CABINET OF MINISTERS OF UKRAINE
RESOLUTION
No. 753 of 2 October
Kyiv

On approval of Technical Regulations for medical devices

In accordance with article 14 of the Law of Ukraine "On standards, technical regulations, and conformity assessment procedures" the Cabinet of Ministers of Ukraine hereby **resolves**:

1. To approve the Technical Regulations on medical devices and the action plan for its application, which is attached hereto.

2. To request the State Administration of Ukraine on Medicinal Products to ensure implementation of the Technical Regulations approved by this Resolution.

3. To revoke the Resolutions of the Cabinet of Ministers of Ukraine according to the list attached hereto.

4. This resolution comes into effect after 6 months from the date of publication, except paragraphs 1,3-6, 8, 9 and 11, list of the Resolutions of the Cabinet of Ministers of Ukraine that have been revoked, as approved by this Resolutions, which shall come into force from 1 July 2014.

Prime Minister of Ukraine **M.AZAROV**

ID. 70

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

TECHNICAL REGULATIONS
on medical devices

{For coming into force and amendments to the Technical Regulations, see section III of Lawакону № 3164-IV of 01.12.2005*}*

General

1. These Technical regulations shall apply to medical devices and their accessories (hereinafter referred to as “medical devices”). For the purposes of these Technical Regulations, accessories shall be treated as medical devices.

These Technical Regulations have been developed on the basis of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

2. For these Technical Regulations, the following definitions shall apply:

1) “putting into service” means a device has been made available to the final user and/or customer 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, 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 patient.

Mass-produced devices which is 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 a legal person or natural person-entrepreneur responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or by a third party authorized to act on his behalf.

The obligations of the manufacturers also apply to the legal person or natural person-entrepreneur who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns 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 their intended purpose for an individual patient;

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 common technologies;

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 the instruction for use;

8) “clinical data” means the safety and/or performance information that is generated from the intended use of a device. 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 performance of the medical device), intended by the manufacturer to be used in human for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, 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, 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 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 natural person-entrepreneur who is a resident of Ukraine or registered in accordance with Ukrainian legislation, represents a foreign economic agent and is duly authorised by the manufacturer to take legal actions on behalf of the manufacturer with regard to the latter's obligations under these Technical Regulations;

For the purpose of these Technical Regulations, “national standards" take the meaning defined in the Law of Ukraine "On standartization"; “declaration of conformity”, “supplier” take the meanings defined in the Law of Ukraine "On confirmation of conformity"; “conformity assessment body”, “risk”, “technical regulations” take the meanings defined in the Law of Ukraine "On standards, technical regulations, and conformity assessment procedures"; and “medicinal products” take the meaning defined in the Law of Ukraine "On medicines".

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

However, 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 to medical devices presented 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 which has effect on the body that is ancillary to that of the device, that device is subject to conformity assessment and putting into service in accordance with these Technical Regulations.

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 which has effect on the body that is ancillary to that of the device, that device is subject to conformity assessment and putting into service as medical devices in accordance with these Technical Regulations.

5. These Technical Regulations shall not apply to:

1) in vitro diagnostic devices;

2) active implantable devices

3) medicinal products covered by the Law of Ukraine "On Medicines". The chief criterion in deciding whether a product falls into the category of medicinal products or medical devices is the principal mode of action of the product;

4) cosmetic products;

5) human blood, blood products, plasma or blood cells of human origin or to devices that incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of devices listed in subparagraph two of paragraph 4 of these Technical Regulations;

6) anatomical materials of human origin and medical devices incorporating or derived from anatomical materials of human origin, with the exception of devices listed in subparagraph two of paragraph 4 of these Technical Regulations;

7) anatomical materials of animal origin, with the exception of devices that are 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 shall also meet the relevant occupational safety and health requirements set forth in the Technical regulations for personal protective equipment approved by Resolution of the Cabinets of Ministers of Ukraine № 761 of 27 August 2008 (Official Bulletin of Ukraine 2008, № 66, art. 2216).

7. The Technical regulations for electromagnetic compatibility of equipment approved by Resolution of the Cabinets of Ministers of Ukraine № 785 of 29 July 2009 (Official Bulletin of Ukraine 2009, № 58, art. 2028) shall not apply to devices governed by these Technical Regulations.

8. These Technical Regulations shall not affect the application of the Technical regulations for sealed sources of ionizing radiation approved by Resolution of the Cabinets of Ministers of Ukraine № 1382 of 5 December 2007 (Official Bulletin of Ukraine 2007, № 93, art. 3408).

Placing on the market and putting into service

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

Medical devices that meet the national standards included into the list of national standards that conform to harmonized European standards, voluntary adoption of which can be considered to be an evidence of device conformity to these Technical Regulations, are considered to meet the requirements of these Technical Regulations.

The national standards conforming to the harmonized European standards, voluntary adoption of which can be considered to be an evidence of the device conformity to these Technical Regulations, include monographs of the State Pharmacopoeia of Ukraine, in particular those concerning surgical suture material and interaction between medicinal products and materials used in devices that incorporate such medicinal products.

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

Requirements to medical devices

11. The medical devices shall meet the requirements set out in Annex 1 which apply to them with account taken of the intended purpose of the devices.

12. The medical devices that are also machinery within the meaning of the Technical regulations for the safety of machinery approved by Resolution of the Cabinet of Ministers of Ukraine № 62 of 30 January 2013 (Official Bulletin of Ukraine 2013, № 9, art. 344) shall meet the general essential health and safety requirements that are to be met during machinery design and manufacture and are set out in Annex 1 to the Technical regulations for the safety of machinery if such requirements are more specific than those set out in Annex 1 hereto.

Language of the information provided to the users or consumers

13. Information that shall be provided to the user/customer in accordance with "Information supplied by the manufacturer" of Annex1 shall be set out in accordance with the Law of Ukraine "On the principles of language politics".

Classification

14. Medical devices are divided into 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 the medical devices falling within Class III (with exception of custom-made devices or those intended for clinical investigations), the manufacturer shall follow the procedure described in Annex 3, or the procedure described 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 the medical devices falling within Class IIa (with exception of custom-made devices or those intended for clinical investigations), the manufacturer shall follow the procedure described in Annex 8 coupled with either the procedure set out in Annex 5, or the procedure described in Annex 6, or the procedure set out in Annex 7.

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

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

18. In order to affix the national conformity mark to the medical devices falling within Class I (with exception of custom-made devices or those intended for clinical investigations), the manufacturer shall follow the procedure described 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, which have been carried out in accordance with these Technical Regulations before, during and after the manufacture.

21. The manufacturer may instruct the 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 his choice within the framework of the tasks for which the body has been designated.

23. The conformity assessment body may require (where duly justified) any information or data necessary for establishing and confirming the conformity to these Technical Regulations 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 remain valid for five years. Their period of validity may be extended for the next five years on 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 paragraphs 15-19 of these Technical Regulations shall be carried on in accordance with the Law of Ukraine "On the principles of language politics".

26. For individual devices that do not meet the requirements set out in paragraphs 15-19 hereof but whose use is in the interest of protection of health and life of a specific person, the procedure for placing on the market and putting into service shall be established by the MOH.

Particular procedure for medical device systems and procedure packs and procedure for sterilization

27. This section shall apply to the medical device systems (hereinafter referred to as "systems") and procedure packs.

28. Any legal person or natural person-entrepreneur 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 in which shall be stated that:

this legal person or natural person-entrepreneur 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;

this legal person or natural person-entrepreneur has put the system or procedure pack together 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 incorporate devices which 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 and as such be subjected to the respective procedure set out in paragraphs 15-19 hereof.

29. Any legal person or natural person-entrepreneur who sterilizes, for the purpose of placing on the market, systems or procedure packs referred to in paragraph 28 of these Technical Regulations or other medical devices bearing the national conformity mark that are intended by their manufacturers to be sterilized 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 for sterility assurance. The person shall draw up a declaration stating that sterilization has been carried out in accordance with the corresponding manufacturer's instructions.

30. The medical devices referred to in paragraphs 28 and 29 hereof are not required to bear an additional national conformity mark, but shall be accompanied by the information stated in 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 paragraphs 28 and 29 of these Technical Regulations shall retain these declarations and grant access to them to 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, and any other legal person or natural person-entrepreneur engaged in the activities referred to in paragraphs 27-30 hereof shall provide the SAUMP with information on his address and the list and descriptions of the devices concerned.

Clinical investigation

32. In the case of devices intended for clinical investigations, the manufacturer or the authorised representative registered in Ukraine shall follow the procedure referred to in Annex 9 and notify the SAUMP by submitting the statement mentioned in paragraph 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 notification to the SAUMP, unless the executive bodies 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 the 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 paragraph 33 hereof) immediately after the date of notification, provided that the ethics committee has approved (issued a favourable opinion on) the programme of the investigation in question.

35. The clinical investigations are to 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 put the clinical investigation on hold 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 subaragraph 8 of paragraph 9 of Annex 10 and provide access to it upon request of the state market surveillance bodies.

38. The provisions of paragraphs 32 and 33 hereof do not apply where the clinical investigations are conducted using devices which are authorized in accordance with paragraphs 15-19 hereof to bear the national conformity mark, unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The relevant provisions of Annex10 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 conforming to the harmonized European standards shall be presumed to meet the relevant criteria.

40. Where a designated conformity assessment body does not meet the criteria set out in paragraph 39 hereof, the respective designation shall be revoked, with account taken 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 respective conformity assessment bodies about certificates suspended, withdrawn or refused and, on request, about certificates issued and refused, and provides other information.

42. Where a conformity assessment body finds that the requirements of these Technical Regulations have not been met or are not being met by manufacturer or that a certificate 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 marking

43. Medical devices (with the exception of custom-made devices or those intended for clinical investigations) that are considered to meet the essential requirements referred to in paragraph 10 hereof, must bear the national mark of conformity when placed on the market.

44. Requirements to the national conformity marking are set out in Annex 11. The national conformity mark shall be affixed to the medical device and to the instruction for use. The marking shall be visible, legible and indelible. Where applicable, the national conformity mark shall also appear on the outer packaging.

Next to the national conformity mark shall be affixed the identification number of the conformity assessment body responsible for implementation of procedures referred to in Annexes 3 and 5-7 (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 affected.

46. Where the SAUMP or revenue bodies find out that the national conformity mark has been affixed unduly or is missing in violation of these Technical Regulations, the manufacturer of his authorised representative shall bring the medical devices into compliance with the requirements of these Technical Regulations.

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

48. Paragraphs 46 and 47 shall also apply where the national conformity mark has been affixed in accordance with the procedures set out in these Technical Regulations, on products that are not covered by these Technical Regulations.

Confidentiality

49. All parties applying these Technical Regulations shall observe confidentiality of all information obtained in carrying out their tasks.

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