lenses) by means of physical action.

24. Medical devices specifically intended for recording of X-ray diagnostic images are in Class IIa.

25. All medical devices manufactured utilizing animal tissues or non-viable animal tissues are in Class III except where such devices are intended to come into contact with intact skin.

26. Blood bags are in Class IIb.

Annex 3
to the Technical Regulation

PROCEDURE

for ensuring performance of the comprehensive quality management system

General provisions

1. The manufacturer must ensure application of the approved quality management system at the stages of design, manufacture and final inspection of medical devices, as defined in the section 'Quality management system' of this Annex and is subject to audit as laid down in the section 'Examination of the design of the device' of this Annex and surveillance as specified in the section 'Surveillance of the quality management system' of this Annex.

2. Full quality assurance is the procedure whereby the manufacturer who fulfils the obligations imposed by clause 1hereof ensures and declares that the devices concerned meet the provisions of the Technical Regulation on Medical Devices that apply to them.

The manufacturer must affix the national conformity mark to medical devices in accordance with clause 18 of the Technical Regulation on Medical Devices and draw up a declaration of conformity. The declaration must cover one or more medical devices manufactured by this manufacturer, in particular the name, code or other unambiguous reference of such devices. The declaration of conformity must be kept by the manufacturer.

Quality management system

3. The manufacturer must submit an application for assessment of the quality management system to a conformity assessment body.

The application must include:

the name and address of the manufacturer and any additional manufacturing site covered by the quality management system;

information on the medical device or device category covered by the procedure;

a statement that no application has been submitted to any other conformity assessment body for the same product-related quality management system;

the documentation on the quality management system;

an undertaking by the manufacturer to fulfil the obligations imposed by the approved quality management system;

an undertaking by the manufacturer to keep the approved quality management system adequate and workable/usable;

an undertaking by the manufacturer to systematically analyse the experience gained from the use of devices after they have been placed on the market, including the provisions referred to in Annex 10 to the Technical Regulation on Medical Devices, and to implement appropriate means to apply any necessary corrective action. In accordance with this undertaking, the manufacturer must immediately notify the SAUMP on the following:

any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a consumer or user or to a serious deterioration in their state of health;

any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in the tenth paragraph of this clause to systematic recall of devices of the same type by the manufacturer.

4. Application of the quality management system must ensure that the products conform to the provisions of the Technical Regulation on Medical Devices which apply to them at every stage, from design to final inspection. Parameters, requirements and provisions adopted by the manufacturer for his quality management system must be documented in the rules and procedures, in particular in the quality programmes, quality plans, manuals and quality reports. The documentation on the quality management system must include, in particular, the details and records arising from the procedures referred to in subclause 3 of clause 5 of this Annex.

5. The documentation on the quality management system must include a description of:

1) the manufacturer's quality objectives;

2) the organization of the business, in particular:

the organizational structures, the responsibilities of the managerial staff and their authority with regard to quality of design and manufacture of the medical devices;

the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of product, including control of devices which fail to conform;
where the design, manufacture and/or final inspection and testing of the devices, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the third party;
3) the procedures for monitoring and verifying the design of the products, including all corresponding documentation, in particular:
a general description of the medical device, including any variants planned, and its intended use;
the technical documentation, including the standards applied and the results of the risk analysis as well as a description of the solution adopted to fulfil the requirements referred to in Annex 1 to the Technical Regulation on Medical Devices if the national standards included in the list of the national standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of the conformity of devices with the requirements of the Technical Regulation on Medical Devices are not applied in full;
a description of the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed;
if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the requirements of the Technical Regulation on Medical Devices when connected to any such device;
a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in clause 4 of Section II of Annex I to the Technical Regulation on Medical Devices and the results of the tests conducted in this connection required to assess the safety, quality and efficacy of that substance or human blood derivative, taking account of the intended purpose of the device;
details indicating whether or not the device is manufactured utilising tissues of animal origin. The requirements for medical devices manufactured utilising tissues of animal origin shall be approved by an order of the MOH;
the solutions adopted as referred to in clause 2 of Section I of Annex 1 to the Technical Regulation on Medical Devices;
the pre-clinical evaluation;
the clinical evaluation in accordance in Annex 10 to the Technical Regulation on Medical Devices;
the draft label and instructions for use;
4) the inspection and quality assurance techniques at the manufacturing stage and in particular:
the processes and procedures which will be used, particularly as regards sterilization and purchasing;
the procedures for product identification at every stage of manufacture, based on drawings, specifications or other relevant documents;
5) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used. It must be possible to trace back the calibration of the test equipment adequately.
6. The conformity assessment body must audit the quality management system to determine whether it conforms to the requirements referred to in clauses 4 and 5 of this Annex. The quality management systems proved to be in conformity with the national standards conforming to the European harmonized standards are presumed to conform to the requirements referred to in clauses 4 and 5 of this Annex.
The committee assembled by the conformity assessment body to assess the quality management system must include at least one specialist with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the devices concerned, an inspection on the manufacturer's premises and, where applicable, on the premises of the suppliers and/or subcontractors to inspect the manufacturing processes.
The decision, which must contain the conclusions of the inspection and a reasoned assessment, is notified to the manufacturer.
7. The manufacturer must inform the conformity assessment body that approved the quality management system of any plan for substantial changes to the quality management system or the device range covered by the system. The

conformity assessment body must assess the proposed changes and verify whether after these changes the quality management system still meets the requirements referred to in clauses 4 and 5 of this Annex. The conformity assessment body must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

Examination of the design of the product

8. In addition to the obligations imposed by the section 'Quality management system' hereof, the manufacturer or his authorised representative must lodge with the conformity assessment body an application for examination of the design of the medical device which he plans to manufacture.

9. The application must describe the design, manufacture and performances of the device. The application must be accompanied by the documents needed to assess whether the medical device meets the requirements of the Technical Regulation on Medical Devices, as referred to in subclause 3 of clause 5 of this Annex.

10. The conformity assessment body must examine the application and, if the device conforms to the provisions of the Technical Regulation on Medical Devices, issue the application with a design examination certificate. The conformity assessment body may require the application to be supplemented with further tests or proof to allow better assessment of the product design for conformity with the Technical Regulation on Medical Devices. The certificate must contain the examination conclusions, the data needed for identification of the approved design, and, where appropriate, a description of the intended purpose of the device.

Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product, as referred to in clause 4 of Section II of Annex 1 to the Technical Regulation on Medical Devices, the conformity assessment body shall consult the State Expert Center of the MOH in order to take a decision whether the device conforms with the requirements of the Technical Regulation on Medical Devices. The opinion of the State Expert Center of the MOH must be issued within 210 calendar days after receipt of complete documentation. The opinion must be included in the documentation concerning the medical device. The conformity assessment body shall take account of the opinions expressed in this consultation when making its decision as to issuing the design examination certificate. The conformity assessment body shall convey its decision to the State Expert Center of the MOH.

Where a device incorporates, as an integral part, a human blood derivative, as referred to in clause 4 of Section II of Annex 1 to the Technical Regulation on Medical Devices, the opinion of the State Expert Center of the MOH must be included in the documentation concerning such medical device. The opinion must be issued within 210 calendar days after receipt of complete documentation. The conformity assessment body shall take this opinion into account when making its decision. The conformity assessment body shall not issue the certificate if the opinion of the State Expert Center is unfavourable. The conformity assessment body shall convey its decision to the State Expert Center of the MOH.

In the case of devices manufactured utilising tissues of animal origin, the conformity assessment body must follow procedures set out in the relevant MOH regulations.

11. If the changes to the approved design can affect the conformity with the requirements of the Technical Regulation on Medical Devices or with the conditions prescribed for the intended use of the device, such changes must receive further approval from the conformity assessment body that issued the design examination certificate. The applicant must inform the conformity assessment body that issued the design examination certificate of any changes made to the approved design. This additional approval must take the form of a supplement to the design examination certificate.

Surveillance of the quality management system

12. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.

13. The manufacturer must give the conformity assessment body access to the inspection, testing and storage locations, and supply it with all relevant information, in particular:

the documentation on the quality management system;

the data stipulated in the part of the quality management system relating to design of product, in particular the results of analyses, calculations, tests, the solutions adopted as referred to in clause 2 of Section I of Annex 1 to the Technical

Regulation on Medical Devices, preclinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up of such devices;
the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned.
14. The conformity assessment body must periodically carry out inspections and assessments to make sure that the manufacturer applies the approved quality management system and must supply the manufacturer with an assessment report.
15. In addition, the conformity assessment body may carry out unannounced inspections. During such inspections, the conformity assessment body may, where necessary, carry out or ask for tests in order to verify that the quality management system is working properly. It must provide the manufacturer with an inspection report and, if a test of devices has been carried out, with a test report.

Administrative provisions

16. The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the SAUMP:
the declaration of conformity;
the documentation referred to in clause 3 of this Annex and the documentation, data and records regarding monitoring procedures and design examination, as referred to in sub clause 3 of clause 5 of this Annex;
the changes referred to in clause 7 of this Annex;
the documentation referred to in paragraph 9 of this Annex;
the decisions and reports from the conformity assessment bodies as referred to in clauses 6, 10, 11, 14 and 15 of this Annex;

Provisions that apply to medical devices in Classes IIa and IIb

17. In accordance with clause 16 and 17 of the Technical Regulation on Medical Devices, this Annex may apply to devices in Classes IIa and IIb, excluding the section 'Examination of the design of the product' hereof.
18. The conformity assessment body, when assessing the quality management system as referred to in clause 6 of this Annex, shall assess:
for devices in Class IIa, the technical documentation regarding the procedures for monitoring and verifying the design of products as described in subclause 3 of clause 5 of this Annex (for at least one representative sample for each device subcategory) for compliance with the provisions the Technical Regulation on medical devices.
for devices in Class IIb, the technical documentation regarding the procedures for monitoring and verifying the design of products as described in subclause 3 of clause 5 of this Annex (for at least one representative sample for each generic device group) for compliance with the provisions the Technical Regulation on medical devices.
19. In choosing representative sample(s) the conformity assessment body shall take into account the similarities in design, technology, manufacturing processes and sterilization methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Technical Regulation. The conformity assessment body shall document and keep available to the relevant competent state authority its rationale for the samples taken.
20. Further samples shall be assessed by the conformity assessment body as part of the surveillance referred to in the section 'Surveillance of the quality management system' of this Annex.

Annex 4
to the Technical Regulation

PROCEDURE

for type examination

1. Type examination is the procedure whereby a conformity assessment body ascertains and certifies that a representative sample of the medical device covered by this Annex is in conformity with the requirements of the Technical Regulation on Medical Devices.

2. The application for type examination must include:

the name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of such representative;

a written statement that no such application has been submitted to any other conformity assessment body;

the documentation referred to in clause 3 of this Annex needed to assess the conformity of the representative sample of the device concerned (hereinafter referred to as the 'type') with the requirements of the Technical Regulation on Medical Devices. The applicant must provide a 'type' to the conformity assessment body. The conformity assessment body may request other samples as necessary.

3. The documentation supporting the application submitted to the conformity assessment body must contain information sufficient to allow understanding of the design, manufacturing processes and performances of the devices concerned, in particular:

a general description of the type, including any variations planned, and its intended use;

design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits, etc.,

the descriptions and explanations necessary to understand the above drawings and diagrams and the operation of the product;

a list of the national standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of compliance with the requirements of the Technical Regulation, applied in full or in part, and descriptions of the solutions adopted to meet the relevant requirements if the above standards have not been applied in full;

the results of the design calculations, risk analysis, investigations, technical tests, etc.;

a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in clause 4 of Section II of Annex I to the Technical Regulation on Medical Devices and the results of the tests conducted in this connection required to assess the safety, quality and efficacy of that substance or human blood derivative, taking account of the intended use of the device;

data indicating whether or not the device is manufactured utilising tissues of animal origin;

the solutions adopted as referred to in clause 2 of Section I of Annex 1 to the Technical Regulation on Medical Devices;

the pre-clinical evaluation;

the clinical evaluation in accordance with in Annex 10 to the Technical Regulation on Medical Devices;

the draft label and, where appropriate, instructions for use.

4. The conformity assessment body must carry out the following procedures:

1) examine and assess the documentation supplied by the manufacturer and verify that the type is in conformity with the technical documentation; it must also record the items designed in conformity with the applicable provisions of the standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of the conformity of devices with the Technical Regulation on Medical Devices, as well as the items not designed on the basis of the relevant provisions of the above standards;

2) carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the requirements of the Technical Regulation on medical devices if the standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of compliance with the Technical Regulation on Medical Devices have not been applied. If the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the

requirements set out in the Technical Regulation on Medical Devices when connected to any such device having performances defined by the manufacturer;

3) carry out or arrange for the appropriate inspections and tests necessary to verify whether the relevant standards chosen by the manufacturer have actually been applied;

4) agree with the applicant on the place where the necessary inspections and tests will be carried out.

5. If the results of the type examination confirm the type's conformity with the Technical Regulation on Medical Devices, the conformity assessment body issues the manufacturer with a type examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, and the data needed for identification of the type approved. A copy of the certificate must be kept by the conformity assessment body.

Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product, as referred to in clause 4 of Section II of Annex 1 to the Technical Regulation on Medical Devices, the conformity assessment body shall consult the State Expert Center of the MOH before taking a decision. The opinion of the Center must be issued within 210 calendar days after receipt of complete documentation. The opinion must be included in the documentation concerning the medical device. The conformity assessment body shall take account of the opinions expressed in this consultation when making its decision. The conformity assessment body shall convey its decision to the State Expert Center of the MOH.

Where a device incorporates, as an integral part, a human blood derivative, the opinion of the State Expert Center of the MOH must be included in the documentation concerning such medical device. The opinion must be issued within 210 calendar days after receipt of complete documentation. The conformity assessment body shall take the opinion of the State Expert Center into account when making its decision. The conformity assessment body shall not issue the certificate if the opinion of the State Expert Center is unfavourable. The conformity assessment body shall convey its decision to the State Expert Center of the MOH.

In the case of devices manufactured utilising tissues of animal origin, the conformity assessment body must follow procedures set out in the Technical Regulation on medical devices.

6. The applicant must inform the conformity assessment body that issued the type examination certificate of any significant changes made to the approved product.

The changes to the approved product must be further approved by the conformity assessment body that issued the type examination certificate wherever such changes can affect the conformity of the device with the relevant requirements or conditions of its intended use. This approval must take the form of a supplement to the design examination certificate.

7. Other conformity assessment bodies may obtain a copy of the type examination certificate and/or the supplements thereto. The annexes to the certificates must be made available to other conformity assessment bodies upon their reasoned request, after the manufacturer has been informed.

8. The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep with the technical documentation copies of the type examination certificates and the supplements thereto and provide them to the SAUMP upon request.

Annex 5
to the Technical Regulation
PROCEDURE
for product verification

General provisions

1. The verification is the conformity assessment procedure whereby the manufacturer or his authorised representative ensures and declares that the devices that are subject to the procedure referred to in clause 4 of this Annex conform to the type described in the type examination certificate and to the requirements of the Technical Regulation on Medical Devices.

2. The manufacturer must take all the measures necessary to ensure that during the manufacturing process devices conform to the type described in the type examination certificate and to the requirements of the Technical Regulation on Medical Devices. Before the start of manufacture, the manufacturer must prepare documents defining the whole manufacturing process (in particular as regards sterilization where necessary) together with the provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the type examination certificate and with the requirements of the Technical Regulation on Medical Devices. The manufacturer must affix the national conformity mark in line with the legislation and draw up a declaration of conformity.

To ensure and maintain sterility of the devices placed on the marked in sterile condition, the manufacturer must apply the provisions of the sections 'Quality management system' and 'Surveillance of the quality management system' of Annex 6 to the Technical Regulation on Medical Devices.

3. The manufacturer must analyse the experience gained from the use of the devices after they have been placed on the marked, taking account of the provisions referred to in Annex 10 to the Technical Regulation on Medical Devices, and to implement appropriate means to apply any necessary corrective action. In accordance with this undertaking, the manufacturer must immediately notify the SAUMP on the following:

any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a consumer or user or to a serious deterioration in their state of health;

any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in the second paragraph of this clause to systematic recall of devices of the same type by the manufacturer.

4. The conformity assessment body must carry out the investigations and tests to verify the conformity of devices with the requirements of the Technical Regulation on Medical Devices either by examining and testing every device as specified in 'Verification by examination and testing of every product' below or by examining and testing products on a statistical basis as specified in 'Statistical verification of medical devices', as the manufacturer decides.

The aforementioned examinations and tests do not apply to those aspects of the manufacturing process designed to secure sterility.

Verification by examination and testing of every product

5. Every device is examined individually. For each medical device, all appropriate tests defined in the relevant standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of the conformity of devices with the Technical Regulation on Medical Devices or equivalent tests must be carried out in order to verify the conformity of each device with the Technical Regulation on Medical Devices and, where necessary, with the type described in the type examination certificate.

6. The conformity assessment body must affix or have affixed its identification number to each verified product and issue a certificate of conformity on the basis of the tests carried out.

Statistical verification of medical devices

7. The manufacturer must produce the devices in the form of homogeneous batches.

8. A random sample is taken from each batch. The devices that make up the sample are examined individually. For such devices, all appropriate tests defined in the relevant standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of the conformity of the device with the Technical Regulation on Medical Devices or equivalent tests must be carried out in order to verify the conformity

of each device with the requirements of the Technical Regulation on medical devices and, where appropriate, with the type described in the type examination certificate in order to determine whether the batch conforms to such requirements or not.

9. Statistical control of products must be based on attributes and/or variables entailing operational characteristics, sampling schemes which ensure a high level of safety and performance according to the state of the art. The sampling schemes must be established by the harmonised standards, the conformity to which is evidence that the product complies with the requirements of the relevant technical regulations, taking account of the specific nature of the product categories in question.

10. If the batch conforms to the requirements of the Technical Regulation on Medical Devices and, where appropriate, to the type described in the type examination certificate, the conformity assessment body must affix or have affixed its identification number to each medical device in the batch and issue a certificate of conformity relating to the tests carried out. All products in the batch can be placed on the marked except those that failed to conform to the requirements of the Technical Regulation on Medical Devices.

If the batch fails to conform to the Technical Regulation on Medical Devices and, where appropriate, with the type described in the type examination certificate, the conformity assessment body must, in accordance with the legislation, take all appropriate measures to prevent the batch from being placed on the market of Ukraine. If non-conformity of batches occurs periodically, the conformity assessment body may suspend the statistical verification.

The manufacturer may affix the identification number of the conformity assessment body to the device labels during the manufacturing process after the conformity assessment body has granted its permission.

Administrative provisions

11. The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the state authorities:

the declaration of conformity;

the documentation referred to in clause 2 of this Annex;

the certificates referred to in clause 6 and 10 of this Annex;

the type examination certificate referred to in Annex 4 to Technical Regulation on Medical Devices.

Provisions that apply to medical devices in Class IIa

12. In accordance with clause 16 of the Technical Regulation on Medical Devices, this Annex may apply to devices in Class IIa, subject to the following:

1) in derogation from clauses 1 and 2 hereof, by virtue of the declaration of conformity the manufacturer guarantees that the products in Class IIa are manufactured in conformity with the technical documentation referred to in paragraph 3 of Annex 8 to the Technical Regulation on Medical Devices and meet the requirements of the Technical Regulation on Medical Devices;

2) in derogation from clauses 1, 2, 5-10 of this Annex, the verifications carried out by the conformity assessment body are intended to confirm the conformity of devices in Class IIa with the technical documentation referred to in paragraph 3 of Annex 8 to the Technical Regulation on medical devices.

Annex 6
to the Technical Regulation

PROCEDURE

for ensuring operation of the quality management system during the manufacturing process

1. The manufacturer must ensure application of the quality management system approved for the manufacture of the devices concerned and carry out the final inspection as specified in the section 'Quality management system' hereof.

2. Production quality assurance is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by clause 1 of this Annex ensures and declares that the devices concerned conform to the provisions of the Technical Regulation on Medical Devices and the type described in the type examination certificate.

The manufacturer must affix the national conformity mark in accordance with the legislation and draw up a declaration of conformity of medical devices with the Technical Regulation on Medical Devices. The declaration must cover one or more medical devices, in particular the name, code or other unambiguous reference of such devices. The declaration must be kept by the manufacturer.

Quality management system

3. The manufacturer must submit an application for assessment of the quality management system to a conformity assessment body.

The application must include:

the name and address of the manufacturer;

all relevant information on the medical device or device category covered by the procedure;

a written statement that no application has been submitted to any other conformity assessment body for the same medical devices;

the documentation on the quality management system;

an undertaking by the manufacturer to fulfil the obligations imposed by the approved quality management system;

an undertaking by the manufacturer to keep the approved quality management system adequate and workable/usable;

where appropriate, the technical documentation on the type approved and a copy of the type examination certificate;

an undertaking by the manufacturer to systematically analyse the experience gained from the use of devices after they have been placed on the market, including the provisions referred to in Annex 10 to the Technical Regulation on Medical Devices, and to implement appropriate means to apply any necessary corrective action. In accordance with this undertaking, the manufacturer must immediately notify the SAUMP on the following:

any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a consumer or user or to a serious deterioration in their state of health;

any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in the eleventh paragraph of this clause leading to systematic recall of devices of the same type by the manufacturer.

4. Application of the quality management system must ensure that devices conform with the type described in the type examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for the quality management system must be documented in a systematic and orderly manner in the form of written policies and procedures. The documentation on the quality management system must ensure unambiguous interpretation of methods and procedures for quality assurance, in particular quality programmes, plans, manuals and reports.

5. The documentation on the quality management system must include a description of:

1) the manufacturer's quality objectives;

2) the organization of the business, in particular:

the organizational structures, the responsibilities of the managerial staff and their authority in regard to the manufacture of medical devices;

the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of product, including control of devices which fail to conform;

where the design, manufacture, final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the third party;

3) the inspection and quality assurance techniques at the manufacturing stage and in particular:

the processes and procedures which will be used, particularly as regards sterilization and purchasing;

the product identification procedures based on drawings, specifications or other relevant documents, at every stage of manufacture;

4) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used. It must be possible to trace back the calibration of the test equipment.

6. The conformity assessment body must audit the quality management system to determine whether it meets the requirements referred to in clauses 4 and 5 of this Annex. The quality management systems complying with the standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence that the product complies with the requirements of the Technical Regulation on Medical Devices are presumed to meet these requirements.

The committee convened by the conformity assessment body to assess the quality management system must include at least one specialist with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, where applicable, on the premises of the suppliers to inspect the manufacturing processes.

The conformity assessment body must notify the manufacturer of its decision, which must contain the conclusions of the inspection and a reasoned assessment.

7. The manufacturer must inform the notified body that approved the quality management system of any plan for substantial changes to the quality management system.

The conformity assessment body must assess the proposed changes and verify whether after these changes the quality management system still meets the requirements referred to in clauses 4 and 5 of this Annex.

The conformity assessment body must notify the manufacturer of its decision, which must contain the conclusions of the inspection and a reasoned assessment.

Surveillance of the quality management system

8. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.

9. The manufacturer must give the conformity assessment body access to the inspection, testing and storage locations, and supply it with all relevant information, in particular:

the documentation on the quality management system;

the technical documentation;

the data stipulated in the quality management system in regard to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned.

10. The conformity assessment body must periodically carry out inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

11. The conformity assessment body may carry out unannounced inspections. During such inspections, the conformity assessment body may carry out or ask the manufacturer for tests in order to verify that the quality management system is working properly. The conformity assessment body must provide the manufacturer with an inspection report and, if a test have been carried out, with a test report.

Administrative provisions

12. The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the SAUMP:

the declaration of conformity;

the documentation on the quality management system as referred to in paragraph 3 of this Annex;

the changes referred to in clause 7 of this Annex;
the decisions and reports from the conformity assessment body as referred to in clauses 10 and 11 of this Annex;
the technical documentation on the approved type and the copies of the type examination certificates as referred to in Annex 4 to the Technical Regulation on Medical Devices.

Provisions that apply to medical devices in Class IIa

13. In accordance with clause 16 of the Technical Regulation on medical devices, this Annex may apply to devices in Class IIa, subject to the following:

1) in derogation from clauses 2 to 5, by virtue of the declaration of conformity the manufacturer guarantees that the products in Class IIa are manufactured in conformity with the technical documentation referred to in clause 3 of Annex 8 to the Technical Regulation on medical devices and meet the requirements of the Technical Regulation on medical devices;

2) for devices in Class IIa, the conformity assessment body shall assess, as part of the assessment referred to in clause 6 of this Annex, the technical documentation as described in clause 3 of Annex 8 to the Technical Regulation on medical devices (for at least one representative sample for each device subcategory) to verify the conformity of such devices with the provisions of the Technical Regulation on Medical Devices;

3) in choosing the representative samples, the conformity assessment body shall take into account the similarities in design, technology, manufacturing processes and sterilization methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with the Technical Regulation on Medical Devices. The conformity assessment body shall document and keep available to the competent state authority its rationale for the samples taken.

4) further samples shall be assessed by the conformity assessment body as part of the surveillance referred to in clause 10 of this Annex.

Annex 7
to the Technical Regulation
PROCEDURE
for ensuring operation of the quality management system

1. The manufacturer must ensure application of the quality management system approved for the final inspection and testing of product as specified in the section 'Quality management system' of this Annex and is subject to the market surveillance as specified in the section 'Surveillance of fulfilment by the manufacturer of the obligations imposed by the approved quality management system' of this Annex.

For medical devices that are delivered in a sterile state, the manufacturer must apply the provisions of the sections 'Quality management system' and 'Surveillance of the quality management system' of Annex 6 to the Technical Regulation on Medical Devices for those aspects of the manufacturing process designed to secure and maintain sterility.

2. Product quality assurance is a part of the procedure whereby the manufacturer who fulfils the obligations imposed by clause 1 of this Annex ensures and declares that the devices concerned conform to the type described in the type examination certificate and to the requirements of the Technical Regulation on Medical Devices.

The manufacturer must affix the national conformity mark to medical devices in accordance with the legislation and draw up a declaration of conformity. The declaration must cover one or more medical devices, in particular the name, code or other unambiguous reference of such devices. The declaration is kept by the manufacturer. The national conformity mark must be accompanied by the identification number of the conformity assessment body that performs the tasks referred to in this Annex.

Quality management system

3. The manufacturer must submit an application for assessment of the quality management system to a conformity assessment body.

The application must include:

the name and address of the manufacturer;

all relevant information on the medical device or device category covered by the procedure;

a written statement that no application has been submitted to any other conformity assessment body for the same medical devices;

the documentation on the quality management system;

an undertaking by the manufacturer to fulfil the obligations imposed by the approved quality management system;

an undertaking by the manufacturer to keep the approved quality management system adequate and workable/usable;

the technical documentation on the approved type and the copies of the type examination certificates;

an undertaking by the manufacturer to systematically analyse the experience gained from the use of devices after they have been placed on the market, including the provisions referred to in Annex 10 to the Technical Regulation on Medical Devices, and to implement appropriate means to apply any necessary corrective action. In accordance with this undertaking, the manufacturer must immediately notify the SAUMP on the following:

any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a consumer or user or to a serious deterioration in their state of health;

any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in the 11th paragraph of this clause to systematic recall of devices of the same type by the manufacturer.

Under the quality management system, to ensure that medical devices conform to the type described in the type examination certificate and to the requirements of the Technical Regulation on medical devices, each product or a representative sample of each batch is examined and the appropriate tests defined in the relevant standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of the conformity of the product with the requirements of the Technical Regulation on Medical Devices, or equivalent tests are carried out. All the elements, requirements and provisions adopted by the manufacturer for the quality management system must be documented in a systematic and orderly manner in the form of written policies and

procedures. The documentation on the quality management system must ensure unambiguous interpretation of methods and procedures for quality assurance, in particular quality programmes, plans, manuals and reports.
The documentation on the quality management system must include in particular a description of:
the manufacturer's quality objectives, the organizational structures, the responsibilities of the managerial staff and their authority in regard to product quality;
the examinations and tests that will be carried out after manufacture. It must be possible to trace back the calibration of the test equipment.
thc methods of monitoring the efficient operation of the quality system;
the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned.
Where the final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality management system are applied to the third party.
The provisions above do not apply to the stages of the manufacture designed to ensure sterility.
4. The conformity assessment body must audit the quality management system to determine whether it meets the requirements referred to in clause 3 of this Annex. The quality management system is considered conforming to the specified requirements if such system implements the standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of conformity with the Technical Regulation on Medical Devices.
The committee assembled by the conformity assessment body to assess the quality management system must include at least one specialist with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, where applicable, on the premises of the suppliers to inspect the manufacturing processes.
The conformity assessment body must notify the manufacturer of its decision, which must contain the conclusions of the inspection and a reasoned assessment.
5. The manufacturer must inform the conformity assessment body that approved the quality management system of any plan for substantial changes to the quality management system.
The conformity assessment body must assess the proposed changes and verify whether after these changes the quality management system still meets the requirements referred to in clause 3 of this Annex.
The conformity assessment body must notify the manufacturer of its decision, which must contain the conclusions of the inspection and a reasoned assessment.

Surveillance of fulfilment by the manufacturer of the obligations imposed by the approved quality management system

6. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.
7. The manufacturer must give the conformity assessment body access to the inspection, testing and storage locations, and supply it with the relevant information, in particular:
the documentation on the quality management system;
the technical documentation;
the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the personnel concerned.
The conformity assessment body must periodically carry out inspections and assessments to make sure that the manufacturer applies the approved quality management system and must supply the manufacturer with an assessment report.
The conformity assessment body may carry out unannounced inspections. During such inspections, the conformity assessment body may carry out or ask the manufacturer for tests of product in order to verify that the quality management system is working properly and the devices manufactured conform with the Technical Regulation on Medical Devices. To this end, a sample of the final product, taken on site by the conformity assessment body, must be tested. In addition, the tests defined in the standards that conform to the European harmonized standards and voluntary

application of which can be considered to be evidence of the conformity of the product with the Technical Regulation on Medical Devices, or equivalent tests must be carried out. Where one or more of the samples fail to conform, the conformity assessment body must take the appropriate measures.

The conformity assessment body must provide the manufacturer with an inspection report and, if a test of devices has been carried out, with a test report.

Administrative provisions

8. The manufacturer or the authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the SAUMP:

the declaration of conformity;

the technical documentation on the approved type and the copies of the type examination certificates;

the changes referred to in clause 5 of this Annex;

the decisions and reports from the conformity assessment body as referred to in clauses 5 and 7 of this Annex;

where appropriate, the type examination certificate referred to in Annex 4 to the Technical Regulation on medical devices.

Provisions that apply to medical devices in Class IIa

9. In accordance with clause 16 of the Technical Regulation on medical devices, this Annex may apply to devices in Class IIa.

When these provisions apply to medical devices in Class IIa, the provisions of the second paragraph of clause 1 do not apply.

10. By way of derogation from clauses 2 and 3 of this Annex, by virtue of the declaration of conformity the manufacturer guarantees that the products in Class IIa are manufactured in conformity with the technical documentation referred to in clause 3 of Annex 8 of the Technical Regulation on Medical Devices and meet the requirements of the Technical Regulation on Medical Devices.

The manufacturer draws up the declaration of conformity in which he declares that such medical device conforms to the technical documentation referred to in clause 3 of Annex 8 of the Technical Regulation on Medical Devices.

11. For devices in Class IIa, the conformity assessment body shall assess, as part of the assessment referred to in clause 4 of this Annex, the technical documentation as described in clause 3 of Annex 8 to the Technical Regulation on medical devices (for at least one representative sample for each device subcategory) to verify the conformity of such devices with the provisions of the Technical Regulation on Medical Devices.

12. In choosing the representative samples the conformity assessment body shall take into account the similarities in design, technology, manufacturing processes and sterilization methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with the Technical Regulation on Medical Devices. The conformity assessment body shall document and keep available to the SAUMP its rationale for the samples taken.

13. Further samples shall be assessed by the conformity assessment body as part of the surveillance referred to in clauses 6 and 7 of this Annex.

Annex 8
to the Technical Regulation

PROCEDURE

for internal control of the manufacture

1. The internal control is the procedure whereby the manufacturer of his authorised representative who fulfils the obligations imposed by clause 2 of this Annex and, in the case of devices placed on the market in sterile condition, the obligations imposed by clause 5 of this Annex, ensures and declares that the devices meet the requirements of the Technical Regulation on Medical Devices.

2. The manufacturer must prepare the documentation referred to in clause 3 of this Annex. The manufacturer or his authorised representative must make the technical documentation, in particular the declaration of conformity, available upon request by the SAUMP for inspection purposes for a period of five years after the last product has been manufactured.

3. The technical documentation must allow assessment of the conformity of medical devices with the requirements of the Technical Regulation on Medical Devices.

The technical documentation must include, in particular:

a general description of the medical device, including any variants planned, and its intended use;

design drawings, methods of manufacture envisaged, and diagrams of components, sub-assemblies,circuits,etc.,

the descriptions and explanations necessary to understand the above drawings and diagrams and the operation of the product;

the result of the risk analysis and information on the standards that conform to the European harmonized standard an voluntary application of which can be considered to be evidence of the conformity of the product to the Technical Regulation on Medical Devices, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the Technical Regulation on Medical Devices if such standards have not been applied in full;

for the devices that are placed on the market in a sterile state, description of the methods used and the validation report;

the results of the design calculations and of the inspections carried out. If the device is to be connected to other devices in order to operate as intended, proof must be provided that it conforms to the requirements of the Technical Regulation on Medical Devices when connected to any such device;

the solutions referred to in clause 2 of Section I of Annex 1 to the Technical Regulation on Medical Devices;

the pre-clinical evaluation;

the clinical evaluation in accordance with Annex 10 to the Technical Regulation on Medical Devices;

the label and instructions for use.

4. The manufacturer must systematically analyse the experience gained from the use of devices after they have been placed on the market, taking account of the provisions referred to in Annex 10 to the Technical Regulation on Medical Devices, and to implement appropriate means to apply any necessary corrective action. In accordance with this undertaking, the manufacturer must notify the SAUMP immediately after learning of the following:

any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a consumer or user or to a serious deterioration in their state of health;

any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in the second paragraph of this clause to systematic recall of devices of the same type by the manufacturer.

5. With medical devices that are placed on the market in a sterile state and Class I devices with a measuring function, the manufacturer must observe not only to the provisions of this Annex but also one of the procedures referred to in Annex 3, 5, 6 or 7 to the Technical Regulation on medical devices. The provisions of the specified Annexes apply to:

in the case of products placed on the market in sterile condition, only the stages of manufacture concerned with securing and maintaining sterile conditions;

in the case of devices with a measuring function, only the stages of manufacture concerned with the conformity of the products with the metrological requirements.

In such case the provisions of clause 6 of this Annex apply.

Provisions that apply to medical devices in Class IIa

6. In accordance with clause 16 of the Technical Regulation on Medical Devices, this Annex may apply to devices in Class IIa, subject to that where the procedure defined in this Annex is applied in conjunction with the procedures defined in Annex 5, 6 or 7 to the Technical Regulation on Medical Devices, the single declaration of conformity is prepared.

Annex 9
to the Technical Regulation
STATEMENT
concerning devices for special purposes

1. For custom-made devices or for devices intended for clinical investigations the manufacturer or his authorised representative must draw up a statement.

2. The statement must contain the following information:

1) for custom-made devices:

the name and address of the manufacturer;

the details necessary for identification of the device;

a statement that the device is intended for exclusive use by a particular consumer, together with the name of the consumer;

the name of the medical practitioner or other authorised person who made out the prescription and, where applicable, the name of the health care institution concerned;

the specific characteristics of the product as indicated by the prescription;

a statement that the device concerned conforms to the requirements set out in Annex 1 to the Technical Regulation on Medical Devices and, where necessary, the list of the relevant requirements that have not been fully met, together with the explanation of this list;

2) for medical devices intended for the clinical investigations covered by Annex 10 to the Technical Regulation on Medical Devices;

the data necessary for identification of the device;

the clinical investigation plan;

the documents that confirm the insurance of subjects;

the documents used to obtain informed consent;

a statemcnt indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in clause 4 of Section II of Annex 1 to the Technical Regulation on Medical Devices;

a statement indicating whether or not the dcvice is manufactured utilising tissues of animal origin;

the opinion of the ethics committee;

the name of the medical practitioner or other authorised person and of the institution responsible for the investigations;

the place, starting date and scheduled duration of the investigations;

a statement that the medical device conforms to the relevant requirements, apart from the aspects covered by the investigations, and that every precaution has been taken to protect the health and safety of the consumer.

3. The manufacturer must keep available for the SAUMP the following documents:

1) for custom-made devices, documentation indicating manufacturing sites and information on the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of the Technical Regulation on Medical Devices.

The manufacturer must take all the measures necessary to ensure that the devices are manufactured in accordance with the above documentation.

2) for medical devices intended for clinical investigations, the documentation that must contain:

a general description of the medical device and its intended use;

design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, sub-assemblies,circuits, etc.,

the descriptions and explanations necessary to understand the above drawings and diagrams and the operation of the product;

the result of the risk analysis and information on the standards that conform to the European harmonized standards an voluntary application of which can be considered to be evidence of the conformity of the product to the Technical Regulation on Medical Devices, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the Technical Regulation on Medical Devices if such standards have been applied only partially;

if the device incorporates, as an integral part, a substance or a human blood derivative referred to in clause 4 of Section II of Annex 1 to the Technical Regulation on Medical Devices, the data on the tests conducted in this connection required to assess the safety, quality and efficacy of that substance or human blood derivative, taking account of the intended purpose of the device;

if the device is manufactured utilising tissues of animal origin, the risk management measures which have been applied to reduce the risk of infection;

the results of the design calculations, investigations, technical tests carried out etc.;

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation referred to in this clause.

The manufacturer must authorise the assessment, or audit where necessary, of the effectiveness of these measures.

4. The information contained in the declarations specified in this Annex must be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years.

5. The manufacturer must analyse and document the experience gained from the use of the custom-made devices after they have been placed on the marked, taking account of the provisions referred to in Annex 10 to the Technical Regulation on Medical Devices, and to implement appropriate means to apply any necessary corrective action. In particular, the manufacturer must immediately notify the SAUMP of:

any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a consumer or user or to a serious deterioration in their state of health;

any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in the second paragraph of this clause to systematic recall of devices of the same type by the manufacturer.

Annex 10
to the Technical Regulation
CLINICAL EVALUATION
of medical devices

General provisions

1. Confirmation of conformity of the medical device with the requirements concerning the characteristics and performances referred to in clauses 1 and 3 of section I of Annex 1 to the Technical Regulation on Medical Devices, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio must be based on clinical data. The evaluation of this data (hereinafter referred to as 'clinical evaluation') where appropriate taking account of any relevant standards, must follow a defined and methodologically sound procedure based on:

1) evaluation of the current scientific literature relating to the safety, performance, design characteristics and intended purpose of the device, where:

it is possible to demonstrate the equivalence of the device to the device to which the data relates;

the data demonstrate compliance with the relevant requirements of the Technical Regulation on Medical Devices;

2) evaluation of the results of all clinical investigations;

3) evaluation of the combined clinical data referred to in subclauses 1 and 2 of this clause.

2. In the case of implantable devices and devices in Class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

3. The clinical evaluation and its outcome shall be documented. This documentation shall be included in the technical documentation of the device.

4. The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

5. Where demonstration of conformity with the requirements of the Technical Regulation on Medical Devices based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk analysis output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the requirements of the Technical Regulation on Medical Devices by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.

6. All the parties involved in the clinical investigations must maintain the confidentiality of the data in accordance with the provisions of clause 49 of the Technical Regulation on Medical Devices.

Clinical investigations

7. The objectives of clinical investigation are:

to verify that the performance of devices conforms to the parameters referred to in Annex 1 to the Technical Regulation on Medical Devices;

to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

8. Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the World Medical Assembly. All measures relating to the protection of human subjects must be carried out in the spirit of the Helsinki Declaration.

9. Clinical investigations must be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device. These investigations must include an adequate number of observations to guarantee the scientific validity of the conclusions.

The procedures used to perform the investigations must be appropriate to the intended use of the device under examination.

Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device.

All the appropriate features, including those involving the safety and performances of the device, and its effect on patients must be examined.
All side-effect must be fully documented and immediately notified to the SAUMP in accordance with the legislation.
The investigations must be performed under the supervision of a medical practitioner or another authorised qualified person in an appropriate environment.
The medical practitioner or other authorised person must have access to the technical and clinical data regarding the device under examination.
The written report, signed by the medical practitioner or other authorised person responsible, must contain evaluation of all the data collected during the clinical investigation.

Annex 11
to the Technical Regulation

REQUIREMENTS

regarding the national mark of conformity

The national mark of conformity shall be applied in accordance with the description of the national mark of conformity, as approved by the Resolution No. 1599 of the Cabinet of Ministers of Ukraine of 29 November 2001 (*Ofitsiinyi Visnyk Ukraiiny*, 2001, No. 49, Art. 2188).

If the mark is reduced or enlarged, the proportions must be respected.

The size of the national conformity mark may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

APPROVED
by Resolution No. 753 of the Cabinet of Ministers of Ukraine
of 2 October 2013

ACTION PLAN

for application of the Technical Regulation on Medical Devices

Actions	Parties responsible	Execution period
1. Where appropriate, to bring their own regulations in compliance with the Technical Regulation on Medical Devices (hereinafter referred to as the 'Technical Regulation')	MOH Ministry for Economic Development	constantly
2. To develop and revise the national standards conforming to the European harmonized standards	SAUMP Ministry for Economic Development	-"-
3. To compile and publish the list of the national standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of conformity of devices with the Technical Regulation on Medical Devices	Ministry for Economic Development SAUMP	-"-
4. To designate conformity assessment bodies for assessment of the conformity of devices with the requirements of the Technical Regulation and publish the list of these bodies	-"-	-"-
5. To prepare, where necessary, and submit for review to the Cabinet of Ministers of Ukraine proposed variations to the Technical Regulation	MOH SAUMP Ministry for Economic Development	-"-
6. To apply the Technical Regulation in a mandatory manner	SAUMP	Starting from the third quarter of 2015

APPROVED
by Resolution No. 753 of the Cabinet of Ministers of Ukraine
of 2 October 2013

LIST

of the revoked Resolutions of the Cabinet of Ministers of Ukraine

1. Resolution of the Cabinet of Ministers of Ukraine of 9 November 2004 No. 1497 'On approval of the Procedure for state registration of medical equipment and medical devices' (*Ofitsiinyi Visnyk Ukraiiny,* 2004, No. 45, Art. 2970).
2. Resolution No. 536 of the Cabinet of Ministers of Ukraine of 11 June 2008 'On approval of the Technical Regulation on Medical Devices' (*Ofitsiinyi Visnyk Ukraiiny*, 2008, No. 43, Art. 1415).
3. Resolution No. 1099 of the Cabinet of Ministers of Ukraine of 17 December 2008 'On amending the Procedure for state registration of medical equipment and medical devices' (*Ofitsiinyi Visnyk Ukraiiny,* 2008, No. 98, Art. 3237).
4. Point 5 of amendments to the resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 1122 of the Cabinet of Ministers of Ukraine of 20 December 2008 (*Ofitsiinyi Visnyk Ukraiiny*, 2008, No. 100, Art. 3313).
5. Point 2 of amendments to the resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 275 of the Cabinet of Ministers of Ukraine of 17 March 2010 'On certain issues of the state quality control of medicinal products' (*Ofitsiinyi Visnyk Ukraiiny*, 2010, No. 21, Art. 868).
6. Point 3 of amendments to the resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 902 of the of the Cabinet of Ministers of Ukraine of 4 October 2010 (*Ofitsiinyi Visnyk Ukraiiny*, 2010, No. 75, Art. 2668).
7. Point 5 of amendments to the resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 902 of the of the Cabinet of Ministers of Ukraine of 4 October 2010 (*Ofitsiinyi Visnyk Ukraiiny*, 2010, No. 75, Art. 2668).
8. Point 8 of amendments to the resolutions of the Cabinet of Ministers of Ukraine concerning protection of documents and goods with security holograms, as approved by Resolution No. 86 of the of the Cabinet of Ministers of Ukraine of 9 February 2011 (*Ofitsiinyi Visnyk Ukraiiny*, 2011, No. 10, Art. 463).
9. Point 2 of amendments to the resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 1171 of the of the Cabinet of Ministers of Ukraine of 16 November 2011 (*Ofitsiinyi Visnyk Ukraiiny*, 2011, No. 89, Art. 3236).
10. Point 4 of amendments to the resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 1171 of the of the Cabinet of Ministers of Ukraine of 16 November 2011 (*Ofitsiinyi Visnyk Ukraiiny*, 2011, No. 89, Art. 3236).
11. Resolution No. 548 of the Cabinet of Ministers of Ukraine of 20 June 2012 'On amending the Procedure for state registration of medical equipment and medical devices' (*Ofitsiinyi Visnyk Ukraiiny*, 2012, No. 47, Art. 1833).
12. Point 1 of amendments to the resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 632 of the of the Cabinet of Ministers of Ukraine of 28 August 2013 (*Ofitsiinyi Visnyk Ukraiiny*, 2013, No. 69, Art. 2533).