Translation of the document

Original text in Ukrainian:http://zakon2.rada.gov.ua/laws/show/754-2013-%D0%BF

CABINET OF MINISTERS OF UKRAINE
RESOLUTION
No. 754 of 2 October 2013
Kyiv

On approval of the Technical Regulation on In Vitro Diagnostic Medical Devices

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

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

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

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

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

until 1 July 2016 - for in vitro diagnostic medical devices whose state registration certificate has no expiry date or expires after 1 July 2016;

until the end of the validity period of the state registration certificate - for in vitro diagnostic medical devices whose state registration certificate expires before 1 July 2016;

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

{The Resolution is amended by adding clause 2^1 in accordance with Resolution № 181 of the CMU of 27.05.2014 - the amendment comes into force on 1 July 2015}

3. The following Resolutions of the Cabinet of Ministers of Ukraine are hereby revoked:

Resolution No. 641 of the Cabinet of Ministers of Ukraine of 16 July 2008 'On approval of the Technical Regulation on In Vitro Diagnostic Medical Devices (*Ofitsiinyi Visnyk Ukraiiny* [Official Gazette of Ukraine], 2008, No. 53, Art. 1773);

point 7 of amendments to the Resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 902 of the Cabinet of Ministers of Ukraine of 4 October 2010 (*Ofitsiinyi Visnyk Ukraiiny*, 2010, No. 75, Art. 2668);

point 6 of amendments to the Resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 1171 of the Cabinet of Ministers of Ukraine of 16 November 2011 (*Ofitsiinyi Visnyk Ukraiiny*, 2011, No. 89, Art. 3236);

point 3 of amendments to the Resolutions of the Cabinet of Ministers of Ukraine, as approved by Resolution No. 632 of the Cabinet of Ministers of Ukraine of 28 August 2013 (*Ofitsiinyi Visnyk Ukraiiny*, 2013, No. 69, Art. 2533).

4. This Resolution shall enter into force in six months from the date of publication.

Prime Minister of Ukraine **M. AZAROV**

ID 70

APPROVED
by Resolution No. 754 of the Cabinet of Ministers of Ukraine
of 2 October 2013

TECHNICAL REGULATION
on In Vitro Diagnostic Medical Devices

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

General

1. This Technical Regulation shall apply to in vitro diagnostic devices and their accessories (hereinafter referred to as 'devices'). For the purposes of this Technical Regulation, accessories shall be treated as in vitro diagnostic devices.
This Technical Regulation has been developed on the basis of Directive 98/79/EEC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
2. For this Technical Regulation, the following definitions shall apply:
1) 'putting into service' means the stage at which a device has been made available as being ready for use for the first time for its intended purpose;
2) 'placing on the market' means the first making available (in return for payment or free of charge) of a device other than a device intended for clinical investigation or performance assessment, with a view to distribution and/or use on the Ukrainian market, regardless of whether it is new or fully refurbished;
3) 'device for self-testing' means any device intended by the manufacturer to be able to be used by lay persons in a home environment;
4) 'device for performance evaluation' means any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises;
5) 'manufacturer' means the legal person or sole proprietor responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or by a third party authorised to act on his behalf.
The obligations of the manufacturers also apply to the legal person or sole proprietor who assembles, packages, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name, excluding the persons who assemble or adapt devices already on the market to their intended purpose for an individual patient;
6) 'accessory' means an article which whilst not being an in vitro diagnostic medical device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with its intended use;
Invasive sampling devices shall not be considered to be accessories to in vitro diagnostic medical devices;
7) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling and/or in the instructions for use;
8) 'medical device' means any device, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for the proper performance of the medical device, intended by the manufacturer to be used for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;
9) 'in vitro diagnostic medical device' (device for clinical laboratory diagnosis) means any medical device, particularly a reagent, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:
concerning a physiological or pathological state;
concerning a congenital abnormality;
to determine the safety and compatibility with potential recipients;
to monitor therapeutic measures.
'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;
10) 'authorised representative' means any legal person or sole proprietor who is a resident in Ukraine or is registered in accordance with Ukrainian legislation, or a representative office of a foreign business entity, that is duly authorised by the manufacturer to act on his behalf with regard to the obligations of the manufacturer under this Technical Regulation;
For the purpose of this Technical Regulation, 'national standards' shall have the meaning defined in the Law of Ukraine 'On standardization'; 'declaration of conformity', 'supplier' take the meanings defined in the Law of Ukraine 'On confirmation of conformity'; 'user' shall have the meaning defined in the Law of Ukraine 'On general safety of non-food products'; 'conformity assessment body', 'risk', 'technical regulations' take the meanings defined in the Law of Ukraine 'On standards, technical regulations and conformity assessment procedures'; and 'medicinal products' shall have the meaning defined in the Law of Ukraine 'On medicines'.
3. For the purposes of this Technical Regulation, calibrators and control materials refer to any substance, material or article intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended use of that device.
4. For the purposes of this Technical Regulation, the collection, storage and use of tissues, cells and substances of human origin shall be governed by law.
5. This Technical Regulation shall not apply to devices manufactured and used only within the same health institution or company without having been transferred to another legal entity.
6. The Technical Regulation on Electromagnetic Compatibility of Equipment, as approved by Resolution № 785 of the Cabinets of Ministers of Ukraine of 29 July 2009 (*Ofitsiinyi Visnyk Ukrainy* 2009, No. 58, Art. 2028), shall not apply to devices governed by this Technical Regulation.

Placing on the market and putting into service

7. The medical devices governed by this Technical Regulation may be placed on the market and put into service only if they fully comply with the requirements laid down in this Technical Regulation. This also applies to devices for performance evaluation.

Essential requirements for in vitro diagnostic medical devices

8. Devices must meet the essential requirements set out in Annex I, taking account of the intended purpose of the devices concerned.
The devices that meet the national standards included in the list of national standards that conform to the European harmonized standards and voluntary application of which can be considered to be evidence of the conformity of products to this Technical Regulation are presumed to meet the requirements of this Technical Regulation.
9. At trade fairs, exhibitions, demonstrations, devices which have not been assessed for conformity with this Technical Regulation may be exhibited, provided that such devices are not used for examination of specimens and that the manufacturer made a clear indication that such devices cannot be placed on the market or put into service until they have been made to comply.

Conformity assessment of in vitro diagnostic medical devices

10. For all devices other than those covered by Annex 2 and devices for performance evaluation, the manufacturer shall, in order to affix the national conformity mark, carry out the conformity assessment procedure referred to in Annex 3 and draw up the declaration of conformity before placing the devices on the market.
For devices for self-testing other than those covered by Annex 2 and devices for performance evaluation, the manufacturer shall, prior to conducting the conformity assessment procedure in line with Annex 3, fulfil the additional requirements set out in clauses 6 to 8 of Annex 3 or apply the procedures referred to in clauses 11 and 12 of this Technical Regulation.
11. In order to affix the national conformity mark to the devices in list A of Annex 2 other than devices for performance evaluation, the manufacturer shall follow the procedure described in Annex 4 or the procedure described in Annex 5, coupled with the procedure described in Annex 7.
12. In order to affix the national conformity mark to the devices in list B of Annex 2 (other than devices for performance evaluation), the manufacturer shall follow the procedure described in Annex 4, or the procedure described in Annex 5, coupled with the procedure described in Annex 6 or with the procedure described in Annex 7.
13. Before placing a device for performance evaluation on the market, the manufacturer shall draw up the statement of performance evaluation and perform the procedure set out in Annex 8.
14. During the conformity assessment procedure, the manufacturer and the conformity assessment body (if involved) shall take account of the results of any assessments and verifications which have been carried out in accordance with this Technical Regulation before, during and after the manufacture.

15. The manufacturer may instruct his authorised representative to initiate the procedures provided for in Annexes 3, 5, 6 and 8.
16. The manufacturer must, for a period ending five years after the last product has been manufactured, keep the following documents:
the declaration of conformity;
the technical documentation referred to in Annexes 3 to 8;
the decisions and certificates from the conformity assessment bodies.
Where the manufacturer is not a resident of Ukraine, the obligation to make the above documentation available to the competent state authorities applies to his authorised representative.
17. Where the conformity assessment procedure involves a conformity assessment body, the manufacturer or his authorised representative may apply to such body of their choice within the framework of the tasks for which the body has been designated.
18. The conformity assessment body may require (where duly justified) from the manufacturer or his authorised representative any information or data necessary to establish and confirm the conformity to this Technical Regulation in view of the chosen conformity assessment procedure.
19. Decisions taken by the conformity assessment bodies in accordance with Annexes 3 to 5 shall be valid for five years. They may be extended for a further period of five years upon application from the manufacturer or his authorised representative submitted at the time agreed in the contract signed by both parties.
20. The correspondence between the manufacturer and the conformity assessment body relating to the procedures referred to in clauses 10 to 13 of this Technical Regulation shall be carried on in accordance with the Law of Ukraine 'On principles of the state language policy'.
21. Any sole proprietor or legal person who manufactures the devices covered by this Technical Regulation and, without placing them on the market, uses them in the context of their professional activity shall fulfil the requirements set out in this section.
22. For individual devices that do not meet the requirements set out in clauses 10 to 13 of this Technical Regulation but whose use is in the interest of protection of health and life of a human, the procedures for placing on the market and putting into service shall be established by the MOH.

Registration of manufacturers and devices

23. Any manufacturer who puts the devices on the market under his own name shall notify the SAUMP:
of his registered place of business;
of information relating to the reagents, reagent products, calibrators and control materials and to any significant changes, including temporary discontinuation of placing on the market;
the data needed for identification of such devices, the analytical and, where necessary, diagnostic parameters, the results of performance evaluation as referred to in Annex 8, the certificates issued;
information on the device that is a new device, and a statement indicating whether the device has been marked with the national conformity mark.
For the purposes of this Technical Regulation, a device is considered 'new' if:
no such device has been placed on the Ukrainian market within the previous three years;
the procedure of the device use involves analytical technology not used in Ukraine within the previous three years.
The SAUMP may within the following two years and on justified ground require the manufacturer to provide information relating to the experience gained from the use of the device after it has been placed on the market.
Where the manufacturer who places the devices on the market under his own name is not a resident of Ukraine, the obligation to submit the information to the SAUMP shall apply to his authorised representative.

Conformity assessment bodies

24. Conformity assessment bodies shall meet the requirements prescribed by law. The conformity assessment bodies that meet the criteria laid down in the national standards that conform to the European harmonized standards shall be presumed to meet the relevant criteria.
25. Where a designated conformity assessment body does not meet the requirements prescribed by law, the designation shall be withdrawn, with account taken of the Law of Ukraine 'On the main principles of the state supervision (control) in the area of economic activity'.
26. The conformity assessment body shall inform other conformity assessment bodies and the SAUMP of all certificates suspended or withdrawn and, on request, about certificates issued or refused, and provide other relevant information.
27. Where a conformity assessment body finds that the relevant requirements of this Technical Regulation have not been met or are no longer met by the manufacturer or that a certificate of conformity should not have been issued, it

shall suspend or withdraw the certificate issued or place any restriction on it until compliance with the requirements is ensured by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or where an intervention of the SAUMP may become necessary, the conformity assessment body shall inform the SAUMP.

28. The conformity assessment body shall, upon request of the Ministry for Economic Development, submit, in accordance with the applicable procedure, the relevant information and documents, including financial ones, necessary to verify the compliance of the conformity assessment body with the requirements prescribed by law.

National conformity mark

29. Medical devices (other that those intended for performance evaluation) that are considered to meet the requirements referred to in clause 8 of this Technical Regulation, must bear the national conformity mark before being placed on the market.

30. The requirements regarding the national conformity mark are set out in Annex 9. The national conformity mark must appear on the instructions for use, where such instructions are mandatory, and on the outer packaging and, if possible, on the device itself. The marking must be visible, legible and indelible. The national conformity mark may also appear on the device label.

{The first paragraph of clause 30 as amended by Resolution № 181 of the CMU of 27 May 2014}

The national conformity mark shall be accompanied by the identification number of the conformity assessment body responsible for implementation of procedures referred to in Annexes 3, 4, 6 and 7.

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

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

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

34. Clauses 32 and 33 of this Technical Regulation shall also apply where the national conformity mark has been affixed in violation of this Technical Regulation on products that are not covered by this Technical Regulation.

Confidentiality

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

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

Annex 1
to the Technical Regulation

ESSENTIAL REQUIREMENTS
for in vitro diagnostic medical devices
General Requirements

1. In vitro diagnostic medical devices (hereinafter referred to as 'devices') must be designed and manufactured in such a way that, when used for the intended purpose and under intended conditions, they will not pose directly or indirectly any risk to the clinical condition or the safety of the consumers, safety or health of the users or other persons, or safety of property. The risks that may arise from the use of such devices must be acceptable when weighed against the benefits for the patient and be compatible with a high level of protection of health and safety.
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to the safety requirements.
The manufacturer must follow the following principles:
eliminate or reduce the risks (safe design and construction);
where necessary, take appropriate safety measures to avoid potential risks that are associated with the use of the devices and cannot be eliminated;
inform the users and consumers of the potential risks that cannot be eliminated by precautionary measures.
3. The medical devices must be designed and manufactured in such a way that they are suitable for their intended purpose indicated by the manufacturer, as set out subclause 8 of clause 2 of the Technical Regulations on In Vitro Diagnostic Medical Devices. The devices must achieve the performances, in particular analytical and diagnostic sensitivity, analytical and diagnostic specificity, accuracy, repeatability and reproducibility, including control of potential interferences, and the limits of detection specified by the manufacturer.
The traceability of the nominal values assigned to calibrators and/or control materials must be ensured through available reference procedures for measurements and/or available reference materials (reference standards) of a higher order.
4. During the lifetime of the device specified by the manufacturer, the characteristics and performances referred to in clauses 1 and 3 of these Essential Requirements must not change or deteriorate to such a degree that they could pose a danger to the health and safety of the consumer or user or other persons, when the device is subjected to stresses that may occur during normal use. If no lifetime is indicated, the same applies to the lifetime reasonably expected for the device of such type.
5. The devices must be designed, manufactured and packaged in such a way that their characteristics and performances during the intended use will not be adversely affected under storage and transport conditions (temperature, humidity etc.), taking account of instructions for use and information supplied by the manufacturer.

Design and manufacturing

6. The devices must be designed and manufactured in such a way as to conform to the characteristics and performances referred to claused 1 to 5 of these Essential Requirements. Particular attention should be paid to possible impairment of analytical properties due to incompatibility between the materials used for the device manufacture and the specimens (such as biological tissues, cells, body fluids and microorganisms) intended to be used with the device, taking account of its intended purpose.
7. The devices must be designed, manufactured and packaged in such a way as to minimize the risks posed by leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of their intended purpose.
8. The devices and their manufacturing processes must be designed in such a way as to eliminate or minimize the risk of infection to the user or other persons. The device construction must allow easy handling and, where necessary, minimize the risk of contamination and leakage from the device during the use and, where the specimen receptacles are used, the risk of contamination of the specimen. The manufacturing processes must ensure that the devices meet these requirements.
9. Where a device incorporates substances of biological origin, the risks of infection must be minimized by selecting appropriate donors and substances and by using appropriate validated procedures for inactivation, conservation, testing and control.
10. The devices labelled as 'Sterile' or as having a special microbiological state must be designed, manufactured and packaged in a special packaging in accordance with an appropriate procedure that ensures that the microbiological state indicated on the label will be maintained when the devices are placed on the marked, under storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened.
11. The devices labelled as 'Sterile' or as having a special microbiological state must be treated by using special validated methods.

12. Packaging systems for devices other then those referred to in clause 10 of these Essential Requirements, must ensure that the devices can be stored without deterioration of the degree of cleanliness specified by the manufacturer and, if the devices are intended to be sterilised prior to use, minimize the risk of microbial contamination.
Measures to minimize the microbial contamination must be taken during selection and use of the raw materials, manufacture, storage and distribution of devices if their characteristics can be adversely affected by such contamination.
13. The devices intended to be sterilised must be manufactured in respective controlled conditions (e.g. in controlled environment).
14. Packaging systems for non-sterile devices must ensure that the specified level of cleanliness will not be compromised during storage and (if the devices are intended to be sterilised before use) minimize the risk of microbial contamination. The packaging must conform to the method of sterilization specified by the manufacturer.
15. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and not impair the specified characteristics of the devices. Any restrictions on use of such devices must be indicated on the label and/or in the instructions for use.
16. The devices must be designed and manufactured in such a way as to minimize the risks arising from their use together with materials, substances and gases with which they may enter into contact under normal conditions of use.
17. The devices must be designed and manufactured in such a way as to eliminate or minimize the following risks:
the risk of injury related to the physical features (in particular the volume/pressure ratio, physical dimensions and, where necessary, ergonomic characteristics);
the risks related to reasonably foreseeable external influences, in particular magnetic fields, external electrical influences, electrostatic discharge, pressure, humidity, temperature, variations in pressure or acceleration, or accidental ingress of substances into the device.
The devices must be designed and manufactured in such a way as to provide an appropriate level of intrinsic resistance to electromagnetic disturbances to ensure their intended performance.
18. The devices must be designed and manufactured in such a way as to minimize the risk of fire or explosion under normal conditions of use and in the event of a single fault. Particular attention must be paid to the devices whose intended use includes the use of flammable substances or substances that can cause combustion.
19. The devices must be designed and manufactured in such a way as to facilitate safe waste disposal.
20. Measuring, monitoring (control) or display scales (including colour and other visual indicators) must be designed and manufactured in conformity with ergonomic principles, taking account of the intended purpose of the device.
21. The devices with a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability and accuracy of measurements within appropriate accuracy limits, taking account of the intended purpose of the device and of available and appropriate reference measurement procedures and materials (reference standards). The limits of accuracy must be indicated by the manufacturer.
22. When the measurement results are expressed numerically, they must be given in standard units (of the International System of Units [SI]) in accordance with the Classification of Codes for Units of Measure and Accounting.
23. The devices must be designed, manufactured and packaged in such a way as to conform to the requirements ensuring that the exposure of the users and other persons to radiation is minimised.
24. The devices intended to emit potentially hazardous, visible and/or invisible radiation:
must ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted;
must be fitted with visual displays and/or audible warnings of such radiation.
25. Instructions for use of the devices emitting radiation must include detailed information on the nature of radiation, means of protecting the user and avoiding misuse and risks related to the installation.
26. The devices incorporating electronic programmable systems, including software, must be designed in such a way as to ensure the reproducibility, reliability and efficacy of these systems according to the intended use.
27. The devices must be designed and manufactured in such as way as to minimize the risks of creating electromagnetic disturbances that can impair the performance of other devices or equipment under normal conditions in the usual environment.
28. The devices must be designed and manufactured in such a way as to avoid, as far as possible, the risks of accidental electric shock during normal use and in single fault condition, provided that the devices are installed and put into service correctly.
29. The devices must protect the user and the consumer against mechanical injuries. The devices must be stable under foreseen operating conditions, withstand the stress that can occur in foreseen working environment and retain this resistance during the lifetime, subject to control and maintenance intended by the manufacturer.

If there is a risk related to the moving parts of the device, the risks of destruction, disconnection or leakage of substances, the appropriate means of protection must be incorporated.
Any protective or other means incorporated into the devices to provide protection, in particular against moving parts, must be safe and not interfere with the access to the devices for normal operation or restrict routine maintenance of such devices as intended by the manufacturer.
30. The devices must be designed and manufactured in such a way as to minimize the possible risks related to vibrations generated by devices, taking account of the technical progress and of means available to limit the vibrations, in particular at the source, unless such vibrations are part of the intended performance.
31. The devices must be designed and manufactured in such a way as to minimize the potential risks arising from noise generated by devices, taking account of technical progress and of the means available to reduce noise, particularly at source, unless such noise is part of intended performance.
32. Terminals and connectors to electricity, gas, hydraulic or pneumatic power sources that the user or consumer has to handle must be designed and manufactured in such a way as to minimize all possible risks.
33. Accessible parts of medical devices (excluding the parts or areas intended to supply heat or reach specified temperatures) must not reach potentially hazardous temperatures under normal use.
34. The devices for self-testing must be designed, manufactured and perform appropriately for their intended purpose, taking into account the skills and the means available to consumers. The information and instructions provided by the manufacturer should be easily understood and applied by the user.
35. The devices for self-testing must be designed and manufactured in such a way as to ensure that they are easy to use by a lay user or consumer at all stages of the procedure, and to minimize the risk of user error during use of the device.
36. The devices for self-testing must, where possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the device will perform as specified in the instructions for use.
37. Each device must be accompanied by the information necessary for its safe and proper use, taking account of the training and qualification of the potential users and consumers, and for identification of the manufacturer.
The information necessary for safe and proper use of the device must appear on the device itself and/or on the sales packaging. If it is not practicable to provide full information on the label of each unit, the information must be provided on the packaging and/or in the instructions for use supplied with one or more devices.
Instructions for use must accompany or be included in the packaging of one or more devices.
Instructions for use are not needed if the device can be used properly and safely without them.
Instructions for use and the label shall be composed in conformity with the Law of Ukraine 'On principles of the state language policy'.
38. Where appropriate, the information accompanying the devices should take the form of symbols. All symbols and colours used must conform to the harmonized standards. If no such standards exist, the symbols and colours used must be described in the documentation supplied with the devices.
39. If the device contains a preparation that can be considered dangerous, taking account of the nature and quantity of its constituents and the form, the danger symbol must be affixed and the device must be labelled as prescribed by law. If there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols must appear on the label and all other necessary information should be given in the instructions for use.
40. The label must include the following particulars which may take the form of symbols:
the name or trade mark and address of the manufacturer. For devices that are imported to be placed on the market, the label, or the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative if the manufacturer is not a resident of Ukraine;
the details that are necessary for the user or consumer to precisely identify the device and the contents of the packaging;
indication of any specific microbiological state or level of cleanliness (the word "Sterile" or a respective symbol);
the batch code following the word "Lot", or the serial number;
the date by which the device or part of it can be safely used without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;
for devices for performance evaluation, the words 'for performance evaluation only';
information regarding the in vitro use of the device;
any special storage and/or handling conditions;
specific operating instructions;
appropriate warnings and/or precautions to be taken;
if the device is intended for self-testing, that fact must be clearly stated.

41. If the intended purpose of the device is not obvious for the user or consumer, the manufacturer must clearly indicate the purpose in the instructions for use and on the label, if available.
42. Where reasonable and practicable, the devices and their separate components must be identified, where appropriate in terms of batches, to allow all appropriate actions to detect any potential risk posed by the devices or their components.
43. Where appropriate, the instructions for use shall include:
the details referred to in clause 40 of these Essential Requirements, excluding paragraphs five and six of clause 40 of these Essential Requirements;
qualitative and quantitative composition of the reagent products or concentrations of the active ingredients of the reagents or reagent kits as well as information that the device contains other ingredients that can influence the measurement;
the storage conditions and shelf-life following the first opening of the primary packaging as well as the storage conditions and stability of working reagents;
the performances referred to clause 3 of these Essential Requirements;
an indication of any special equipment required, including information necessary to identify such special equipment for proper use;
the type of specimens to be used for investigation, any special conditions of collection, pre-treatment and storage of specimens, and instructions for the preparation of the patient;
a detailed description of the procedure for using the device;
the measurement procedure to be followed with the device, including:
- the principle of the method of measurement;
- the specific analytical characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for control of known relevant errors), limitations of the method and information about the use of available reference measurement procedures and materials (reference standards) by the users;
- the details of any further procedure or handling needed prior to use of the device (e.g. reconstitution, incubation, dilution, instrument checks, etc.);
- the indication whether any particular training is required;
approach upon which the calculation of the analytical result is made;
measures to be taken in the event of changes in the analytical performance of the device;
information for users on internal quality control, including specific validation procedures and the traceability of the calibration of the device;
the reference intervals for the quantities to be determined;
the information needed to verify whether the device is properly installed and can operate correctly and safely as well as additional information regarding the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal;
details of any further treatment or handling needed before the device can be used (e.g. sterilisation, final assembly, etc.);
the necessary instructions in the event of damage to the protective packaging and information on appropriate methods of resterilization or decontamination;
precautions to be taken, in reasonably foreseeable environmental conditions, as regards exposure to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;
precautions to be taken against any special, unusual risks related to the use or disposal of the device, including special protective measures (where the device incorporates substances of human or animal origin, attention must be drawn to their potential infectious nature (infectogenic potential);
date of issue or the latest revision of the instructions for use;
specifications for devices for self-testing.
If the device is reusable, instructions for use must include details of the appropriate processes to prepare the device for reuse, including cleansing, disinfection, packaging and resterilization or decontamination, and any restriction on the number of reuses.
If the device must be used in combination with or installed with or connected to other medical devices in order to operate as required for its intended purpose, instructions for use must contain sufficient details of the characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination.

The results of the device operation must be expressed and presented in a way that is readily understood by a lay user and/or consumer; information must include advice to the user/consumer on the actions to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result.
Specific particulars may be omitted if other information provided to the users/consumers is sufficient to enable them to use the device for self-testing properly and to understand the results produced by the device.
This information must include a clear statement that the consumers should not take any medical decision (without first consulting a medical practitioner).
The information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patients should only administer the treatment after they have received the appropriate training to do so.

Annex 2
to the Technical Regulation

LISTS
of in vitro diagnostic medical devices
List A

Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: AB0 system, rhesus (C, c, D, E, e), anti-Kell

Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.

Test for blood screening, diagnosis and confirmation of variant Creutzfeldt–Jakob (vCJD) disease

List B

Reagents and reagent products, including related calibrators and control materials:
for determining the following blood groups: anti-Duffy and anti-Kidd;
for determining irregular anti-erythrocytic antibodies;
for the detection and quantification in human samples the following congenital infections: rubella and toxoplasmosis;
for diagnosing the following hereditary disease: phenylketonuria;
for determining the following human infections: cytomegalovirus, chlamydia;
for determining the following HLA tissue groups: DR, A, B;
for determining the tumoral marker PSA

Reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21

Devices for self-testing intended for the measurement of blood sugar

Annex 3
to the Technical Regulation

PROCEDURE

for internal control of the manufacture of in vitro diagnostic medical devices

1. The internal control of the manufacture of in vitro diagnostic medical devices (hereinafter referred to as 'devices') is the procedure whereby the manufacturer of his authorised representative who fulfils the obligations imposed by clauses 2 to 5 of this Annex and, in the case of devices for self-testing, the obligations imposed by clause 6 of this Annex, ensures and declares that the devices satisfy the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices which apply to them.

The manufacturer must affix the national conformity mark to medical devices in accordance with clauses 29 to 31 of the Technical Regulation on In Vitro Diagnostic Medical Devices.

2. The manufacturer must prepare the technical documentation referred to in clause 3 of this Procedure and ensure that the the manufacturing process follows the principles of quality assurance as set out in clause 4 of this Procedure.

3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices.

The technical documentation must include:

a general description of the product, including any variants planned;

the documentation on the quality management system;

design information, the determination of the characteristics of the basic materials, characteristics and limitation of the use of the device, methods of manufacture and, where necessary, diagrams of components, sub-assemblies, circuits, etc.;

information on the origin of the tissue of human origin or substances derived from such tissue and on the conditions in which it was collected (in the case of devices containing tissues of human origin or substances derived from such tissue);

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

the results of the risk analysis and, where appropriate, a list of the national standards that conform to the European harmonized standards and conformity with which is evidence of conformity with the requirements of the technical regulations, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices if the above standards have not been applied in full;

a description of the procedures used in the case of sterile products or products with a special microbiological state or other state of cleanliness;

the results of the design calculations and of the inspections carried out, etc.,

if the device is to be combined with other device(s) in order to operate as intended, proof must be provided that it conforms to the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices when combined with any such devices having the characteristics specified by the manufacturer;

the test reports;

performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (when available), with information on the reference methods, the reference materials (reference standards), the known reference values, the accuracy and measurement units used (such data should originate from studies in a clinical or other appropriate environment or result from relevant biographical references);

the labels and instructions for use;

the results of stability studies.

4. The manufacturer must take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured.

Such quality management system must address:

the organisational structure;

the manufacturing processes and systematic quality control of product;

the means to monitor the performance of the quality management system.

5. The manufacturer shall develop and keep up to date a systematic procedure to review experience gained from the device use after they have been placed on the marked and implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. The manufacturer must notify the SAUMP of the following incidents immediately on learning of them:

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

any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in clause 5 of this Procedure leading to systematic recall of devices of the same type by the manufacturer.

6. For devices for self-testing, the manufacturer shall lodge an application for examination of the design with a conformity assessment body.

The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices to be assessed.

The application must include:

the test reports;

data showing the handling suitability of the device in view of its intended purpose for self-testing;

the information to be provided with the device on its label or in its instructions for use.

7. The conformity assessment body must examine the application and, if the device conforms with the provisions of the Technical Regulation on In Vitro Diagnostic Medical Devices, issue the applicant with a design examination certificate. The conformity assessment body may require the application to be completed with the additional tests or proof to allow assessment of the product design for conformity with the Technical Regulation on In Vitro Diagnostic Medical Devices. The certificate must contain the examination conclusions, the data needed for identification of the approved design, and, where appropriate, a description of the intended use of the device.

8. The applicant must inform the conformity assessment body that issued the design examination certificate of any changes made to the approved design. The changes to the approved design must be further approved by the conformity assessment body that issued the design examination certificate wherever such changes can affect the device conformity with the established requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices or conditions of its intended use. The additional approval must take form of a supplement to the design examination certificate.

Annex 4
to the Technical Regulation

PROCEDURE
for ensuring performance of a comprehensive quality assurance system

1. Full quality assurance is the procedure whereby the manufacturer of in vitro diagnostic medical devices (hereinafter referred to as 'devices') ensures and declares that the devices concerned meet the provisions of the Technical Regulation on In Vitro Diagnostic Medical Devices that apply to them.
The manufacturer must affix the national conformity mark to devices in accordance with clauses 29 to 31 of the Technical Regulation on In Vitro Diagnostic Medical Devices and must draw up a declaration of conformity covering the devices concerned.
2. The manufacturer must lodge an application for assessment of his quality management system with a conformity assessment body.
The application must include:
the name and address of the manufacturer and any additional manufacturing site covered by the quality management system;
the necessary full information on the device or device category covered by the assessment procedure;
a written statement that no application has been submitted to any other conformity assessment body for the same device-related quality system;
the documentation on the quality management system;
an undertaking by the manufacturer to fulfil the obligations imposed by the approved quality management system;
an undertaking by the manufacturer to keep the approved quality system adequate and efficacious;
an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices after their being placed on the marked and to implement appropriate means to apply any necessary corrective actions, in particular regarding notification, as specified in this Procedure.
3. Application of the quality system must ensure that the devices conform to the provisions of the Technical Regulation on in vitro diagnostic medical devices which apply to them at every stage (from design to final inspection). Parameters, requirements and provisions adopted by the manufacturer for his quality management system must be documented in the rules and procedures, in particular in the quality programmes, quality plans, manuals and quality reports.
The documentation on the quality management system must include a description of:
the manufacturer's quality objectives;
the organisation of the business, in particular:
- the organizational structures, the responsibilities of the managerial staff and their authority in regard to quality of design and manufacture of medical devices;
- the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of product, including control of devices which fail to conform;
the procedures for monitoring and verifying the design of the devices, in particular:
- a general description of the device, including any variants planned;
- the documentation referred to in paragraphs three to thirteen of clause 3 of Annex 3 to the Technical Regulation on In Vitro Diagnostic Medical Devices;
- in the case of devices for self-testing, the information referred to in clause 6 of Annex 3 to the Technical Regulation on In Vitro Diagnostic Medical Devices;
- the techniques used to control and verify the design and the manufacturing processes and systematic measures which are used when the devices are being designed;
the inspection and quality assurance techniques at the manufacturing stage and in particular:
- the processes and procedures which will be used, particularly as regards sterilisation;
- the procedures in relation to purchasing;
- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used (it must be possible to trace back the calibration).
The manufacturer shall carry out the required controls and tests according to the latest state of the art; these shall cover the whole manufacturing process, including the examination of the raw material and the individual devices or each batch of devices manufactured.

In testing the devices covered by List A in Annex 2 to the Technical Regulation on In Vitro Diagnostic Medical Devices, the manufacturer shall take into account the information regarding the biological complexity and variability of the specimens to be tested with the device concerned.

4. The conformity assessment body must audit the quality management system to determine whether it meets the requirements referred to in clause 3 of this Procedure. The quality systems that implement the relevant harmonised standards are presumed to conform to the requirements.

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

The manufacturer must be notified of the decision taken on the basis of the assessment results. The decision must contain the conclusions and a reasoned assessment.

5. The manufacturer must inform the conformity assessment body that approved the quality management system of any plan for changes to the quality management system or the device-range covered by the system.

The conformity assessment body must assess the proposed changes and verify whether after these changes the quality management system still meets the requirements referred to in clause 3 of this Procedure. The conformity assessment body must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

6. For devices covered by List A in Annex 2 to the Technical Regulation on In Vitro Diagnostic Medical Devices, in addition to the obligations imposed by clause 2 of this Procedure, the manufacturer must lodge with the conformity assessment body an application for examination of the design dossier relating to the device which he plans to manufacture and which falls into the category referred to in clause 2 of this Procedure.

The application for examination of the design dossier must describe the mechanism of design, manufacture and performances of the device in question. The application must include the documents needed to assess whether the device conforms to the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices as regards the procedures for monitoring and verifying, as referred to in clause 2 of this Procedure.

7. The conformity assessment body must examine the application and, if the design conforms to the relevant provisions of the Technical Regulation on In Vitro Diagnostic Medical Devices, issue the design examination certificate. The conformity assessment body may require the application to be completed with the results of additional tests or proof to allow assessment of the product design for conformity with the Technical Regulation on In Vitro Diagnostic Medical Devices. The certificate must contain the examination conclusions, the conditions of validity, the data needed for identification of the approved design, and, where appropriate, a description of the intended use of the device.

8. The applicant must inform the conformity assessment body that issued the design examination certificate of any changes made to the approved design, which must receive further approval wherever such changes could affect the conformity with the Technical Regulation on In Vitro Diagnostic Medical Devices or with the conditions prescribed for use of the device. The data of the additional examination must take the form of a supplement to the original design examination certificate.

9. The manufacturer must inform the conformity assessment body of obtained information about changes to the pathogen and markers of infections to be tested, in particular as a consequence of biological complexity and variability. In this connection, the manufacturer must inform the conformity assessment body whether any such change is likely to affect the performance of the device concerned.

10. In order to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system, surveillance is carried out.

The manufacturer must authorise the notified body to carry out the necessary inspections and supply it with relevant information, in particular:

the documentation on the quality management system;

the data stipulated in the part of the quality management system relating to design;

the data stipulated in the part of the quality management system relating to manufacture, in particular inspection reports and test data, calibration data, qualification reports of the personnel concerned.

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

In addition, the conformity assessment body may carry out unannounced inspections. During such inspections, the conformity assessment body may, where necessary, carry out or ask for tests in order to check that the quality

management system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

12. In the case of devices covered by List A in Annex 2 to theTechnical Regulation on In Vitro Diagnostic Medical Devices, the manufacturer shall forward to the conformity assessment body without delay after the conclusion of the controls and tests the relevant reports on the tests carried out on each manufactured device or each batch of devices. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the conformity assessment body and where necessary provide samples in accordance with the pre-agreed conditions.

13. The manufacturer may place the devices on the market, unless the conformity assessment body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

Annex 5
to the Technical Regulation

PROCEDURE
for type examination

1. Type examination of in vitro diagnostic medical devices (hereinafter referred to as 'devices') is the procedure whereby a conformity assessment body ascertains and certifies that a representative sample ('type') of the devices covered by this Procedure is in conformity with the Technical Regulation on In Vitro Diagnostic Medical Devices which apply to them.
2. The application for type examination must be lodged by the manufacturer or by his authorised representative with a conformity assessment body. The application must include:
name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of the latter;
the documentation referred to in clause 3 of this Procedure needed to assess the conformity of the representative sample with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices. The applicant must provide a 'type' to the conformity assessment body. The conformity assessment body may request other samples as necessary.
a written statement that no such application has been submitted to any other conformity assessment body;
3. The documentation supporting the application submitted to the conformity assessment body must allow understanding of the design, manufacturing processes and performances of the devices concerned, and contain the following:
a general description of the type, including any variants planned;
the documentation referred to in paragraphs three to thirteen of clause 3 of Annex 3 to the Technical Regulation on In Vitro Diagnostic Medical Devices;
in the case of devices for self-testing, the information referred to in clause 6 of Annex 3 to the Technical Regulation on In Vitro Diagnostic Medical Devices.
4. The conformity assessment body shall:
examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the national standards that conform with the harmonised European standards and voluntary application of which can be considered to be evidence of conformity with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices, as well as the items not designed on the basis of the provisions of the above standards;
perform or have performed appropriate examinations and the tests necessary to verify whether the solutions adopted by the manufacturer meet the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices if the national standards that conform to the harmonised European standards and voluntary application of which can be considered to be evidence of conformity with the Technical Regulation on In Vitro Diagnostic Medical Devices have not been applied; if the device is to be combined with other device(s) in order to operate as intended, proof must be provided that it conforms to the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices when combined with any such device(s) having the characteristics specified by the manufacturer;
carry out or arrange for the appropriate examinations and tests necessary to verify whether the relevant standards chosen by the manufacturer have actually been applied;
agree with the applicant on the place where the necessary inspections, examinations and tests will be carried out.
5. If the type conforms with the Technical Regulation on In Vitro Diagnostic Medical Devices, the conformity assessment body shall issue the applicant with a type examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the examination, the conditions of the certificate validity and the data needed for identification of the type approved. The relevant parts of the documentation shall be annexed to the certificate and a copy shall be kept by the conformity assessment body.
6. The manufacturer must without delay inform the conformity assessment body that issued the type examination certificate of any changes to the pathogen and markers of infections to be tested, in particular if those are a consequence of biological complexity and variability. In this connection, the manufacturer must inform the conformity assessment body whether any such change is likely to affect the performance of the device concerned.
All the changes to the approved design must be further approved by the conformity assessment body that issued the type examination certificate wherever such changes may affect the device conformity with the established requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices or the conditions of its intended use prescribed by the manufacturer. The applicant must without delay inform the conformity assessment body that issued the type examination certificate of any changes made to the approved design. The changes to the approved design shall take form of a supplement to the type examination certificate.

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

Annex 6
to the Technical Regulation

PROCEDURE
for product verification

1. The product verification is the conformity assessment procedure whereby the manufacturer or his authorised representative ensures and declares that the in vitro diagnostic medical devices (hereinafter referred to as 'devices') that are subject to the procedure referred to in clause 4 of this Procedure conform to the type described in the type examination certificate and to the Technical Regulation on In Vitro Diagnostic Medical Devices that apply to them.
2. The manufacturer must take the measures necessary to ensure that the manufacturing process produces devices that conform with the type described in the type examination certificate and with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices that apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization and the suitability of starting materials, where necessary, and define the necessary testing procedures according to the state of the art.
To the extent that for certain aspects the final testing according to paragraph three of clause 6 of this Procedure is not applicable, adequate process testing, monitoring and control methods shall be established by the manufacturer with the approval of the conformity assessment body. The provisions of clause 10 of Annex 4 to the Technical Regulation on In Vitro Diagnostic Medical Devices shall apply accordingly in relation to the above approved procedures.
3. The manufacturer shall develop and keep up to date a systematic procedure to review experience gained from devices after they have been placed on the marked and implement appropriate means to apply any necessary corrective and notification action as referred to in clause 5 of Annex 3 to the Technical Regulation on In Vitro Diagnostic Medical Devices.
4. The conformity assessment body must carry out the appropriate examinations and tests, taking account of the second paragraph of clause 2 of this Procedure, in order to verify the conformity of the product with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices either by examining and testing every product as specified in clause 5 of this Procedure or by examining and testing products on a statistical basis as specified in clause 6 of this Procedure, as the manufacturer decides. When carrying out statistical verification according to clause 6 of this Procedure, the conformity assessment body has to decide when statistical procedures for lot-by-lot inspection or isolated lot inspection have to be applied. Such decision must be taken in consultation with the manufacturer.
In as far as the conduct of examinations and tests on a statistical basis is not appropriate, examinations and tests may be carried out on a random basis provided that such procedure in conjunction with the measures taken in accordance with the second paragraph of clause 2 of this Procedure ensures a sufficient level of conformity.
5. Every device is examined individually. The appropriate tests defined in the relevant national standards that conform to the harmonised European standards and voluntary application of which can be considered to be evidence of the conformity of devices to the Technical Regulation on In Vitro Diagnostic Medical Devices or equivalent tests must be carried out in order to verify the conformity of the device with the type described in the type examination certificate and with the applicable requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices.
The conformity assessment body must affix or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.
6. The manufacturer must produce the devices in the form of homogeneous batches.
One or more random samples are taken from each batch. The products which make up the sample are examined and the appropriate tests defined in the relevant national standards that conform to the harmonised European standards and voluntary application of which can be considered to be evidence of conformity with the Technical Regulation on In Vitro Diagnostic Medical Devices or equivalent tests must be carried out to verify the conformity of the products with the type described in the type examination certificate and with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices which apply to them in order to determine whether to accept or reject the batch.
Statistical control of products will be based on attributes and/or variables, entailing operational characteristics, sampling schemes which ensure a high level of safety and performance. The sampling scheme must be established by the national standards that conform to the harmonised European standards and voluntary application of which can be considered to be evidence of the conformity of the products with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices, taking account of the specific nature of the product categories in question.
If the batch is accepted, the conformity assessment body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform to the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices.

If the batch is rejected the conformity assessment body must take appropriate measures to prevent the batch from being placed on the market, in line with the legislation. In the event of periodical rejection of batches, the conformity assessment body may suspend the statistical verification.
The manufacturer may, on the responsibility and by consent of the conformity assessment body, affix the conformity assessment body's identification number during the manufacturing process.

Annex 7
to the Technical Regulation

PROCEDURE
for production quality assurance

1. The manufacturer must ensure application of the quality management system approved for the manufacture of the in vitro diagnostic medical devices (hereinafter referred to as 'devices') concerned and carry out the final inspection as specified in clause 3 of this Procedure, and is subject to the surveillance as defined in clause 4 of this Procedure.
2. The production quality assurance is the part of the procedure whereby the manufacturer ensures and declares that the products conform to the type described in the type examination certificate and with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices that apply to them.
The manufacturer must affix the national conformity mark to devices in accordance with clauses 29 to 31 of the Technical Regulation on In Vitro Diagnostic Medical Devices and must draw up a declaration of conformity covering the devices concerned.
3. The manufacturer must submit an application for assessment of the quality management system to a conformity assessment body.
The application must contain the technical documentation on the approved types and the copies of the type examination certificates;
Application of the quality management system must ensure that devices produced conform to the type described in the type examination certificate.
All the parameters, requirements and provisions adopted by the manufacturer for the quality management system must be documented in the respective procedures. This documentation on the quality management system must ensure unambiguous interpretation of procedures for quality, in particular programmes, plans, manuals and reports.
4. The documentation on the quality management system must include a description of:
the manufacturer's quality objectives;
the organisation of the business, in particular:
the organizational structures, the responsibilities of the managerial staff and their authority in regard to the manufacture of the devices;
- the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of products, including control of products which fail to conform;
the inspection and quality assurance techniques at the manufacturing stage and in particular:
- the processes and procedures which will be used, particularly as regards sterilization;
- the procedures in relation to purchasing;
- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; (it must be possible to trace back the calibration).
5. The conformity assessment body must audit the quality management system to determine whether it meets the requirements referred to in clause 3 of this Procedure. The quality systems that implement the relevant national standards conforming to the harmonised European standards are presumed to conform to the requirements.
The committee convened by the conformity assessment body to assess the quality management system must include at least one specialist with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, where applicable, on the premises of the suppliers and/or subcontractors to inspect the manufacturing processes.
The respective decision must be notified to the manufacturer. This decision must contain the conclusions of the inspection and a reasoned assessment.
6. The manufacturer must inform the notified body that approved the quality management system of any plan for substantial changes to the quality management system.
The conformity assessment body must assess the proposed changes and verify whether after these changes the quality management system still meets the requirements referred to in clause 3 of this Procedure. The conformity assessment body must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.
7. During surveillance, the provisions of clause 10 of Annex 4 to the Technical Regulation on In Vitro Diagnostic Medical Devices shall apply.
8. In the case of devices covered by List A in Annex 2 to the Technical Regulation on In Vitro Diagnostic Medical Devices, the manufacturer must forward to the conformity assessment body without delay after the conclusion of the control tests the relevant reports on the tests carried out on each manufactured device or each batch of devices.

Furthermore, the manufacturer shall make the samples of the manufactured devices (batches of devices) available to the conformity assessment body and where necessary provide samples in accordance with the pre-agreed conditions. The manufacturer may place the devices on the market, unless the conformity assessment body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision.

Annex 8
to the Technical Regulation

PROCEDURES

concerning in vitro diagnostic medical devices for performance evaluation

1. In order to place the devices for performance evaluation of the market, the manufacturer or his authorised representative shall draw up the statement containing the information stipulated in clause 2 of these Procedures and ensure that the relevant provisions of the Technical Regulation on In Vitro Diagnostic Medical Devices are met.

2. The application must include:

the data necessary for identification of the device concerned;

an evaluation plan stating in particular the purpose, scientific, technical or medical grounds, scope of the evaluation and number of devices concerned;

the list of laboratories or other institutions taking part in the evaluation study,

the starting date and scheduled duration for the evaluations and, in the case of devices for self-testing, the location and number of persons involved;

a statement that the device in question conforms to the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices, apart from the aspects covered by the evaluation and apart from those specifically indicated in the statement, and that every precaution has been taken to protect the health and safety of the consumer, user and other persons.

3. The manufacturer shall also make available to the SAUMP on request the documentation allowing an understanding of the design, manufacture and performances of the product so as to allow assessment of conformity with the requirements of the Technical Regulation on In Vitro Diagnostic Medical Devices. This documentation must be kept for a period ending at least five years after the end of the performance evaluation.

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products that conform with the documentation referred to in the first paragraph of clause 3 of these Procedures.

Annex 9
to the Technical Regulation

REQUIREMENTS
regarding the national mark of conformity

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

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

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

APPROVED
by Resolution No. 754 of the Cabinet of Ministers of Ukraine
of 2 October 2013

ACTION PLAN

for application of the Technical Regulation on In Vitro Diagnostic Medical Devices

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

{Action plan as amended by Resolution No. 215 of the CMU of 1 July 2014}