CABINET OF MINISTERS OF UKRAINE

DECREE
of 09/07/2008 No 621
Kyiv

On approval of the Technical Regulation on active medical products which are implanted

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. approval of the Technical Regulation on active medical products which are implanted (hereinafter – the Technical Regulation) that is enclosed.

2. designation of the Ministry of Health as a responsible body for the introduction of the Technical Regulation as well as supervision of compliance with the requirements thereof.

3. the Ministry of Health, together with the State Committee for Technical Regulation and Consumer Policy, shall develop and approve within one month the road map for the introduction of the Technical Regulation.

Prime Minister of Ukraine
Ju. Tymoshenko

APPROVED
by Decree of the Cabinet of Ministers of Ukraine
of 09/07/2008 No 621
GENERAL PROVISIONS

1. This Technical Regulation determines the general requirements for active medical products which are implanted, and the safety and procedures required in order to confirm the compliance thereof with the said requirements.

2. This Technical Regulation has been drafted in accordance with the requirements of European Council Directive 90/385/EC of 20 June 1990 on active medical products which are implanted.

3. For the purpose of this Technical Regulation, terms shall have the following meanings:

1) active medical product shall mean a medical product relying on a source of electrical energy or any source of power other than that generated by the human body or gravity in order for it to function.

Medical products designed to transfer power, substances, etc. from an active medical product to a patient without the introduction of any significant changes are not regarded as active medical products;

2) an active medical product which is implanted shall mean a medical product which is to be introduced - in part or in full, surgically or medically - into the human body or by medical intervention into a natural orifice and which is intended to remain in the human body, relying on a source of electrical energy or another source of power other than that generated by the human body or gravity in order for it to function;

3) custom-made active medical product which is implanted shall mean a medical product specifically manufactured in accordance with a written prescription of a physician who is solely responsible for identifying the specific design characteristics and that is only intended to be used by the named patient;

A mass-produced medical product, the construction of which has been adapted to satisfy individual requirements of the practicing medical physician, or any other user, shall not be regarded as a custom-made active medical product.

4) active medical product which is implanted intended for clinical investigation shall mean any active medical product which is implanted and intended for use by a qualified specialist physician during clinical investigations, identified in DSTU 4569-1-2:2006 “Clinical Investigations of Medical Products for Humans” (ISO 14155-1:2003, MOD);

5) Putting into service shall mean the readiness of an active medical product which is implanted for first use and for an intended purpose;
6) placing on the market shall mean the first appearance of an active medical product which is implanted, with the exception of products intended for clinical investigations, for the purpose of distribution and/or use on the Ukrainian market, irrespective of whether the product is brand new or modified.


4. Requirements specified by this Technical Regulations are mandatory for:

- manufacturers of active medical products which are implanted;
- persons – residents of Ukraine - who are authorised by the manufacturer (hereinafter – authorised person);
- persons responsible for placing active medical product which are implanted on the market or bringing them into service if the manufacturer or authorised person do not exercise activities on the territory of Ukraine (hereinafter – person who placed active medical products which are implanted on the market or brought them into service);
- central executive authorities and their bodies functioning in technical regulation and supervision the safety of active medical products which are implanted (hereinafter – central executive bodies);
- designated bodies for assessing conformity of active medical product which is implanted that conforms to 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 Implementation of Procedure of Appointment of Bodies Assessing the Conformity of Products, Processes and Services to Requirements of Technical Regulations” (Ofitsijnyj Visnyk Ukrajiny, 2007, No 6, p. 223) (hereinafter – designated bodies).

5. Active medical products which are implanted intended for introduction of the medicine into the human body is 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 active medical product which is implanted and the medicine constitute an integral whole and the medical product cannot be used again, such product shall be a subject for regulation by 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.

In case when a substance, which is an integral part of an active medical products which are implemented, can be used as a medicine identified in the Law of Ukraine “On Medicines” (123/98-VR) and that is capable of effecting an auxiliary action on
human body in relation to the action of an active medical product which is implanted, then safety, quality and effectiveness of this medicine shall be verified taking into account of the expected purpose of the product in line with Law of Ukraine “On Medicines” (123/96-VR).


The Technical Regulation in part concerning confirmation of compliance of electromagnetic compatibility does not cover active medical products which are implanted.

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

8. The manufacturer or authorised person, or the person that brought/is responsible for putting an active medical product which is implanted into service or placing it on the market shall be held responsible for the failure to implement all procedures of conformity assessment of safety requirements specified in this Technical Regulation, in accordance with the law.

Such requirements also concern legal entities and natural persons that assemble, pack, process, modify and/or provide markings for one or more prepared medical products.

The abovementioned requirements do not cover persons that are not manufacturers but supply medical products that have already been placed on the market following their intended application for the specified patient.

9. If an active medical product which is implanted conforms to the requirements of the national standards, from the index of such standards that are officially published by the central executive bodies on standardisation, voluntarily applied in full or in part, then this is proof of compliance of the product with this Technical Regulation and the product shall be considered to be in conformance with the requirements of this Technical Regulation.

For the purpose of this Technical Regulation, the index of national standards shall additionally include that submitted by the Ministry of Health monographs of European Pharmacopoeia concerning surgical sutures and interactions between medicines and materials that are used in active medical products which are implanted that contain such medicines.

10. Prior to the placing on the market or putting into service of an active medical products which is implanted, the National Mark of Conformity shall be affixed thereto or to the packaging thereof and/or placed in the documentation, notifications or instructions that accompany the product, with the exception of custom-made active
medical products which are implanted and products intended for clinical investigations, in accordance with Decree of the Cabinet of Ministers of Ukraine of 29/11/2001 No 1599 (159902001-p) “On Approval of Description and Rules of Application of the National Mark of Conformity” (Ofitsijnyj Visnyk Ukrajiny, 2001, No 49, p. 2188).

Application of the National Mark of Conformity should be made in accordance with the requirements set out in Decree of the Cabinet of Ministers of Ukraine of 07/10/2003 No 1585 (1585-2003 – p) “On Approval of Technical Regulation of Modules of Conformity Assessment and Requirements to Marking with the National Mark of Conformity, that are Applied in Technical Regulations” (Ofitsijnyj Visnyk Ukrajiny, 2003, No 41, p. 2175).

11. Presence of the National Mark of Conformity on active medical products which are implanted indicates that legal entity or natural person who has performed marking or who is responsible for that action, has had checked and testifies to conformity of medical products to requirements of this Technical Regulation, that cover those products, and that products have passed proper procedures of conformity assessment.

12. If active medical products which are implanted fall within the scope of other technical regulations that stipulates the marking thereof with the National Mark of Conformity, then the medical products shall also conform to the requirements of those technical regulations. Conformity of an active medical product which is implanted with all such technical regulations shall be a condition for the marking thereof with the Mark.

Where one or several technical regulations stipulates the right of the manufacturer to choose the method of confirmation of compliance, marking with the National Mark of Conformity signifies conformity only with those technical regulations that have been used by the manufacturer. In such a case, documents, notifications and instructions that are enclosed to active medical products which are implanted shall incorporate references to the technical regulations that have been used.

13. If it is discovered that the National Mark of Conformity is used in violation of the requirements of this Technical Regulation, then the manufacturer or its authorised person or the person that placed the active medical products which are implanted on the market or put them into service shall take action to cease such violation in order to ensure the medical products are brought into conformity with the requirements of this Technical Regulation and to confirm such compliance according to established order.

In the case of violation of the law, central executive bodies shall undertake appropriate action to restrict or ban such medical products from being placed on the market or to withdraw them from the market.

Any decision made regarding this Technical Regulation in respect to the restriction or banning of active medical products which are implanted from being placed on the market or putting them into service, or their withdrawal from the market, shall contain a clear list of the reasons on which the decision was based. The concerned party shall
be informed immediately of this decision and of the permitted timeframe within which corrective actions towards the identified violations should be taken.

14. Following the results of the application of active medical products which are implanted, the Ministry of Health shall perform constant monitoring and assessment of any information about those products that have been placed on the market or put into service, and concerning:

   failure or degeneration of parameters and/or properties of active medical products which are implanted, any misleading information on the label or in the user manual that could result or has already resulted in death or deterioration to the of patients, users and other persons;

   technical or medical reasons for alteration of parameters and/or properties of active medical products which are implanted that resulted in the systematic recall 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.

15. If it is revealed that active medical products which are implanted with correct installation, servicing and application provided are still likely 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 them from being put into service, in accordance with the law.

Requirements concerning the design and manufacturing of active medical products which are implanted

16. Implantable active medical products shall be designed and produced so as to minimise any risks to the health of patients, users and other persons where the products are implanted under appropriate conditions and for the intended purposes.

17. Implantable active medical products shall be designed and manufactured so as to perform the following functions:

   preventive measures, diagnostics, treatment, monitoring and relieving the condition of the patients who are sick, injured or 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 fertilisation.

18. Implantable active medical products shall be designed, produced and packaged so that their technical parameters and properties do not change during storage and transportation.
19. If the technical characteristics and properties of an implantable active medical product change during storage or use even though it has been correctly installed, serviced and used with observance of the storage period under the conditions specified by the manufacturer, such changes shall not continue to such an extent that the life and health of patients, users and other persons are at risk.

20. The manufacturer or its authorised representative shall be responsible for the basic principles of integrated safety when designing and constructing implantable active medical products.

21. Implantable active medical products that are supplied sterile, shall be designed, produced and sterilised in accordance with the approved methods under the correct conditions and packaged in disposable packaging and/or following corresponding procedures that ensure their sterility during transportation and storage until the packaging is opened immediately prior to implantation.

22. Constructing and packaging of implantable active medical products shall be carried out in a manner that will eliminate or minimise any possible risks that may arise in connection with:

- their physical properties, including dimensions;
- use or sources of energy. If the functioning of the product depends on a source of electrical energy, special attention shall be paid to the insulation, wiring and heating of the product;
- environmental conditions, such as magnetic fields, external electrical interference, electrostatic discharges, pressure and pressure fluctuation, acceleration, etc.
- medical intervention, especially when defibrillators or high-frequency active implantable surgical products are used;
- ionising radiation, emitted by radioactive substances that are contained in an implantable active medical product, with the observance of appropriate technical safety arrangements.
- inability to service or to calibrate due to excessive wiring, ageing of materials used, excessive emission of heat by the product or reduction in accuracy of a testing and control device.

23. Implantable active medical products shall be designed and produced in such a way as to secure technical parameters and productivity in accordance with the general requirements specified in Clauses 16 – 21 of this Technical Regulation, including the following special characteristics:

- selection of materials used, especially in view of their toxicity;
- compatibility of materials used with human tissues, cells and fluids, taking into account the expected purpose of the implantable active medical product;
compatibility of implantable active medical products with substances that they transfer;

quality of connecting terminals with the observance of appropriate safety requirements;

reliability of energy sources;

proper tightness;

correct functioning of operating, programming and monitoring systems, including software;

24. Implantable active medical products and parts thereof (where required) shall be marked to make it possible to identify them and to intervene, where necessary, if life and/or health are endangered by such medical products or parts thereof.

25. Implantable active medical products must bear a code by which they and their manufacturer can be unambiguously identified (particularly with regard to the type of product and year of manufacture). This code, if necessary, must be readable without the need for a surgical operation.

26. If the implantable active medical product and/or parts thereof are subject to instructions necessary for the operation of the product or to operating or adjustment parameters using indicating systems, such information must be understandable by the user and the patient.

27. The packaging of the active medical product which is implanted must bear legible and permanent marking for the period of its operation and storage that contain the following details:

1) on individual (sterile) and sales/transporting packaging:

the name of the product;

the words “exclusively for clinical investigations” on active medical products which are implanted that are intended for clinical investigations;

the wording “custom made product” on active medical products which are implanted that are custom made;

a declaration that the product is in a sterile condition;

the month and year of the manufacture;

the expiry date for implanting a product safely;

2) on the individual (sterile) packaging only:

the methods of sterilisation;
the indication of the packaging sterility;

the surname and the signature of the manufacturer;

3) on the sales/transporting packaging only:

the address of the manufacturer;

the data on the intended purpose of the product;

the characteristics for its use;

the conditions for transportation and storage of the product.

28. When placed on the Ukrainian market, each active medical product which is implanted must be accompanied with instructions for use giving the following particulars:

the year of the marking with the National Mark of Conformity;

the information marked on individual (sterile) and sales/transporting packaging, with the exception of the information concerning the month/year of manufacture and the expiry date for implanting a product safely;

data about performances in accordance with requirements for design and manufacturing, procedures of conformity assessment, design and construction and possible undesirable side-effects;

the necessary technical data allowing the physician to select a suitable active medical product which is implanted and the corresponding software and accessories;

information about the use allowing the physician and, where appropriate, the patient to use the active medical product which is implanted, its accessories and software correctly, as well as information on the type, scope and time frames for operating controls, and information about iterative functional control and maintenance arrangements;

requirements that should be adhered to in order to avoid risks in connection with the implantation of the product;

information regarding the risks of reciprocal interference in connection with the presence of the active medical product which is implanted during specific investigations or treatment;

instructions in the event of the sterile pack being damaged together with details of appropriate methods of re-sterilisation;
information that an active medical product can be reused only if it is capable of performing in accordance with the basic requirements under the responsibility of the manufacturer.

The instruction manual shall also include details about possible contraindications and the precautions to be taken. These details shall cover in particular:

information about service life and the energy sources;

precautions to be taken should changes occur in the active medical product's performance;

precautions to be taken regarding exposure to magnetic fields, external electrical influences, electrostatic discharges, pressure or variations in pressure, acceleration, etc.;

information regarding the medicinal purpose of the active medical product which is implanted;

29. Confirmation that the active medical product which is implanted conforms to the requirements in respect of characteristics and performances, in accordance with requirements of design and manufacturing, referred to in Clauses 16 – 29 of this Technical Regulation, in appropriate conditions of use, and the assessment of the side effects or undesirable effects must be based on clinical data established in accordance with DSTU 4569-1-2:2006. "Clinical Investigations of Medical Products for Human Subjects" (ISO 14155-1:2003, MOD).

Procedures for conformity assessment

30. Assessment of conformity of active medical products which are implanted, in accordance with this Technical Regulation, shall be performed with the use of modules of conformity assessment procedures or combinations thereof as specified in the Decree of the Cabinet of Ministers of Ukraine of 07/10/2003 No 1585 (1585-2003-p) “On Approval of the Technical Regulation of Conformity Assessment Modules And Requirements Towards Marking with the National Mark of Conformity that Are Used in Technical Regulations” (Ofitsijnyj Visnyk Ukrayiny, 2003, No 41, p. 2175; 2007, No 1, p.31) taking into account the specifics of application of active medical products which are implanted as follows:

1) for module B (verification of type):

the technical documentation that is submitted with an application, with the exception of the documentation identified in Clause 28 of the Technical Regulation of Conformity Assessment Modules And Requirements Towards Marking with the National Mark of Conformity that Are Used in Technical Regulations” approved by the Decree of Cabinet of Ministry of Ukraine of 7/10/2003, No 1585 (1585-2003-p), shall include:
- design drawings, methods of manufacture and sterilisation envisaged, diagrams of parts, blocks, circuits, etc.;

- the descriptions and explanations necessary for the design drawings, diagrams of parts, circuits and operation of the product;

- results of design calculations, risk analyses, investigations and technical tests carried out;

- a statement that identifies whether or not the product incorporates, as an integral part, a substance as referred to in Clause 5 of this Technical Regulation, and results of trials;

- the data of clinical tests carried out in accordance with DSTU 4659-1-2:2006 “Clinical Investigations of Medical Products for Human Subjects” (ISO 14155-1:2003, MOD);

- the draft label and user manual.

If an active medical product which is implanted contains, as an integral part, a substance in accordance with Clause 5 of this Technical Regulation, the designated body, prior to making the decision on issuing the type conformity certificate, shall receive an explanation from the Ministry of Health in respect to the application of this substance together with the product.

The Ministry of Health shall be informed by the designated body of the decision that is taken.

If the issuing of the certificate of type verification is refused, the designated body shall provide an explanation of such a decision in writing.

The manufacturer or its authorised person shall inform the designated body that issued the certificate of verification of type of all alterations to the approved product that must undergo additional verification, if those alterations may influence the conformity of the product to the requirements of this Technical Regulation or conditions for use of active medical products which are implanted.

Data following the additional verification shall be annexed to the original certificate of type verification of active medical product which is implanted.

The manufacturer or its authorised person shall keep copies of certificates of type verification and any annexes together with technical documentation for at least 5 years following the manufacturing of the last active medical product which is implanted.

If the manufacturer or its authorised person is not available, the responsibility to keep the technical documentation shall be vested on the person who placed the active medical product which is implanted on the market;
2) for module D (ensuring production quality) – where this module is applied in conjunction with module B, the manufacturer or the authorised person that fulfils the obligations in accordance with this Technical Regulation shall guarantee and declare that active medical products which are implanted conform to the type specified in the certificate of type verification and with the requirements of this Technical Regulation.

The manufacturer or its authorised person shall mark each active medical product which is implanted with the National Mark of Conformity and shall draw up a declaration of conformity, following the attached form.

The National Mark of Conformity shall be accompanied with the identification number of the designated body.

The manufacturer shall have an approved by the designated body system of quality management of production, control and testing of active medical products which are implanted that shall be a subject to supervision by the designated body in accordance with the law.

A request for evaluation of quality management system for active medical products which are implanted submitted to the designated body, with the exception of the information identified in Clause 41 of the Technical Regulation of Conformity Assessment Modules And Requirements Towards Marking with the National Mark of Conformity that Are Used in Technical Regulations” approved by the Decree of Cabinet of Ministry of Ukraine of 7/10/2003, No 1585 (1585-2003-p), shall include:

the name and location of the manufacturer and its authorised person;

the necessary information about product or category of active medical products which are implanted, covered by the quality management system;

written confirmation that the request has not been submitted to an alternative designated body;

the quality management system documentation;

an undertaking to respect the obligations arising from the approved quality system;

an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious;

the technical documentation for verified type and copy of the certificate of the type verification;

an undertaking by the manufacturer to establish and frequently update a systematic analysis of use of active medical products which are implanted following their manufacturing and placing on the market and take appropriate steps to ensure any necessary corrective actions are taken;
All the elements, requirements and provisions adopted by the manufacturer for quality management system, shall be systematically and orderly documented in the form of written programme policies and procedures;

The quality management system documentation must enable an unequivocal interpretation of the quality assurance programmes, plans, manuals and quality protocols and shall include the information about:

the manufacturer's objectives with regards to quality;

the organisation of the business and, in particular:

- the organisational structures, the responsibilities and authority of the managerial staff in respect to the quality of the active medical products which are implanted;

- the methods of constant monitoring to ensure the desired quality of active medical products which are implanted and effective operation of quality management system is achieved;

the verification and quality assurance at the manufacturing stage, in particular:

- processes and procedures used, methods of sterilisation, supplies and the relevant documentation;

- the procedures of identification of the product, developed and updated from the data from drawings, specifications and other relevant documents at every stage of manufacture;

examinations and trials to be carried out before, during and after the production of active medical products which are implanted, the frequency with which they will take place, the equipment used for testing, ensuring the availability of calibration of testing equipment to its primary values.

The designated body shall assess quality management system so as to determine its compliance with the related requirements.

The quality management system shall be deemed adequate to the specified requirements, if it is introduced into the manufacturing process 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;

The manufacturer or its authorised person shall keep for at least five years following the production of last active medical product which is implanted and submit if requested by the central executive authorities and their bodies:

the declaration of conformity;

product and quality management system documentation;
the documentation regarding alterations to the quality management system;

the decisions and reports of the designated body;

3) for module F (products inspection) – where this module is applied in combination with module B, the manufacturer or its authorised person shall inspect and confirm that an active medical product which is implanted conforms to the type identified in the certificate of type verification and the requirements of this Technical Regulation.

The manufacturer shall ensure conformity of the production process to the certificate of type verification and requirements of this Technical Regulation.

Prior to production of active medical products which are implanted, the manufacturer shall prepare the documentation relating to the production process, including methods of sterilisation as well as all other agreed provisions that should be introduced so as to guarantee uniformity of production and, where necessary, conformity of active medical products which are implanted to the type specified in the certificate of the type verification, as well as to the related requirements of this Technical Regulation.

The manufacturer or its authorised person shall mark each active medical product which is implanted with the National Mark of Conformity and shall draw up a declaration of conformity, following the attached form.

The Declaration of conformity shall be drawn up for the certain quantity of produced active medical products which are implanted (batch, series).

The examinations and trials of every product shall be carried out in accordance with the appropriate national standard(s) or equivalent testing for verification of conformity of every active medical product which is implanted shall be carried out in accordance with the certificate of type verification and requirements of this Technical Regulation.

The designated body shall mark or issues an order in respect to the marking with the identification number of every verified active medical product which is implanted and shall issue the certificate of conformity on the basis of the testing performed. In some cases, the manufacturer or its authorised person may mark the products with the identification number during the production process under the responsibility of the designated body.

Statistical verification for active medical products which are implanted shall be performed in the following order:

the manufacturer shall present the designated body with products of every batch and ensure that every produced batch is homogeneous;

the designated body shall perform a random sample selection of active medical products which are implanted from every batch, examine and test every sampled
product in accordance with appropriate national standard(s) or shall carry out equivalent tests to verify the conformity to the type described in the certificate of type verification, and requirements of this Technical Regulation and shall make a decision to accept or to reject the batch of products;

Statistical control shall be carried out on the basis of alternative attributes, entailing a sampling control with the following characteristics:

- a level of quality, that corresponds to a probability of acceptance of 5 percents, with a non-conformity percentage of between 0.29 and 1 percent;

- a limit of quality that corresponds to a probability of acceptance of 5 percent, with a non-conformity percentage of between 3 and 7 percent.

The sampling method shall be established by national standards, taking into account the specifics of the product category in question;

Where the batch conforms to the established requirements, the designated body shall mark or accordingly instruct the manufacturer to mark the identification number of every active medical product which is implanted of the batch and shall draw up a certificate of conformity on the basis of the tests carried out. All of the products from such a batch may be placed on the market, with the exception of those products in the sample that were found not to be in conformance with the established requirements.

In cases in which the batch does not conform to the established requirements, the designated body or central executive body shall take steps in accordance with the law to prevent this batch from being placed on the market. In the case of multiple non-conformities of the batches to the established requirements, the designated body may cease statistical verification.

The manufacturer shall keep for at least five years following the production of last product and submit if requested by the central executive bodies:

- the declaration of conformity;

- the technical documentation concerning the production process and methods of sterilisation;

- the certificates of conformity of the batch;

- the certificate of the type verification;

4) for module H (comprehensive quality assurance) – for the requirements of this Technical Regulation module H shall be applied by itself, not in combination with other modules.

During the conformity assessment of active medical products which are implanted according to the requirements of module H of this Technical Regulation, the manufacturer guarantees and declares that the products conform to the requirements of this Technical Regulation.
The manufacturer shall mark each active medical product which is implanted with the National Mark of Conformity and shall draw up the declaration of conformity, following the attached form.

The National Mark of Conformity shall be accompanied with the identification number of the designated body.

The manufacturer shall have a quality management system for designing, production, control and testing of the final products, approved by the designated body, which shall be a subject to supervision by the designated body.

The quality management system introduced into the manufacturing process, shall guarantee conformity of active medical products which are implanted to the requirements of this Technical Regulation.

A request submitted to the designated body for evaluation of quality management system of active medical products which are implanted, except for the information, identified in clause 41 of the Technical Regulation of Conformity Assessment Modules And Requirements Towards Marking with the National Mark of Conformity, that Are Used in Technical Regulations” approved by the Decree of Cabinet of Ministry of Ukraine of 7/10/2003, No 1585 (1585-2003-p), shall include:

- the name and location of the manufacturer or its authorised person;
- the necessary information about the product or category of active medical products which are implanted covered by the quality management system;
- written confirmation that application had not been submitted to an alternative designated body;
- the quality management system documentation;
- an undertaking to respect the obligations arising from the approved quality management system;
- an undertaking to maintain the approved quality management system in such a way that it remains adequate and efficient;
- the technical documentation for verified type and copy of the certificate of the type verification;
- an undertaking by the manufacturer to establish and keep continually update a systematic analysis of the use of active medical products which are implanted following their manufacturing and placing on the market and to take appropriate steps to ensure any necessary corrective actions are taken.

All the elements, requirements and provisions adopted by the manufacturer for the quality management system shall be systematically and orderly documented in the form of written programme policies and procedures;
The quality management system documentation must enable an unequivocal interpretation of the quality assurance programs, plans, manuals and quality protocols and shall include the information concerning:

- the manufacturer’s objectives with regards to quality;
- the organisation of the business and in particular:
  - the organisational structure, the responsibilities and authority of the managerial staff concerning the quality of the active medical products which are implanted;
  - the methods of constant monitoring to ensure the desired quality of active medical products which are implanted, and effective operation of the quality management system are achieved;
- the procedure for monitoring and inspection of the product designing state, and in particular:
  - the technical specifications, including the standards applied from the index of national standards, results of the risk evaluations, descriptions of the decisions taken to observe the requirements of this Technical Regulation, if aforementioned standards have not been applied;
  - methods to manage the design, design examination, processes and systematic actions to be employed during the product development;
  - confirmation that the product conforms to the requirements when it is connected to the product(s) with characteristics identified by the manufacturer, if the active medical product which is implanted according to its intended use is connected to other product(s);
  - the notification as to whether or not the active medical product which is implanted incorporates, as an integral part, a substance as referred in clause 5 of this Technical Regulation, and results of the trials carried out;
  - the clinical data in accordance with DSTU 4659-1-2:2006 “Clinical Investigations of Medical Products for Humans”;
- the draft of the label and, where required, of the user manual;
- the verification and methods of quality assurance at the manufacturing stage, in particular:
  - the processes and procedures, which are used, methods of sterilisation, supply and the relevant documentation;
- the procedures of identification of product, developed and kept up-to-date from the data from drawings, specifications and other relevant documents at every stage of manufacture;

the examinations and trials to be carried out before, during and after production of active medical products which are implanted, the frequency with which they shall take place, the equipment used for testing, ensuring the availability of calibration of testing equipment to its primary values.


The manufacturer or its authorised person shall keep for at least five years following the production of last active medical product which is implanted and submit to the central executive bodies at their request, the following:

the declaration of conformity;

product and quality management system documentation;

the documentation regarding alterations to the quality management system;

the decisions and reports of the designated body;

31. In addition to the requirements of sub-clause 4 of Clause 30 of this Technical Regulation, the manufacturer or its authorised person may submit to the designated body the request for the examination of the engineering design of active medical product which is implanted.

32. The designated body, following the conclusions of examination of the request, shall make a decision with regards to the conformity of the engineering design to the requirements of this Technical Regulation. In case of a positive resolution, a requestor shall be issued with the certificate of the examination of the engineering design. The designated body may ask for additional tests to be carried out or for proof to be presented in order that the conformity assessment in accordance with this Technical Regulation can take place. The certificate shall contain the conclusion of the examination, conditions of its validity, the data required for identification of the approved engineering design, and, if required, description of intended purpose of the product.

If the active medical product which is implanted contains, as an integral part, a substance that can be used separately as a product, which is capable of effecting an auxiliary action on human organism in relation to action of an active implantable product, than the designated body shall receive an explanation from Ministry of Health regarding the use of such substance.
The decision of the designated body shall take into account the concept, elaborated during consultations, and shall inform the public health central executive body of the result.

33. The manufacturer or its authorised person shall inform the designated body that issued the certificate of the engineering design examination of any alterations in the approved design. If those alterations may affect the conformity of the approved design to the requirements of this Technical Regulation, or condition of use of active medical product which is implanted, further approval shall be received from the designated body and annexed to the original certificate of the engineering design examination.

34. Active medical products which are implanted that are not custom made or intended for clinical investigations, shall undergo conformity assessment at the manufacturer’s discretion, according to module H or module B in conjunction with modules D, or module F.

35. The manufacturer or its authorised person shall institute and keep up-to-date the systematic analysis of use of active medical products which are implanted following their manufacturing and take appropriate steps to ensure any necessary corrective actions are taken with regards to quality and safety of use of active medical products which are implanted.

36. The manufacturer or its authorised person must inform the Ministry of Health immediately after they are notified about:

1) any failures or deterioration of performance levels and/or working standards of the active medical product which is implanted as well as any inadequacy in the label and user’s manual, that may have caused or may cause death or essential health deterioration of the patient or the user;

2) any technical and medical precautions, concerning performance levels or working standards of the active medical product which is implanted, that because of reasons, determined in sub-clause 1 of this clause, shall result in systematic recall of such products by the manufacturer.

37. During the conformity assessment procedure of active medical products which are implanted, the manufacturer and/or designated body shall take into account the results of all assessments and verifications that have been undertaken in correspondence with this Technical Regulation at the intermediate stage of production.

38. The designated body may request any additional information or data, needed to determine conformation to the selected procedure.

39. The period of validity of the decision made by the designated body in accordance with procedures of modules B and H, shall not exceed five years and may be extended for further five years, following the application submitted within the period stipulated in the agreement, signed by both parties.
40. The conformity assessment documentation and correspondence shall be written in Ukrainian.

**Placing on the market and putting into service of custom made active medical products which are implanted.**

41. When placing custom made active medical products which are implanted on the market or putting them into service, the manufacturer shall draw up a notification, containing:

- the data necessary for identification of the corresponding product;
- the statement that this product is prescribed for use by the specified patient only;
- the surname of a physician or other authorised person that issued the prescription for that product, and the name of the clinic;
- the particular parameters of the product according to the relevant medical prescription;
- confirmation that the prescribed product conforms to the requirements of this Technical Regulation and, if certain requirements are not fully satisfied, the specification of these requirements and appropriate explanations.

The marking of the custom made active medical products which are implanted with the National Mark of Conformity is not applicable.

In addition, the manufacturer shall draw up and preserve for five years the paperwork that shall enable an understanding of the engineering design of the product, its production and working parameters, including the ones expected, in the detail that will allow assessing conformity to requirements of this Technical Regulation.

The manufacturer shall take all actions necessary to ensure that the manufacture of products corresponds to the paperwork.

42. The list of custom made active medical products which are implanted shall be submitted to the Ministry of Health by the manufacturer.

**Specifics in placing on the market and putting into service of active medical products which are implanted intended for clinical investigations**

43. In order to place on the market and put into service active medical products which are implanted, intended for clinical investigations, the manufacturer or its authorised person shall draw up a notification containing:

- the data needed for the product identification;
- the investigations’ program, specifying its objectives, scientific, technical or medical reasons, the scope and quantity of products;
the conclusion of the ethics committee and the description of studied aspects;

the surname of the practicing physician or other authorised person, and the name of the clinical institution that is responsible for the investigations;

the data regarding the location, commencement date and planned duration of investigations;

the data regarding conformity of the product to the requirements, except for aspects in conjunction with investigations, and that for these aspects all necessary steps are taken to ensure safety and health of the patient.

In addition, the manufacturer shall draw up and preserve for five years for submission to the central executive authorities, at their request, the following paperwork:

the general description of the product;

the technical design drawings, anticipated methods of production, methods of sterilisation, schemes of parts, blocks and circuits;

the descriptions and comments, essential for understanding of said drawings, schemes and operation of the product;

the conclusions of risk analysis and application in full or partially of national standards, as well as summaries of the decisions taken in order to implement the requirements of this Technical Regulation, if standards are partially applied;

the results of design calculations and completed inspections or technical trials, etc.

The marking on the active medical products which are implanted intended for clinical investigations with the National Mark of Conformity is not applicable.

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

The manufacturer shall issue a permission to inspect the assessment of effectiveness of abovementioned actions.

44. The manufacturer shall notify Ministry of Health of the conducting of relevant clinical investigations.

45. The manufacturer is permitted to commence clinical investigations, using medical products after 60 days following the notification about conducting of such investigations, unless during this period the Ministry of Health issued a decision to the contrary.

The Ministry of Health may sanction the commencement of relevant clinical investigations by the manufacturers during the period of 60 days, provided
ethics commission issues a positive decision regarding the proposed investigation programme.

46. Clinical investigations shall be carried out in accordance with the provisions of DSTU 4659-1-2:2006 “Clinical Investigations of Medical Products for Humans” (ISO 14155-1-2; 2003, MOD).

47. The manufacturer or its authorised person shall submit a report to the Ministry of Health in accordance with DSTU 4659-1-2:2006 “Clinical Investigations of Medical Products for Humans” (ISO 14155-1-2; 2003, MOD).

48. The provisions of Clauses 46-47 of this Technical Regulation shall not cover clinical investigations that use active medical products which are implanted that, in accordance with the requirements of this Technical Regulation, are marked with the National Mark of Conformity if only during the investigations the products are not used for purposes other than intended, according to the relevant procedure of conformity assessment.

The related provisions of DSTU 4659-1-2:2006 “Clinical Investigations of Medical Products for Humans” are in force for the mentioned clinical investigations.

Annex to the Technical Regulation

DECLARATION
of conformity

(full name of the manufacturer, or its authorised agent, that are residents of Ukraine, or supplier; their locations and code according to EDPNOU (if registered))
represented by ____________________________
(position, surname, first name, patronymic name of the manufacturer, or its authorised agent, or supplier)

confirms that the active medical product which is implanted
(full name of the medical product, type, brand, model)
that is being produced following ____________________________
(name and code of the technical documentation)

conforms to the Technical Regulation for active medical product which is implanted according to ____________________________
(title and code of normative documents (if present))
Technical documentation on the active medical product in compliance with the Technical regulation is available.

Certificate of the type inspection (if present) ________________________________

(number of the certificate of the type verification, its registration date, expiry date, name and location of the designated body)

The log sheet of trials of the active medical product which is implanted, carried out by the designated body, or under its supervision (if required) ________________________________

(number of the log sheet, date of filling out, name and location of the designated body)

This Declaration is drawn up under full responsibility of the manufacturer, its authorised agent and supplier.

_____________________________                ____________________                ____________________

(title)                                (signature)                                 (printed name)

SEAL

Date

Document publications: