



CABINET OF MINISTERS OF UKRAINE

DECREE
of 11/07/2008 No 536
Kyiv

On approval of the Technical Regulation
concerning medical products

In accordance with Article 14 of the Law of Ukraine “On Standards, Technical Regulations and Conformity Assessment Procedures” (3164-15) the Cabinet of Ministers of Ukraine hereby **orders**:

1. To approve the Technical Regulation concerning medical products (hereinafter – the Technical Regulation) that is enclosed.

2. To designate the Ministry of Health as a responsible body for the introduction and application of the Technical Regulation as well as supervising the compliance with requirements thereof.

3. The Ministry of Health and the Ministry of Industrial Policy together with the State Committee for Technical Regulation and Consumer Policy shall develop and approve in a month term the road map for the introduction of the Technical Regulation.

Prime Minister of Ukraine

Ju. Tymoshenko

APPROVED
by the Decree of the Cabinet of Ministers of Ukraine
of 11/07/2008 No 536

TECHNICAL REGULATION
concerning medical products

General provisions

1. This Technical Regulation determines the general requirements for medical products and the related safety and procedures to confirm their compliance with said requirements.

2. For the purposes of this Technical Regulation, the following terms shall take the following meanings:

1) commissioning – readiness of the medical product for first use and for an intended purpose;

2) placing on the market – first appearance of medical product, with the exception of products for clinical trials, for the distribution and/or for use for an intended purpose on the Ukrainian market irrespective of whether this product is brand new or modified;

3) medical products – any tools, apparatus, instruments, gadgets, equipment, implants, materials and other devices, including invasive and those that are intended not for achieving a major medicinal purpose in a patient but for assisting pharmacological, immunobiological or metabolic remedies to achieve this objective, as well as devices that are used either alone or in combination, including the software necessary for their proper functioning, as intended by the manufacturer and with the purpose to provide:

preventive measures, diagnostics, curing, monitoring and alleviating the condition of the patient when it is unwell, injured, disabled as well as compensation for organ failure or physical disability;

investigation, replacement or modification of the structure (anatomy) of organs, tissues or physiological processes;

monitoring the process of conception.

Any equipment that is supplied as a set with medical products and intended to be coupled with other external (additional) equipment shall be considered as an integral part of those medical products;

4) custom-made medical products – any medical products manufactured specifically following the prescription of a properly qualified physician with specified parameters and design and intended to be used for a specified patient.

The abovementioned prescription could be issued by a different, fully qualified person.

Medical products of mass production that require adaptation according to specific requirements of a properly qualified physician or any other professional user are not regarded as custom-made devices;

5) medical products intended for clinical studies – medical products intended for use by a properly qualified physician during their studies in a clinic.

During clinical studies any other person who has the necessary qualifications to carry out such studies is equal to the properly qualified physician;

6) use as intended – use of medical products in compliance with the data specified by the manufacturer in the identification mark, user manuals and/or advertising materials;

7) kit – items that are not medical products, but which are specifically intended by the manufacturer to be used together with medical products for the purpose of their intended use.

Other terms shall be used in the meaning specified in Laws of Ukraine “On Confirmation of Compliance” (2406-14), “On Standardisation” (2408-14), “On Accreditation of Conformity Assessment Bodies” (2407-14), “On Standards, Technical Regulations and Conformity Assessment Procedures” (3164-15), “On Medicines” (123/96-VR).

3. Requirements established by this Technical Regulations are mandatory for:

manufacturers of medical products and the corresponding kit;

persons – residents of Ukraine who are authorised by the manufacturer (hereinafter the authorised representative);

persons who are responsible for launching medical products on the market or putting them into service if the manufacturer or the authorised representative do not exercise activities within Ukraine (hereinafter person who placed medical products on the market or put them into service);

key executive authorities and their bodies functioning in technical regulations and supervision of the safety of medical products and corresponding kits (hereinafter key executive bodies);

designated bodies for assessing the conformity of medical products and kits that comply with the requirements established in the Decree of the Cabinet of Ministers of Ukraine of 24/01/2007 No 59 (59-2007-p) “On Approval of the Order of

the Implementation of Procedure of Appointment of Bodies Assessing the Conformity of Products, Processes and Services to Requirements of Technical Regulations” (Ofitsijnyj Visnyk Ukrainy, 2007, No 6, p. 223) (hereinafter designated bodies).

4. The medical product intended for humans shall be covered by this Technical Regulation, as well as by the Law of Ukraine “On Medicines” (123/96-VR) according to the requirements concerning the medicine.

If the medicine and the medical product constitute an integral whole and the latter cannot be re-used, such product shall be regulated by the Law of Ukraine “On Medicines” (123/96-VR). Requirements established in this Technical Regulation cover the parameters of the medical product related to its safety and effectiveness only.

If a substance that constitutes an integral part of a medical product that is capable of effecting an auxiliary action on a patient and if applied is considered as medicine, then it shall comply with the requirements of this Technical Regulation.

5. Electromagnetic compatibility of medical products is regulated by DSTU IEC 60601-1-2-2001 “Medical Electrical Equipment”.

The Technical Regulation concerning confirmation of compliance of electromagnetic compatibility does not cover medical products.

6. Medical products can be divided into classes of potential risks on application: I, IIa, IIb and III. Allocation of medical products to one or another class is based on the vulnerability of the patient, taking into account the potential risks associated with design and manufacturing of those products. This allocation is carried out with the help of criteria and rules of classification defined in DSTU 4388:2005 “Medical Products. Classification with Regards to Potential Risks on Application. General Requirements”.

If the dispute arises between the manufacturer and the designated body regarding determination of the class of medical product, the case shall be resolved by the Ministry of Health in compliance with the established order.

7. Placing medical products that are covered by this Technical onto the market and putting them into service shall be allowed if this does not endanger life and health of patients, users and other persons, on condition that the correct installation, servicing and application are provided.

8. The manufacturer or authorised person or the person who put medical products into service or placed them on the market shall be held responsible in accordance with legislation for the implementation of all procedures of conformity assessment established in this Technical Regulation.

Those requirements also concern legal entities and natural persons who assemble, renovate and/or provide packaging and marking of prepared medical products.

The abovementioned requirements do not concern individuals who are not manufacturers but assemble and commission medical products that already exist on the market following their intended application and for specified patients.

9. Compliance of medical products with requirements of National Standards is a proof of compliance of products with this Technical Regulation.

The list of National Standards shall include monographs of European Pharmacopoeia concerning surgical sutures and interactions between medicines and materials that are used in medical products that contain such medicines. Monographs shall be submitted by the State Committee for Technical Regulation and Consumer Policy.

10. Before placing medical products that have passed conformity assessment according to the procedures established by this Technical Regulation on the market or putting them into service, they shall be labelled with the National Mark of Conformity in accordance with the Decree of the Cabinet of Ministers of Ukraine of 29/11/2001 No 1599 (1599-2001-p) "On Approval of Description and Rules of Application of the National Mark of Conformity" (Ofitsijnyj Visnyk Ukrainy, 2001, No 49, p. 2188).

11. The presence of the National Mark of Conformity on medical products indicates that the natural person, who has performed labelling or who is responsible for the task, has checked and testifies to the conformity of the medical products with the requirements of this Technical Regulation, that covers those products, and that products have passed the correct procedures of conformity assessment.

12. If medical products fall within the framework of other technical regulations that may be labelled with the National Mark of Conformity, then medical products shall also comply with requirements of those technical regulations. Conformity of medical products with all such technical regulations shall be a condition for labelling with the Sign.

In the event that one or several technical regulations foresee the right of the manufacturer to choose the method of confirmation of compliance, labelling with the National Mark of Conformity signifies conformity with only those technical regulations only that have been used by the manufacturer. In this case, all documents, notifications and instructions that are enclosed with the medical products shall incorporate references to the technical regulations that have been used.

13. If it has been discovered that the National Mark of Conformity has been used in violation of the requirements of this Technical Regulation, then the manufacturer, its authorised representative, or the person who placed the medical products on the market or put them into service shall take actions to cease violation, and shall ensure that the medical products conform to the requirements of this Technical Regulation.

In the event that the law is violated, key executive authorities shall undertake the appropriate action to restrict or to ban such medical products from being placed on the market or shall withdraw them from the market.

14. If custom-made medical products conform to the requirements of clause 54 of this Technical Regulation, they shall not be labelled with the National Mark of Conformity.

15. If a physician uses any medical product that is intended for clinical studies and conforms to the requirements of Clause 56 of this Technical Regulation, they shall not be labelled with the National Mark of Conformity.

16. Exposing of medical products, that did not meet the conformity assessment procedures according to the requirements of this Technical Regulation, on trade fairs, exhibitions, demonstrations of medical products shall be allowed on condition that the manufacturer has performed distinct tagging with the information that those products cannot be placed on the market or put into service until they conform to the requirements set out in this Technical Regulation.

17. Following the results of their application, the Ministry of Health will undertake continuous monitoring and assessment of any information about medical products that have been placed on the market or put into service, and concerning:

failure or degeneration of performance levels and/or properties of products, any misleading information on the label or in the user manual, that could result or has resulted in death or serious health deterioration of patients, users and other individuals;

technical or medical reasons for the alteration of performance levels and/or properties of products that resulted in systematic withdrawal thereof by the manufacturer.

Physicians and public health institutions shall submit the abovementioned information to the Ministry of Health, manufacturers or their authorised representatives in order to keep records and to carry out analyses.

18. If it has been revealed that medical products with correct installation, servicing and application provided are still prone to endanger the health and safety of patients, users and other persons, all possible actions shall be taken to withdraw such products from the market or to ban or to restrict in compliance with legislation their commissioning or placing on the market.

Requirements concerning the safety of the application of medical products

19. The application of medical products as intended shall not pose a risk for the health and safety of patients, users and other individuals.

It is assumed that any potential risks which might be related to the application of medical products are tolerable when compared to positive effect for the patient, and if an improved quality of life and protection of health is provided.

20. Medical products shall correspond to exploitation properties, specified by the manufacturer, and shall be designed, produced and packaged so as to function as intended by the manufacturer.

21. If, during operation, the medical product under proper application conditions or during storage under terms and conditions, specified by the manufacturer is prone to alter its performance levels and/or properties that are specified in Clauses 25-44 of this Technical Regulation, these parameters and properties shall not deteriorate to a degree when clinical state, safety of patients, users and other individuals are subjected to risk.
22. Medical products shall be designed, produced and packaged in the way that transportation, application or storage under conditions specified by the manufacturer do not cause deterioration of their parameters and/or properties.
23. Any unwanted side effects of the medical product shall present tolerable potential risks on its application when compared to its intended effect.
24. Technical solutions implemented by the manufacturer in the process of design and production of medical products shall correspond to the most recent safety requirements within the industry.

When making solutions, the manufacturer shall be predominantly governed by the following guidelines:

elimination or maximum reduction of potential risks on the application of medical products;

taking proper protection measures including alarm signals to avoid potential risks that cannot be eliminated on the application of medical products;

informing users about the potential risks on the application of medical products that exist because proper protection measures cannot be used.

Requirements for development and production of medical products

25. Medical products shall be designed, produced and packaged so as to ensure performance levels and/or properties specified in clauses 25-50 of this Technical Regulation.

In order to achieve this, special care shall be taken in:

the selection of materials in part of their toxicity and, if required – their flammability;

the compatibility of materials with tissues, cells and liquids of the human body, when taking into account the intended use of the product;

the minimisation of risks of contamination by medical products and the influence thereof on individuals who take part in the transportation, storage and application thereof, taking into account the intended use of the product;

the effect on human tissues, for how long and how often it happens;

the safety of use in combination with materials, substances and gases that are in contact with medical products under conditions of their proper application or during treatment procedures;

the minimisation of risks arising from substances leaking from the equipment;

the minimisation of the risk of accidental contact of dangerous substances with the product, taking into account its engineering design, materials and working environment;

the elimination or minimisation of risk of contagion of patients, users and other individuals.

26. Devices, intended for the application of medicines, shall be developed and produced considering the compatibility with such medicines and in accordance with established requirements for the application of such devices and under the condition of preserving their properties according to intended use.

27. If the device contains, as an integrated part, a substance that can be considered a medicine when used on its own, and that is intended to cause an effect on the human body that is complementary to the effect of the device, it shall be necessary to check, following the established order, the safety, quality and efficiency of this substance, taking into account the intended use of the device.

28. Animal tissues that are employed in medical products following the intended use shall be taken from animals that have passed the State disease and sanitation inspection.

State bodies of veterinary medicine shall keep data on the territorial origin of such animals.

Processing, storage, testing and treatment of animal tissues, cells and other substances shall be carried out under maximum protection. In particular, protection against viruses and other diseases shall be performed by the application of approved methods of their destruction or viral inactivation during the production process.

29. Medical products that are supplied sterile shall be designed, produced, sterilised according to approved methods in proper conditions and wrapped into disposable packaging and/or following corresponding procedures that ensure their sterility, if placed on the market. They shall also be transported and stored in proper conditions before the protective packaging is damaged or opened.

30. Packaging systems for non-sterile medical products shall ensure their proper purity degree, minimise the risk of bacterial infection, if products are supposed to be sterilised before use, adequacy for application with taking into account their sterilisation method, specified by the manufacturer.

31. The packaging and/or labelling shall enable individuals to distinguish identical or similar medical products that are supplied both as sterile and non-sterile.

Engineering and ecological properties of medical products

32. If medical products are intended for use together with other products or equipment, such combination, including an interface system, shall be safe and shall not deteriorate parameters of products. Any restrictions concerning the application of such products shall be identified on the label or in the user manual.

33. Medical products shall be designed and manufactured so as to minimise risks as follows:

causing injury, related to physical characteristics, in particular - to volume/pressure ratio, dimensions and ergonomic parameters;

related to following reasonably expected external conditions – magnetic fields, electric interactions, electrostatic discharge, pressure, temperature, pressure gradient and acceleration;

interaction with other products that are used for investigations and treatments;

related to inability to service or to calibrate (as in the case of implantation) due to the ageing of materials used or fall in accuracy of any measuring or monitoring instrument;

34. Medical products shall be developed and produced so as to minimise the risk of items catching fire or explosion under normal conditions of use and in the event of accidental failure.

Special attention should be paid to devices on application of which action of inflammable substances or substances that could cause an ignition is expected upon them.

Medical products with measuring function

35. Medical products with measuring function shall be designed and produced in the way to ensure appropriate accuracy and stability in proper limits, taking into account their intended use.

A display board for measured values, controls and indicators shall be developed in compliance with ergonomic principles and with account of intended use of the product.

Measurements taken with the aid of medical products with a measuring function shall be presented in units SI.

Medical radiation products

36. Medical radiation products shall be designed and produced so as to ensure the prevention of:

the irradiation of patients, users and other individuals without the restriction of levels that are necessary to achieve therapeutic or diagnostics objectives;

harmful irradiation of patients, users and other individuals.

If medical products are intended to radiate on a dangerous level that is necessary for special medical objectives, when the advantages are considered to outweigh the risk of irradiation, the user shall be capable of controlling such radiation. Such products shall be developed and produced so as to ensure reproducibility and not exceeding tolerances of preset parameters.

If medical products are intended to create potentially dangerous visible and/or invisible radiation, they shall be equipped with systems of visual and audible warning of such radiation.

The user manuals for medical radiation products shall contain detailed information about types of radiation, method of protection for patients, users and other individuals and ways to prevent misuse.

37. Medical ionising radiation products shall be designed and produced according to the intended use thereof and so as to ensure the regulation and control of quantitative and qualitative parameters of radiation.

38. Medical ionising radiation products intended for X-ray diagnostics shall be developed and produced so as to ensure the required level of image quality and/or initial indexes for intended medical objectives is attained with minimised risks of irradiation of patients, users and other individuals.

39. Medical ionising radiation products intended for X-ray treatment shall be developed and produced so as to ensure reliable control over and regulation of optimal irradiation doze, type of beam, power and intensity (if needed) of radiation.

Requirements to medical products that are connected to power source or equipped with such source

40. Medical products with electronic software systems shall be designed and produced so as to ensure reproducibility, reliability and effectiveness of these systems according to the intended use of the product. It shall be necessary to take actions to eliminate or minimise risks, arising upon system failure.

If, during the application of medical products, the safety of patients relies on an internal power source, then the means to determine the condition of this source shall be provided.

If, during the application of medical products, the safety of patients relies on an external power source, the alarm system shall be provided to signal power failure.

Medical products, intended to monitor one or several clinical parameters of the patient, shall be equipped with a signal system that warns users about situations that may cause death or serious health deterioration of patients, users and other individuals.

41. Medical products that are connected to a power source, or equipped with such source shall be designed and produced whilst ensuring:

the prevention risk of creating electromagnetic fields that may interfere with other products and equipment on condition of proper use;

the elimination or minimising risk of electrocuting on the condition of their proper installation and use, as well as on occasional misuse;

the protection of patients, users and other persons from hazards, related to the strength and durability of the device and moving parts;

minimising hazards originating from vibrations created by the product including the means to restrict vibration especially at its source, apart from vibration that is one of working parameters;

minimising hazards originating from noise generated by the product, including means of restriction noise especially at its source, if noise belongs to working parameters.

Lead terminals and other terminals, connecting the medical product to the electricity source, gas supply, hydraulic and pneumatic power mains which are touched by the user, shall be developed and produced so as to minimise all potential risks.

42. Accessible parts of medical products (except for parts and areas intended for the supply of heat or heating up to specified temperatures) and areas around them shall not gain potentially hazardous temperatures under condition of their proper use.

43. Medical products, intended for the relay of energy or substances to patients, shall be designed and produced so as to ensure setting up and maintaining the intensity of transmission with high accuracy to keep patients, users and other individuals safe.

44. Medical products shall be equipped with a means to prevent and/or to signal any non-conformity in intensity of energy transmission that could be hazardous. They shall also comprise (if possible) a suitable means of preventing accidental and dangerous surge of energy and/or excess of substances, with clear and comprehensible indication of handling and signalling functions.

If the labelling of the medical product contains instructions or labels that are essential for its operation and indicate preset and/or regulated parameters, such information shall be clear to the user and the patient.

Information that shall be provided by the manufacturer

45. Every medical product shall be accompanied with information that is essential for its safe use, with accounting for background and qualification of users and identifying the manufacturer.

Information shall be provided in Ukrainian and any other language at the manufacturer's discretion, it shall be placed on the label and in the user manual.

Information that is essential for safe use of the medical product shall be placed directly on the product and/or on the packaging, or in suitable cases on the transport container. If products cannot be packaged individually, information shall be placed in a booklet that shall be supplied with one or more medical products.

The user manual shall be included with the packaging of each medical product.

46. Information concerning the application of the medical product may be provided in codes. All codes or identification colours shall comply with corresponding standards. In cases, when there are no established standards, code and colour legends shall be indicated in all paperwork accompanying the product.

47. The label on the medical product shall contain the following information:

1) name and geographical location of the manufacturer. For medical products that are imported in order to be placed on the market, the label, external packaging or user manual (when there is no manufacturer's registered office in Ukraine) shall contain the name and location of the authorised representative or the responsible supplier, registered in Ukraine;

2) data, needed for the identification of the medical product and its specification by the user;

3) the word "STERILE", code of the batch after the word "BATCH", or serial number, date before which safe use of the product is guaranteed, information that the product is disposable (if applied);

4) the words "custom-made product" (custom-made medical product) and "for clinical studies only" (intended for clinical studies);

5) any special conditions for the storage of the medical product and/or handling it, special operation instructions and preventive measures and/or warnings;

6) year of manufacture – for active medical products;

7) sterilisation method – for sterile medical products.

48. If the intended application of the medical product is not clear to the user, the manufacturer shall clearly indicate it on the label and in user manual.

Medical products and spare parts shall be identified by batch numbers to avoid any potential risk related to these medical products and spare parts.

49. Where appropriate, the user manuals may contain:

1) data from clause 47 (with the exception of sub-clauses 3 and 4) of this Technical Regulation;

2) working properties and any unwanted side effects;

3) detailed description of parameters of these products or equipment that is essential for the correct selection and safe joint application (if the medical product for the purpose of its intended use has to be combined or connected with other medical products or equipment);

4) full scope of information that is necessary for the inspection of proper installation of the medical product and its safe use together with data on the specifics and frequency of technical servicing and calibration to ensure the accurate and safe operation for the entire working lifespan;

5) information that is necessary to prevent risks, associated with the implantation of the medical product;

6) information about the risk of interference, associated with the accommodation of the medical product during special investigations or patient treatments;

7) comprehensive guidance for the occasion of damage of sterile packaging and methods for iterated sterilisation;

8) information about processes for preparation for iterated use, including cleaning up, disinfection, packaging, method of sterilisation and any restrictions on iterations' number (provided medical products are intended for repeated use).

If medical products require sterilisation before use, this requirement shall be indicated either on the packaging or on the product itself. Instructions on cleaning up and sterilisation shall comply with the provisions specified in clauses 19-24 of this Technical Regulation;

9) detailed information on pre-treatment that should be applied before use of the medical product (e.g. sterilisation, completion of assembling);

10) detailed information on the character, type, intensity and transmission of the radiation employed (if medical products are intended for radiation for medical purposes).

User manuals for medical products shall also contain information that allows medical staff to warn a patient about all possible contraindications as well as about:

precautionary measures if working parameters of medical products change;

precautionary measures from the effect of magnetic fields, external electric oscillations, electrostatic discharge, pressure and its fluctuation, acceleration, sources of thermo-induced ignition, etc.;

medicines and treatments that are intended for use together with medical products and in particular about any restrictions on the selection of these remedies;

precautionary measures against any special and extraordinary hazards, related to the disposal of medical products;

medicines that constitute an integrated part of the medical product;

accuracy rate, specified for the medical product with measuring function.

50. If compliance with requirements that are established in this Technical Regulation is based on clinical data, such data shall be generated according to DSTU 4659-1-2:2006 “Clinical investigations of medical devices for human subjects” (ISO 14155-1-2; 2003, MOD).

General requirements

51. It shall be mandatory for the manufacturer:

1) to carry out systematic analysis of medical products’ operation and corresponding measures to undertake any necessary corrective actions taking into account the performance levels and/or properties of medical product and related risks;

2) to inform the Ministry of Health of Ukraine immediately about:

any failures or deterioration of performance levels and/or working standards of the medical product as well as any inadequacy in the label and user manual, that may cause death or severe deterioration to the health of patients, users and other individuals;

any technical and medical precautions, concerning the performance levels and/or working standards of the medical product, that because of reasons, determined in sub-clause 1 of this clause, shall result in the withdrawal of medical products of the same type by the manufacturer.

Conformity assessment procedures

52. The assessment of conformity of medical products that are marked with the National Mark of Conformity shall be performed with the use of modules of conformity assessment procedures or their combinations in compliance with the Decree of the Cabinet of Ministers of Ukraine of 07/10/2003 No 1585 (p.1585-2003) “On Approval of the Technical Regulation of Conformity Assessment Modules and Requirements Towards Labelling with the National Mark of Conformity, that are Used in Technical Regulations” (Ofitsijnyj Visnyk Ukrajinj, 2003, No 41, p. 2175;

2007, No 1, p.31) taking into account the specifics of application of medical products as follows:

1) for module A (internal production control):

the internal production control constitutes the procedure of conformity assessment, by which the manufacturer or its authorised representative, who ensures fulfilment of requirements of clauses 19-50 of this Technical Regulation, and in the case of placing sterile products and products with measuring function on the market, requirements of this clause of the Technical regulation, guarantees and declares conformity of medical products with established requirements;

the manufacturer or its authorised representative shall label each medical product with the National Mark of Conformity and shall draw up a declaration of conformity following the blank form attached;

the technical documentation shall comprise:

- a description of sterilisation methods (if the medical product is placed on the market in sterile form);
- confirmation that the product complies with requirements, if coupled with the product with parameters, specified by the manufacturer (if the medical product is coupled with other medical product(s) to be used as intended);
- label and user manual.

If medical products are placed on the market in sterile form, or if they are products of class I with the function of measuring, the manufacturer shall additionally carry out one of the conformity assessment procedures following modules D, or E, or F.

The implementation of the abovementioned procedures shall cover:

for medical products that are placed on the market in sterile form – production processes related to providing and maintaining sterility only;

for products with the measuring function – production processes related to the conformity of products with metrological requirements only.

If such module is applied to products of IIa class, together with procedures envisaged in modules D, or E, or F the manufacturer shall draw up a single declaration only, in which he shall confirm and declare the compliance of the products' engineering design with requirements of this Technical Regulation, that cover the module;

2) for module B (verification of type) – technical documentation shall comprise:

the results of engineering design calculations, risk assessments, studies performed and technical trials;

a statement, declaring whether the product contains a substance as an integrated part in accordance with clause 4 of this Technical Regulation and trial results;

draft of the label and, if required, of the user manual.

If medical products contain, as an integrated part, a substance in accordance with clause 4 of this Technical Regulation, the designated body, following provisions of this clause, shall receive consultations or explanations from the Ministry of Health, concerning application of this substance prior to taking a decision;

3) for module D (ensuring production quality):

system of quality management of medical products shall be deemed adequate to these requirements, if it is introduced into the enterprise in accordance with the provisions of DSTU ISO 13485:2005 “Medical products. System of quality management. Regulation requirements. (ISO 13485:2003, IDT)”, with the exception of clause 7.3;

to assess the system of quality management of medical products, the manufacturer shall submit a request to the designated body (at its own discretion) that comprises:

- the name and location of the manufacturer;
- information about the medical product, that is produced in accordance with the quality management system;
- written confirmation, that similar request shall not be submitted to alternative designated body;
- paperwork, concerning the quality management system;
- if required, the technical documentation on the verified type and copy of the certificate concerning type verification;
- information on the systematic analysis of operation of medical products and the undertaking of appropriate actions.

If this module is applied to products of class IIa, the manufacturer shall draw up the conformity declaration, in which he guarantees and declares conformity of such products to technical documentation, that is composed according to module A, and ensures compliance with the requirements of this Technical Regulation that cover them;

4) for module E (products quality assurance) – for medical products, that are placed on the market in sterile form, in order to ensure and to maintain it the

manufacturer shall apply provisions, determined for systems of quality management and supervision by the designated body, according to module D.

The designated body undertakes assessment of the quality management system to determine its compliance with requirements of DSTU ISO 13485:2005 “2005 “ Medical products. System of quality management. Regulation requirements. (ISO 13485:2003, IDT)”.

If this module is applied to class IIa products, the manufacturer shall draw up a conformity declaration, in which he guarantees and declares the conformity of such products to technical documentation, that is composed, according to module A, and ensures compliance with the requirements of this Technical Regulation;

5) for module F (product inspection) prior to the production of medical products the manufacturer shall document the operation of the production process, including sterilisation, taking into account the moments that guarantee uniformity of production and its adequacy to the choice of type, specified in the certificate of the type verification, as well as to the requirements of this Technical Regulation that cover it.

Additionally for medical products that are being placed on the market in sterile form, in order to ensure and to maintain it, the manufacturer shall apply provisions determined for systems of quality management and supervision by the designated body, according to module D.

If this module is applied to products of class IIa, the manufacturer shall draw up the conformity declaration, in which he guarantees and declares the conformity of such products to technical documentation that is composed according to module A and ensures compliance with the requirements of this Technical Regulation that cover them;

6) for module H (comprehensive quality assurance) the designated body shall carry out the assessment of the quality management system at the company to determine its compliance with requirements of DSTU ISO 13485:2005 “2005 “ Medical products. System of quality management. Regulation requirements. (ISO 13485:2003, IDT)”.

This module may be applied to products of IIa – IIb classes without provisions concerning the investigation of engineering composition.

Conformity assessment of different classes of medical products

53. Medical products, assigned to class III, that are not custom-made or intended for clinical investigations, shall undergo at the manufacturer’s discretion a conformity assessment according to module H or module B in conjunction with module D or module F.

Medical products, assigned to class IIa, that are not custom-made or intended for clinical investigations, shall undergo at the manufacturer’s discretion a conformity

assessment, according to module H without the investigation of engineering composition or module A in conjunction with modules D, or F, or E.

Medical products, assigned to class IIb, that are not custom-made or intended for clinical investigations, shall undergo at the manufacturer's discretion a conformity assessment, according to module H without investigation of engineering composition, or module B in conjunction with modules D, or F, or E.

Medical products, assigned to class I, that are not custom-made or intended for clinical investigations, shall undergo a conformity assessment, according to module A.

Placing on the market and commissioning custom-made medical products

54. In order to place on the market or commission any custom-made medical products, the manufacturer or its authorised representative shall draw up a notification, designating:

data necessary for the identification of the corresponding product;

a statement that this product is "intended for use by" specified by the surname of the patient only;

surname of a doctor or other authorised person who issued the prescription and the name of the clinic;

particular parameters of the product according to the medical prescription;

conformity of the medical product with safety requirements, specified in this Technical Regulation, and appropriate motivation if requirements of this Technical Regulation are not fully observed.

Custom-made medical products shall not be marked with the National Mark of Conformity.

In addition, the manufacturer shall draw up and preserve paperwork for five years that shall enable to understand the engineering design of the product, its working parameters, including the ones expected and to assess conformity to requirements of this Technical Regulation.

The manufacturer shall take actions to ensure the conformity of the production process to the drawn up paperwork.

The manufacturer of custom-made medical products shall submit their list to the Ministry of Health.

During the procedure of conformity assessment of the medical product, the manufacturer and/or designated body shall take into account results of corresponding assessments and inspections that have been undertaken, in accordance with this Technical Regulation, on the intermediate production stage.

The manufacturer shall be entitled to instruct its authorised representative about the application of confirmation procedures of compliance assessment according to approved modules and taking into account the peculiarities of the application thereof, depending on potential risk of the operation of the medical product.

As an exception, the Ministry of Health can satisfy the request to allow certain medical products that have not undergone the abovementioned procedures but the use of which is essential for public health to be placed on the market and commissioned.

Specifics when placing on the market and commissioning systems and treatment complexes

55. An authorised representative of the manufacturer that awards medical products that are marked with the National Mark of Conformity in limits of intended use and in application domain specified by the manufacturer with the aim of their supply for the market as a system or a treatment complex, shall draw up the declaration confirming that they:

inspected the compatibility of products and performed operations observing the manufacturer's instructions;

packaged the system or the treatment complex and provided it with user information and manufacturer's instructions;

observed the methods of internal control and inspection.

If the aforementioned conditions are not adhered to, or if the system or the treatment complex comprise medical products without marking with the National Mark of Conformity, or when combination of products is inappropriate from the point of view of their intended use, such system or treatment complex shall be considered as an individual medical product, that shall undergo the procedure of conformity assessment in compliance with clause 53 of this Technical Regulation.

If any authorised manufacturer's representative has performed sterilisation of the system, or of the treatment complex, or of the other medical product, marked with the National Mark of Conformity, that is stipulated by the manufacturer before application, they shall undertake one of the procedures from module F, module D or module E at its discretion.

Medical products, specified in clauses 54-56 of this Technical Regulation, shall not be additionally labelled with the National Mark of Conformity. Such products shall be accompanied with the information corresponding to clauses 45-50 of this Technical Regulation.

Declarations, related to the abovementioned products, shall be stored for at least five years.

Specifics when placing on the market and commissioning medical products intended for clinical investigations

In order to place on the market and commission medical products intended for clinical investigations, the manufacturer or its authorised representative shall draw up a notification comprising:

data necessary for the identification of the product;

the investigation programme, specifying the objectives, medical and scientific reasons for the implementation thereof, the scope of the work planned and quantity of medical products to be studied;

conclusion of the ethics committee and results of similar studies;

surname of the doctor or another representative, who is authorised to conduct clinical investigations in addition to the name of the institution that is authorised to carry out studies;

location and time parameters of investigations.

The manufacturer shall draw up and store the paperwork for at least 5 years as follows:

general description of the product;

technical design drawings, production technology, including sterilisation methods, layout of parts and blocks;

descriptions and comments, essential for understanding said drawings, layout and the product operation principles;

results of the risk analysis of the medical product taking into account the application in full or in part the national standards, as well as summaries of decisions taken in order to implement requirements of this Technical Regulation, if standards are partially applied;

results of design calculations, completed metrological inspections and technical trials.

The manufacturer shall take the necessary action to ensure the production of medical products in accordance with the abovementioned documentation.

The manufacturer shall issue a permit to inspect the assessment of these actions.

Medical products, intended for clinical studies shall not be labelled with the National Mark of Conformity.

The manufacturer shall inform the Ministry of Health about the realisation of clinical investigations of medical products in accordance with DSTU 4659-1-2:2006 “Clinical investigation of medical devices for human subjects”.

Clinical investigations that are carried out with the use of medical products that are labelled according to this Technical Regulation with the National Mark of Conformity under the condition that those products are not used for purposes that do not fit those specified in the conformity assessment procedure, shall not be covered with provisions of this clause. Such clinical investigations shall be carried out in accordance with DSTU 4659-1-2:2006 “Clinical investigation of medical devices for human beings”.

Appendix to the Technical Regulation

DECLARATION
of conformity

_____ (full name of the manufacturer, or

its authorised representative, or supplier, their
locations and codes according to EDPNOU (if registered))

represented by _____
(position, surname, first name, patronymic of the manufacturer,

authorised representative, or supplier)

confirms that the medical product _____
(full name of the medical product, type, brand, model)

that is being produced following _____
(name and code of the technical documentation)

complies with the Technical Regulation for medical products according to _____

_____ (titles of normative documents (if present))

Technical documentation on the medical product is drawn out.

Certificate of the type inspection (if present) _____

_____ (number of the certificate of the type of inspection, its registration date,
valid until, name and location of the designated
body)

The log sheet of trials of the medical product, carried out by the designated body, or under its
supervision (if required) _____

_____ (number of the log sheet,

_____ date of completion, name and location
of the designated body)

The Declaration is drawn up under full responsibility of the manufacturer/authorised
representative/supplier.

_____ (position)

_____ (signature)

_____ (printed name)

SEAL

Date

Publications to follow with the document:

- Ofitsijnyj Visnyk Ukrainy of 23/06/2008-2008,N 43, p.101, Article 1415, code 43331/2008
- Urjadovyj Kurjer of 25/06/2008 – N 115