LAW
on medical devices
(L 176/2000)

The Parliament of Romania has adopted this law:

CHAPTER I

General provisions

Article 1

This law shall apply to medical devices and their accessories. For the purpose of this Law, accessories shall be treated as medical devices in their own right. Both medical devices and their accessories shall be hereinafter termed *devices*.

Article 2

For the purpose of this Law, the following definitions shall apply:

a) *medical device* - means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including any software needed for its proper application, intended by the manufacturer to be used for human beings and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means; for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological
- process;
- control of conception;

b) *active medical device* - means any medical device relying for its functioning on a source of electrical energy or any source of power, other than that directly generated by the human body or gravity;

c) *active implantable medical device* - means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or into a natural orifice, and which is intended to remain after the procedure;

d) *accessory* - means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

e) *'in vitro diagnostic medical device'* means any medical device which is a reagent, reagent product, 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, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures; specimen receptacles are considered to be *in vitro diagnostic* medical devices; '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.

f) *custom-made device* - means any medical device specifically made in accordance with a written prescription of a duly qualified medical practitioner who gives, under his

responsibility, specific design characteristics and it is intended for the sole use of a particular patient; such a prescription may also made out by another person authorised by virtue of his professional qualifications to do so; mass-produced medical devices requiring special adaptations in order to meet the specific requirements of the medical practitioner or any other authorised person shall not be considered custom-made devices;

g) *device intended for clinical investigation* - means any medical device intended for use by a qualified medical practitioner when conducting clinical investigations as referred to in Annex X enclosed in an adequate human clinical environment; for the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorised to carry out such investigations shall be accepted as equivalent to a duly qualified medical practitioner;

h) *European Directives on medical devices* – means the regulations prepared by the European Community, acting as laws in force in the Member States, stating the essential quality and safety requirements of medical devices, in order to remove any trade barriers of a technical nature;

i) *certification* – means the overall procedures, verifications, tests, concluded under the form of a certificate/document, certifying the respective medical device conformity with the safety and performance requirements needed for its intended purpose;

j) *registration* – means the document providing objective evidence of activities performed or of results obtained in relation to medical devices;

k) *essential requirements* – means the main characteristics and performance required of medical devices considering the intended purpose of the same, as specified in the European directives and norms for each category of devices;

l) *harmonised standard* – means the standard adopted by a European standardisation body, specifically referring to the scope of a certain directive; a standard shall be deemed as harmonised in case of a parallel approval of ISO and CEN standards;

m) *notified body* – means that body assigned by the specialised department within the Ministry of Health to evaluate the conformity of medical devices and certify them in accordance with the strategy established by the specialised department of the Ministry of Health;

n) *surveillance in operation* – means the overall measures assuring and confirming the safe operation and the performance, deriving from the intended purpose, throughout the operation life of the respective device, as well as the detection of any operation incidents;

o) *incident* - means those defects which have or might have caused death, injury or any serious deterioration of the state of health of the patient, user, third parties or which may have a negative effect on the environment, as well as those defects which, may, if repeated, cause medical activity disturbances, material loss, waste of time and others similar;

p) *registration*– means the document recording the certified medical devices, the manufacturers and suppliers of medical devices;

r) *manufacturer* – means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before its being placed on the market, under his own name, regardless of whether these operations are carried out by that legal / natural person directly or on its behalf by a third party (responsible for placing the device on the market); this term shall also apply to the natural or legal person who assembles, packages, processes, refurbishes and / or labels products and / or assign to them the intended purpose of medical devices with a view to placing them on the market under his own name; this definition does not apply to the person who, while not being a manufacturer within the meaning of the first subparagraph, assembles or adapts medical devices already on the market to fit an individual patient;

s) intended purpose - means the use for which the medical device is suited according to the data supplied by the manufacturer on the labelling, in the instructions and / or in promotional materials (commercial leaflets);

ş) 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 evaluation, with a view to distribution and / or use, regardless of whether it is new or fully refurbished;

t) putting into service – means the stage at which a medical device is ready for its use on the market for the first time for its intended purpose;

ţ) authorised representative - means any legal or natural person established in Romania, who explicitly designated by the manufacturer, acts on behalf of the manufacturer and may be addressed by authorities and competent bodies instead of the manufacturer in respect of the latter's obligations under this Law;

u) device for self-testing - means any device intended by the manufacture to be used at home;

v) device for performance evaluation – means any device designed 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.

Article 3

(1) When a medical device is intended to administer a medicinal product, that device shall be subject to the present Law, without prejudice to the provisions of the laws governing the respective medicinal product.

(2) If however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral part, exclusively intended for use in the given combination and which is not reusable, the single product shall be treated as medicine.

(3) The relevant essential requirements stated in Annex I shall apply to the respective device as well.

Article 4

(1) The medical devices shall only be placed on the market, put into service or used if certified and registered in accordance with the provision of this Law, so as not to compromise the safety and health of patients, users or, where applicable, other persons or the environment.

(2) The medical devices shall be properly installed, maintained and used in accordance with their intended purpose.

Article 5

The medical devices shall comply with the provisions of Article 4 above provided they meet the essential requirements set out in Annex I, requirements which are also specified in the harmonised standards.

Article 6

The medical devices shall be certified and / or registered on the basis of the conformity assessment procedures, described in Annexes II – VIII, X and XIII.

Article 7

This Law shall not apply to:

a) medicine;
b) cosmetics;

c) human blood, products derived from human blood, human plasma or human blood derived cells or to those devices which, when placed on the market, incorporate such products derived from human blood, plasma or cells.

d) transplants of human derived tissues or cells or products incorporating or deriving from human tissues or cells;

e) transplants, except for the case when the device is manufactured using non-viable animal tissues or non-viable products derived from animal tissues.

Article 8

(1) This Law shall not apply to personal protection equipment.

(2) If it is decided that such a product falls within the scope of this Law, then its main intended purpose shall be the most important consideration.

CHAPTER II

Authorities and agreed bodies in the field of medical devices

Article 9

(1) The Ministry of Health shall be the competent and decision-making authority as far as medical devices are concerned.

(2) The Ministry of Health incorporates a specialised department responsible for carrying out the ministerial policy relating to medical devices.

Article 10

The Commission on medical devices is a body whose members are experts in the various branches of medicine, appointed by a special order of the Minister of health. The Commission shall also include a representative of manufacturers and users, appointed by their associations.

Article 11

The Commission on medical devices shall, together with the specialised department of the Ministry of Health, conduct clinical investigations relating to medical devices on human subjects, in accordance with the rules and regulations in force.

Article 12

The notified bodies shall be those bodies assessing the conformity of medical devices with the safety and performance requirements needed for their use.

Article 13

The Ministry of Health shall, as far as medical devices are concerned, have the following main duties:

a) to prepare the rules of procedure of the specialised department on medical devices operating within the Ministry of Health;

b) to approve the list of notified bodies, acting on the proposal of the specialised department of the Ministry of Health;

c) to appoint the members of the Commission on medical devices.

Article 14

The specialised department for medical devices of the Ministry of Health shall have the following main duties:

a) to submit the list with the proposed notified bodies to the Ministry of Health; the technical competence of the notified bodies shall be established on the basis of the activity of

the national authorisation bodies; the notified bodies shall be selected according to the criteria listed in Annex IX and shall be subject to the approval of other bodies responsible in the field;

b) to permanently control and evaluate the activity carried out by the notified bodies; to withdraw their notification if they do no longer have the required technical competence;

c) to decide upon the classification of a medical device, in case of any dispute arising between the manufacturer and the notified bodies;

d) to authorise, in duly justified cases, the placing on the market and putting into service of individual medical devices, when such an action is in accordance with its protection policy;

e) to authorise, in duly justified cases, the implementation of clinical investigation procedures using medical devices intended for clinical investigation; together with the Commission on medical devices, it may also ask the manufacturer or its authorised representative established in Romania to submit the investigation report, as referred to in Annex X;

f) to participate in the preparation of standardisation programmes aimed to issue Romanian medical standards, with a view to their harmonisation with the European directives on medical devices;

g) to approve the regulations and detailed rules applicable to medical devices, with the exception of national standards;

h) to ensure that the review of the regulations and detailed rules on medical devices observe European and international rules and standards;

i) to take into account international recommendations on medical devices adopted in other fields of activity if such recommendations fall within the scope of the regulations;

j) to co-ordinate the surveillance of medical devices;

k) to temporary withdraw medical devices from the market in case such devices are responsible for any incidents;

l) to restrict or forfeit the use of medical devices existing on the market in case such devices are responsible for any incidents;

m) to forfeit the production and / or marketing of unregistered medical devices if such devices are placed on the market;

n) to deliver opinions on manufacture, marketing, importation, repair, verification and putting into services of medical devices, in accordance with the conformity assessment procedures provided for in Annexes II – VIII, with a view to the registration of natural and legal persons in the Registry on medical devices;

o) to register medical devices certified in Romania, medical devices bearing the CE marking, medical devices certified by notified bodies published in the Official Journal of the European Communities or by other authorised certification bodies with whom international agreements have been concluded, provided they strictly observe the essential requirements set out in Annex I, with a view to their registration in the registry of certified medical devices;

p) to register and deliver competence certificates to the legal or natural persons responsible for placing medical devices on the market, with a view to their registration in the Registry of authorised distributors of medical devices;

r) to draw up and publish in the Official Journal of Romania, Part I, the instructions relating to the approval and registration requirements provided for in points (n) to (p) above, instructions approved by order of the Ministry of Health, taking into account the opinions of competent bodies in the field;

s) to charge for the services provided for in points (n) to (p) above and in Article 15 (b).

Article 15

The notified bodies for medical devices shall have the following main duties:

a) to certify the medical devices in accordance with the conformity assessment procedures;

b) to examine and audit the manufacture, marketing, importation, repair, verification and putting into service of medical devices.

CHAPTER III

Classification of medical devices

Article 16

(1) Medical devices shall be divided into classes I, IIA, IIB and III, depending on their use-related risks.

(2) The classification of medical device shall be in accordance with Annex IX.

Article 17

In case of a dispute arising between the manufacturer and the conformity assessment body assessing the conformity with respect to the classification of a medical device, the parties shall refer the case to the specialised department of the Ministry of Health.

CHAPTER IV

Free movement of certified medical devices and of devices intended for special purposes

Article 18

Medical devices shall only be placed on the market and used in Romania, if they meet the following conditions:

a) they are certified and registered in accordance with this Law;

b) they bear the CE marking as provided for in Annex XII, a marking complying with the essential requirements described in Annex I, and they are registered by the specialised department within the Ministry of Health;

c) in the case of imported medical devices, they are certified by the notified bodies published in the Official Journal of the European Communities or by other agreed bodies with whom international agreements have been concluded, provided they strictly observe the essential requirements set out in Annex I;

d) in the case of custom-made devices built in accordance with medical prescriptions, they are previously registered with the specialised department of the Ministry of Health.

Article 19

Free testing of medical devices intended for clinical investigation shall be allowed in Romania, in accordance with the provisions of Annexes II – VIII, X and XIII.

Article 20

Medical devices which are not certified and/or registered under this Law may be exhibited at fairs, exhibitions and demonstrations, provided they bear a clearly visible text indicating that the respective devices are not certified.

Article 21

(1) The information which accompany the medical device and is available to the user and/or the patient shall be in Romanian; the Romanian version shall be subject to the approval of the specialised department of the Ministry of Health, regardless of whether the device is meant or not for professional use.

(2) The registrations and the correspondence regarding the implementation of conformity procedures shall also be in Romanian.

CHAPTER V

Harmonisation of national standards and regulations regarding medical devices

Article 22

The essential requirements applicable to medical devices as referred to in Annex I shall be those provided for in the European standards, adopted as Romanian standards.

Article 23

The list of national harmonised standards for medical devices is included in the official publications of the standardisation authority.

CHAPTER VI

Surveillance of medical devices

Article 24

In the event of incidents related to the use of medical devices, the manufacturer or his authorised representative and / or the inspection personnel of notified bodies and / or the users shall inform the specialised department of the Ministry of Health thereof.

Article 25

An assessment of the incident shall be made by the notified bodies other than the bodies which certified the device, the specialised department of the Ministry of Health, if possible together with the manufacturer and / or his representative, shall take all the necessary measures under Article 14 (k) to (m), as the case may be.

Article 26

In the event of incidents caused by medical devices failing to meet the essential requirements provided for in the applicable European directives, or by the improper implementation of or by differences between standards, the specialised department of the Ministry of Health shall take the necessary measures referred to in Article 14 (k) and (l).

Article 27

If the CE marking is unduly affixed on non-complying medical devices, the specialised department of the Ministry of Health shall inform the European Commission thereof within 72 hours of the finding.

Article 28

The surveillance of medical devices when in use shall be the responsibility of their users; the surveillance is meant to ensure that medical devices retain their initial technical and safety features, as well as their level of performance according to the intended purpose. In this respect, the users shall:

a) set up and apply a medical device surveillance programme in respect of the risks, scope of application and complexity of medical devices;

b) ensure the periodical verification, maintenance and repairs of medical devices;

c) inform the manufacturer and the specialised department within the Ministry of Health of any incidents related to the use of the medical device concerned.

Article 29

(1) Any decision made by the specialised department of the Ministry of Health so as to withdraw, restrict or forfeit the use on the market of medical devices shall be justified.

(2) Such a decision shall be immediately notified to the concerned party. In its turn, this party shall inform the specialised department of the Ministry of Health of the possible remedy and the time needed by such remedy.

Article 30

In case of decisions made according to Article 29 above, the manufacturer or his authorised representative shall be given the opportunity to express their point of view, except for the case when direct consultation is not possible due to the emergency of the measures to be taken.

Article 31

The manufacturer or his authorised representative, as the case may be, shall provide the required maintenance and spare parts for medical devices placed on the market, for a period of 10 years.

Article 32

The notified body shall inform the specialised department of the Ministry of Health of all suspended or withdrawn certificates and, on request, shall provide all the relevant additional information.

CHAPTER VII

Penalties

Article 33

Any violation of this Law shall lead to disciplinary, material, civil or penal liability, as the case may be, in accordance with the laws in force.

Article 34

The following acts perpetrated by legal or natural persons shall be deemed as minor offences, unless perpetrated under circumstances which, according to the law, make them criminal offences:

a) the production and/or placing on the market of uncertified medical devices, or of medical devices with expired validity or with incident-causing deviations from the operation and safety requirements;

b) the alteration of operation parameters and/or production conditions or configuration of medical devices after certification, which has a negative impact on the quality of the medical device concerned;

c) the preventing, in any way, of authorised persons to carry out their control duties under this Law, with respect to medical devices;

d) the use of medical devices which are not certified, registered or periodically verified, either in healthcare units or for clinical investigation purpose, with the exception of medical devices under clinical experimentation or performance assessment with a view to their certification;

e) the manufacturer’s or authorised representative’s failure to provide maintenance services for the medical devices in warranty;

f) the authorised units failure to keep or update their records of installed, repaired or verified medical devices;

g) the absence of the approval referred to in article 14 (n) and of the registration provided for in Article 14 (o) and (p).

Article 35

(1) The penalties for minor offences shall be as follows:

a) a fine of ROL 15,000,000 to ROL 25,000,000 – for minor offences referred to in Article 34 (a) to (c);

b) a fine of ROL 5,000,000 to ROL 15,000,000 – for minor offences referred to in Article 34 (d) to (g);

(2) In case of the offences referred to in Article 34 (a) to (c), the control body may decide to suspend the production and/or placing on the market of medical devices;

(3) The amount of fines shall be periodically adjusted to inflation, pursuant to a Government decision.

Article 36

The authorised staff of the specialised department of the Ministry of Health and of the notified bodies shall establish the offence and apply the fines.

Article 37

(1) The concerned legal or natural person may complain against the Offence Report, within 15 days of notification, at the competent jurisdictional Court of Law.

(2) The Court decision may be challenged according to the laws in force.

Article 38

The provisions on liability for minor offences in this Law shall be supplemented with the provisions of Law No 32/1968 regarding the establishment and sanction of minor offences, with the exception of Articles 25 – 27 therein.

CHAPTER VIII
Database

Article 39

(1) The data on the rules and regulations in application of this Law shall be stored in a database made available to competent authorities to help them carry out their duties under this law on the basis of real and complete information.

(2) The database shall include:

a) data on the registration of producers and medical devices, according to the instructions laid down by the specialised department of the Ministry of Health;

b) data on issued, modified, filled in, suspended, withdrawn or refused certificates, in accordance with the conformity assessment procedures applicable to medical devices;

c) data produced by the surveillance procedure applicable to medical devices.

Article 40

The implementation procedures provided for in Article 39 shall be adopted in accordance with Articles 9 to 12, Article 14 (a) and (b) and the articles dealing with the surveillance of medical devices.

CHAPTER IX

Transitory and final provisions

Article 41

(1) The specialised department of the Ministry of Health shall charge for the approval and registration services provided for in Article 14 (n) to (p):

a) ROL 5,000,000 – for the approval referred to at letter n) and the registration referred to in point (p);

b) ROL 10,000,000 – for the registration referred to in point (o).

(2) The charges shall be periodically adjusted to inflation, pursuant to a Government Decision.

(3) The notified bodies shall charge for their certification and examination services, the rates shall be established according to the rules and regulations in force.

Article 42

Pursuant to Government Ordinance No 22/ 1992 regarding the financing of public health, approved by Law No 114/1993, the amounts resulting from the fines and charges referred to in Article 41 shall be an income to the public budget, while the amounts resulting from the rates applied shall be own income. These amounts shall be used in conformity with relevant legal provisions.

Article 43

The provisions of this Law shall apply to legal and natural persons who manufacture, sell, install, use, verify and provide maintenance for medical devices.

Article 44

The personnel of the specialised department of the Ministry of Health and of the notified bodies, authorised to control medical devices, shall be entitled to access to all places and premises where medical devices are present and/or used.

Article 45

The legal and natural persons involved in the application of this Law shall be bound to observe the confidentiality with regard to all information obtained in carrying out their tasks. This shall not affect their obligation to provide information under criminal law.

Article 46

The Ministry of Health shall issue the detailed rules in application of this Law within three months of its coming into force.

Article 47

Annexes I – XIII are an integral part of this Law.

Article 48

(1) This Law shall enter into force after three months from its publication in the Official Journal of Romania, Part I.

(2) On the same day, the provisions of Articles 171 and 172 of Law No 3/1978 regarding health protection, published in the Official Journal of Romania, Part I, No 54 of 12 July 1978, as well as any other provisions to the contrary shall be repealed.

The Romanian Senate adopted this Law, in its session of 18 September 2000 in full observance of the provisions of Article 74 (2) of the Constitution of Romania.

For the President of the Senate
DORU IOAN TARACILA

The Romanian Chamber of Deputies adopted this Law, in its session of 19 September 2000 in full observance of the provisions of Article 74 (2) of the Constitution of Romania.

For the President of the Chamber of Deputies,
VASILE LUPU

Bucharest, 18October 2000.
No 176.

ANNEX I

ESSENTIAL REQUIREMENTS

I. General requirements

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the intended purposes, they do not compromise the clinical condition or safety of patients, or the safety and health of users or, where applicable, of other persons. Any risk associated to the use of medical device should stay within acceptable limits when weighed against the benefits to the patient and a high level of health protection and safety.

2. The solutions adopted by the manufacturer for the design and construction of devices must comply with safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles:

- eliminate or reduce risks as far as possible, inherently safe design and construction;
- where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 2 (a), as specified by the manufacturer, taking account of the generally acknowledged state of the art.

As provided for in Article 2 (e), the *in vitro diagnostic* devices must achieve the performances of analytical sensitivity, diagnosis sensitivity, analytical specificity, diagnosis specificity and accuracy, repeatability, reproducibility, including control of relevant interference and limit detection, stated by the manufacturer.

4. The characteristics and performances referred to at points 1 – 3 must not be adversely affected to such a degree that the health or the safety of the patient or the user and, where applicable, of other persons, are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended purpose will not be adversely affected under transport and storage conditions taking account of the instructions and information provided by the manufacturer.

6. Any side effect should be an acceptable risk when weighed against the benefits to the patient.

II. Design and manufacturing requirements

7. Chemical, physical and biological properties

7.1. The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in Section I 'General requirements'. Particular attention must be paid to:

- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;
- the compatibility between the materials used and the biological tissues, cells and body fluids, taking account of the intended purpose of the device.

7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.

7.3.The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use; if the devices are intended for the administration of medicinal products, they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned, according to the provisions and restrictions governing these products, while their performance conforms with the intended purpose.

7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device.

7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.

7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

8. Infection and microbial contamination

8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize the contamination of the device by the patient or vice versa during use.

8.2. Tissues of animal origin must originate from animals that have been subject to veterinary controls and surveillance adapted to the intended purpose of the tissues.
The notified body shall retain information on the geographical origin of the animals.
The processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation.

8.3. The devices delivered in a sterile state must be designed, manufactured and packed in a single-use package and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.

8.5. Devices intended to be sterilized must be manufactured in appropriately controlled environmental conditions.

8.6. Packaging systems for non-sterile devices must protect the product from deterioration at the degree of cleanliness stipulated; if the devices are to be sterilized prior to use, the risk of microbial contamination must be minimized; the packaging system must be adequate and take into account the method of sterilization indicated by the manufacturer.

8.7. The packaging and/or labelling of devices must distinguish between identical or similar products marketed in both sterile and non-sterile condition.

9. Construction and environmental properties

9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, should be safe and not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

9.2. The devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:

- the risk of injury, in relation to their physical features, including the volume/pressure-size ratio, and, where appropriate, the ergonomic features;
- the risks relating to environmental conditions, such as magnetic fields, external electrical influence, electrostatic charges, pressure, temperature or variations in pressure and acceleration;
- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;
- the risks arising where maintenance or calibration are not possible, from aging of materials used or loss of accuracy of any measuring or control mechanism.

9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended purpose includes exposure to flammable substances or to substances which could cause combustion.

10. Devices with a measuring function

10.1. The devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The manufacturer must indicate the limits of accuracy.

10.2. The measuring, monitoring and display equipment must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3. Measurements made by devices with a measuring function must be expressed in legal units.

11. Protection against radiation

11.1. Generals

11.1.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible taking into account the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnosis purposes.

11.2. Intended radiation

11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, wherever practicable, with visual displays and/or audible warnings of such emissions.

11.3. Unintended radiation

11.3.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended or scattered radiation is reduced as far as possible.

11.4. Instructions

11.4.1. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5. Ionising radiation

11.5.1. Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended purpose.

11.5.2. Devices emitting ionising radiation intended for diagnosis radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

11.5.3. Devices emitting ionising radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and, where appropriate, the quality of radiation.

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

12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended purpose. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as possible any consequent risks.

12.2. Devices where the safety of patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.

12.3. Devices where the safety of patients depends on an external power supply must include an alarm system to signal any power failure.

12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields likely to impair the operation of other devices or equipment in the usual environment.

2.6. Protection against electrical risks

Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are correctly installed and used.

12.7. Protection against mechanical and thermal risks

12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.

12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available to limit vibrations, particularly at the source, unless the vibrations are part of the specified intended purpose.

12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at the source, unless the noise emitted is part of the specified intended purpose.

12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies, which the user has to handle, must be designed and constructed in such a way as to minimize all possible risks.

12.7.5. Accessible parts of the devices - excluding the parts or areas intended to supply heat or reach given temperatures - and their surroundings must not attain potentially dangerous temperatures under normal operation conditions.

12.8. Protection against the risks posed to the patient by energy supplies or substances.

12.8.1. Devices supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate that could pose a danger.

Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

12.9. The function of the controls and indicators must be clearly specified on the devices.

The instructions required for the operation or adjustment of its parameters must be understandable to the user and, as appropriate, to the patient.

12.10. Requirements for devices for self-testing

Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skill and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The instructions and information provided by the manufacturer should be easily understood and applied by the user.

12.10.1. Devices for self-testing must be designed and manufactured in such a way as to:

- ensure that the device is easy to use by the intended lay user at all stages of the procedure, and
- reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results.

12.10.2. Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.

13. Information supplied by the manufacturer:

13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

This information comprises the data on the label and in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or on the individual package or, where appropriate, on the sales package. If individual packaging is not practicable, the information must be set out in the leaflet supplied with one or more devices.

Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or II if they can be used safely without any such instructions.

13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the standards used. In areas for which no

standards exist, the symbols and colours must be described in the documentation supplied with the device.

13.3. The label must bear the following particulars:

a) the name or trade name and address of the manufacturer; for devices imported with a view to their distribution in Romania, the label, the outer packaging or the instructions for use shall contain in addition the name and address of either the person responsible or of the authorised representative of the manufacturer or of the importer, as appropriate;

b) the details strictly necessary for the user to identify the device and the contents of the packaging;

c) the word 'STERILE', for the sterile delivered devices;

d) the batch code, preceded by the word 'LOT', or the serial number, where appropriate;

e) an indication of the date by which the device should be used, in safety, expressed as the year and month;

f) an indication ‘disposable’, in the case of disposable devices;

g) if the device is custom-made, the words 'custom-made device';

h) in case of devices for clinical investigations or performance evaluation, the words ‘for clinical investigations only' or ‘for performance evaluation only’;

i) any particular storage and/or handling conditions;

j) any particular operating instructions;

k) any warnings and/or precautions to take;

l) the year of manufacture for active devices other than those covered by point (e); this indication may be included in the batch or serial number;

m) where applicable, the method of sterilization.

n) an indication that the device is an *in vitro* device, where appropriate.

13.4. If the device area of use and functions are not obvious, the manufacturer must clearly define it on the label and in the instructions for use.

13.5. The devices and their detachable components must be identified, where appropriate, in terms of batches, to allow detection of any potential risk posed by the devices and detachable components.

13.6. The instructions for use must contain the following particulars:

a) the details referred to in point 13.3, with the exception of points (d) and (e);

b) the performances referred to in point 3 and any undesirable side-effects;

c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required by its intended purpose, sufficient details of its characteristics to allow the correct and safe combination and operation;

d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

e) information to avoid certain risks in connection with implantation of the device, where appropriate;

f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;

g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

h) if the device is reusable, information on the appropriate cleaning, disinfecting, packaging and, where appropriate, the method of sterilization and any restriction on the number of reuses, where appropriate; all devices requiring sterilization before being used shall be accompanied by instructions on their proper cleaning and sterilization methods;

i) details of any further treatment or handling needed before the device can be used, such as for example, sterilization, final assembly;

j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation and in particular details on any contraindication and any precautions to be taken during the use;

k) precautions to be taken in the event of changes in the performance of the device;

l) precautions to be taken as regards exposure to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources;

m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;

n) precautions to be taken against any special, unusual risks related to the use of the device;

o) precautions with respect to the medicinal substances incorporated into the device as an integral part;

p) degree of accuracy claimed for devices with a measuring function.

14. Where conformity with the essential requirements must be based on clinical data only, such data must be established in accordance with Annex X.

ANNEX II

DECLARATION OF CONFORMITY
Full quality assurance system

1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in point 3, and is subject to audit as laid down in points 3.3 and 4 and to surveillance inspections as stated in point 5.

2. The *declaration of conformity* is the procedure whereby the manufacturer who fulfils the obligations imposed by point 1 ensures and declares that the products concerned meet the provisions of this Annex.

The manufacturer must draw up a declaration of conformity. This declaration must cover a given number of manufactured products and shall be kept by the manufacturer.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality 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 system;
- all the relevant information on the product or product category covered by the procedure;
- a written declaration that no application has been submitted to any other notified body for the same product in relation to the quality system;
- the documentation on the quality system;
- an undertaking by the manufacturer to meet all the requirements of the quality 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 use the experience gained in production and to implement any necessary corrective action; this undertaking must include an obligation for the manufacturer to notify

the competent specialised department of the Ministry of Health of the following incidents, immediately on learning of them:

i) 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 patient or user or to a serious deterioration in his state of health;

ii) any technical or medical reasons in connection with the characteristics or performance of a device leading to the recall of such devices by the manufacturer.

3.2. The quality system must be applied at every stage, from design to final inspection, taking account of the essential requirements. All the provisions adopted by the manufacturer for his quality system must be systematically documented in the form of written procedures, quality programmes, quality plans, and quality records.

The quality system shall include in particular:

a) a description of the manufacturer's quality objectives;

b) a description of departments, the responsibilities of the managerial staff and of the quality assurance system responsible; a description of the methods used to monitor the efficient operation of the quality system and in particular its ability to achieve the desired quality of design, production and control of the products concerned;

c) a description of the procedures for monitoring and verifying the design of the products and in particular:

- a general description of the product, including any variants planned;
- the design specifications, including the applicable standards and the results of the risk analysis, a description of the solutions adopted to fulfil the essential requirements applicable to the products;
- the techniques used to control and verify the design and the implementation of the respective design;
- if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer;
- a statement indicating whether or not the device incorporates, as an integral part, a medicinal substance;
- the clinical data referred to in Annex X;
- the draft label and, where appropriate, instructions for use;

d) a description of 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, purchasing of materials and the relevant documents;
- the product identification and control procedures and the updating procedures for drawings, specifications or other relevant documents at every stage of production;

e) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency of such tests and trials, and the testing equipment used; it must be possible to trace back the performed measurements and calibration.

3.3. The conformity assessment body must audit the quality system to determine whether it meets the requirements referred to in point 3.2. It is presumed that quality systems that implement the relevant harmonized standards comply with these requirements.

The assessment team should include at least one member with past experience of assessments of the technology concerned.

The assessment procedure shall include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of suppliers and/or subcontractors.

The conclusions of the inspection shall be notified to the manufacturer.

3.4. The manufacturer shall inform the notified body which approved the quality system of any plan for substantial change to the quality system or the product-range covered. The notified body shall assess the changes proposed and verify whether, after the changes, the

quality system still meets the requirements referred to in point 3.2. The notified body shall notify the manufacturer of its decision.

4. Examination of the design of the product

4.1. In addition to the obligations provided for in point 3, the manufacturer shall submit to the notified body an application for examination of the design of the product he intends to manufacture according to the quality system.

4.2. The application must describe the design, manufacture and performances of the product concerned, the documents needed to assess whether the product complies with the requirements referred to in point 3.2 (c).

4.3. The notified body shall examine the application and, if the product complies with the relevant provisions of this Annex, shall issue a design-examination certificate. The notified body may require that the application be further documented by tests or trials certificates meant to prove its conformity with the requirements of this Annex. The examination certificate shall include the examination conclusions, the validation conditions, the identification data needed for the approved design, and, where appropriate, a description of the intended purpose of the product.

In the case of devices referred to in Annex I, point 7.4, the notified body shall consult with one of the competent bodies, before making a decision.

The notified body shall give due consideration to the views expressed during this consultation; the final decision shall be made by mutual agreement.

4.4. Changes to the approved design must receive prior approval from the notified body having delivered the design-examination certificate wherever the changes could affect conformity with the essential requirements or with the conditions prescribed for the use of the product. The applicant shall inform the notified body having delivered the design-examination certificate of any such changes made to the approved design. This additional approval must take the form of a supplement to the design-examination certificate.

5. Surveillance

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

5.2. The manufacturer shall authorise the notified body to carry out all the necessary inspections and shall provide all relevant information, in particular:

- the documentation regarding the quality system,
- the quality system data the relating to design, such as the results of analyses, calculations, tests, etc.,
- the quality system data relating to manufacture, such as inspection reports and test data, calibration data, qualification certificates of the personnel concerned, etc.

5.3. The notified body shall carry out periodical inspections on the manufacturing premises to ensure that the manufacturer applies the approved quality system and shall supply the manufacturer with an inspection report.

5.4. In addition, the notified body may pay unannounced visits to the manufacturer’s premises and carry out or ask that tests be carried out in order to check the adequate operation of the quality system. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

6. Administrative provisions

6.1. The manufacturer shall, for at least five years following the production of the last batch, make available to the specialised department of the Ministry of Health:

- the declaration of conformity;
- the documentation referred to in the fourth indent of point 3.1;
- the documentation referred to in point 4.2;
- the decisions and reports from the notified body as referred to in points 3.3, 4.3, 4.4, 5.3 and 5.4.

6.2. The notified body shall make available to the other notified bodies and to the specialised department of the Ministry of Health, on request, all relevant information concerning the quality system approvals issued, refused or under assessment.

6.3. In respect of devices subject to the procedure provided for in point 4, when neither the manufacturer nor his authorised representative is established in Romania, the obligation to make the technical documentation available shall fall to the person responsible for placing the device on the market, pursuant to the provisions referred to in Annex I, point 13.3 (a).

7. Verification of products referred to in Annex XIII, List A

7.1. In the case of products listed in Annex XIII, list A, the manufacturer shall immediately submit to the notified body the inspection conclusions and the relevant test reports of the tests and trials carried out on the manufactured devices or batches of manufactured devices. The manufacturer shall therefore have samples of the devices or batches of devices, which he shall make available to the notified body in accordance with the agreed conditions and methods.

7.2. The manufacturer shall only place the devices on the market after being informed of the notified body's decision and of the validity conditions governing the certificates issued; this information shall be provided to the manufacturer in the established time-frame, but no later than 30 days from the receipt of samples.

8. Applicability to devices in Class IIA and IIB:

The provisions in this Annex may be applied to the products in Class IIA and IIB, with the exception of point 4, which does not apply.

ANNEX. III

TYPE-EXAMINATION

1. The *type-examination* is the procedure whereby a notified body ascertains that a representative sample of the production covered fulfils the relevant provisions of this Annex.

2. The application shall include:

- the name and address of the manufacturer and the name and address of the authorised representative, if the application is submitted by the representative;
- the documentation described in point 3, needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the *'type'*, according with the requirements of this Annex. The applicant must make a *'type'* available to the notified body, while the notified body may request other samples as necessary;
- a written declaration that no application has been submitted to any other certification notified body for the same type-examination.

3. The documentation must allow an understanding of the design, manufacture and performances of the product and must include in particular the following items:

- a general description of the type, including all variants planned;
- drawings, methods of manufacture envisaged, in particular as regards sterilization, diagrams of components, sub-assemblies, circuits, etc.;
- the descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the operation of the product;
- a list of the standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements;

- the results of calculations, risk analysis, investigations, technical tests carried out, etc.;
- a statement indicating whether or not the device incorporates, as an integral part, a medicinal substance and the results of the tests made in this respect,
- the clinical data referred to in Annex X,
- the draft label and, where appropriate, instructions for use.

4. The notified body shall:

4.1. examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it must also record the items conforming with the applicable provisions of the standards referred to in Chapter V, as well as the items nonconforming with the same standards;

4.2. carry out or have the appropriate inspections and tests carried out as are necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements, if the standards referred do not apply; if the device, with the characteristics specified by the manufacturer, is to be connected to other devices, proof must be provided that it conforms to the essential requirements when connected to any such devices;

4.3. carry out or have the appropriate inspections and tests carried out as are necessary to verify whether the manufacturer applies the relevant standards;

4.4. agree with the applicant on the place where the necessary inspections and tests shall be carried out;

5. If the type conforms to the provisions of this Annex, the notified body shall deliver a type-examination certificate to the applicant. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed to identify the type approved. The relevant parts of the documentation shall be appended to the certificate and the notified body will keep a copy.

In the case of devices referred to in Annex I, paragraph 7.4, the notified body shall consult with one of the specialised bodies before making his final decision.

The notified body will give due consideration to the views expressed in the consultation with the specialised body and the final decision shall be mutually agreed upon.

6. The applicant shall inform the notified body having delivered the type-examination certificate of any significant change made to the approved product.

Changes to the approved product must receive prior approval from the notified body having delivered the type-examination certificate wherever the changes may have an effect on the product conformity with the essential requirements or with the conditions prescribed for the use of the product. This new approval shall, where appropriate, take the form of a supplement to the initial type-examination certificate.

6.1. The manufacturer shall inform the notified body, as soon as possible, whether he obtained information about the changes of markers or pathogen agents of the tested infections, especially when they are a consequence of biological complexity and diversity. In this respect, the manufacturer shall inform the notified body whether or not such changes have an effect on the performances of the device used *in vitro*.

7. Administrative provisions

7.1. The notified body shall make available to the other notified bodies, on request, all relevant information on type-examination certificates and supplements issued, refused or under assessment.

7.2. Other notified bodies may obtain a copy of the type-examination certificates and/or the supplements thereto. The Annexes to the certificates must be made available to other notified bodies on their reasoned application, after the manufacturer has been previously informed.

7.3. The manufacturer or his authorised representative must keep the technical documentation copies of type-examination certificates and their additions, for a period of at least five years after the last device has been manufactured.

7.4. When neither the manufacturer nor his authorised representative is established in Romania, the obligation to make the technical documentation available shall fall to the person responsible for placing the device on the market under the provisions of Annex I, point 13.3 (a).

ANNEX. IV

‘EC’ VERIFICATION

1. The *‘EC verification’* is the procedure whereby the manufacturer or his authorised representative ensures and declares that the products which have been subject to the procedure provided for in point 4 comply with the type described in the type-examination certificate and meet the requirements of this Annex.

2. The manufacturer must take all the necessary measures to ensure that the manufacturing process results in products which conform to the type described in the type-examination certificate and to the requirements of this Annex. Before starting the production thereof, the manufacturer shall prepare documents defining the manufacturing process, in particular with respect to sterilization, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the type-examination certificate and with the requirements of this Annex. In this respect, the manufacturer shall issue a declaration of conformity.

In the case of sterile products, the manufacturer must apply the provisions of Annex V, points 3 and 4 regarding sterilization security and preservation.

3. The manufacturer must to institute and keep up to date a systematic procedure to review experience gained from devices in the production phase and to implement appropriate means to apply any necessary corrective actions.

This undertaking must include an obligation for the manufacturer to notify the specialised department of the Ministry of Health of the following incidents, immediately on learning of them:

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

(ii) any technical or medical reasons in connection with the characteristics or performance of a device leading to the recall of such devices by the manufacturer.

4. The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of this Annex, either by examining and testing every product as specified in point 5 or by examining and testing products on a statistical basis as specified in point 6, as the manufacturer decides.

The aforementioned checks do not apply to those aspects of the manufacturing process relating to sterilization.

5. Verification by examination and testing of every product

5.1.Every product is examined individually and appropriate tests defined in the relevant harmonized standards or equivalent tests is carried out in order to verify the conformity of the products with the type described in the type-examination certificate and with the requirements of this Annex.

5.2. The notified body shall issue a written certificate of conformity regarding the tests carried out.

6. Statistical verification

6.1. The manufacturer must submit manufactured products of the same type, from various batches.

6.2. A random sample is taken from each batch. In order to verify the conformity of the products with the type described in the type-examination certificate and with the requirements of this Annex and to establish the acceptance or rejection of the batch, the

samples are examined individually against the applicable standards or equivalent tests are carried out.

6.3. The statistical verification of products will be based on a sampling system ensuring a limit quality corresponding to an acceptance probability of 5 %, with a non-conformity percentage of 3% to 7 %. The sampling method will be defined by the harmonized standards, taking into account the specific nature and the class of the product concerned.

6.4. If the batch is accepted, the notified body shall issue a written certificate of conformity relating to the tests carried out for each product. All products in the batch may be placed on the market, with the exception of samples found nonconforming.

If a batch is rejected, the notified body shall take adequate measures to prevent the batch from being placed on the market. In case of frequent rejection of batches, the notified body may suspend the statistical verification.

7. Administrative provisions

The manufacturer or his authorised representative shall, for at least five years after manufacture of the last product, make available to the specialised department of the Ministry of Health the following documents:

- the declaration of conformity,
- the documentation referred to in point 2,
- the certificates referred to in points 5.2 and 6.4,
- where appropriate, the type-examination certificate referred to in Annex III.

8. Applicability of procedure to devices in Class IIA

The provisions of this Annex may apply to products in Class IIA, with the following exceptions:

8.1. by derogation from points 1 and 2, by virtue of the declaration of conformity, the manufacturer ensures and declares that the products in Class IIA are manufactured in conformity with the technical documentation referred to in point 3 of Annex VII and meet the requirements of this Annex;

8.2. by derogation from points 1, 2, 5 and 6, the verifications carried out by the notified body are meant to confirm the conformity of the products in Class IIA with the technical documentation referred to in point 3 of Annex VII.

ANNEX V

DECLARATION OF CONFORMITY
Production quality assurance

1. The manufacturer must ensure the application of the quality system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in point 3, and is subject to the surveillance procedure referred to in point 4.

2. The *declaration of conformity* is that part of the procedure whereby the manufacturer who fulfils the obligations referred to in point 1 above ensures and declares that the products concerned conform to the type described in the type-examination certificate and meet the provisions of this Annex.

The manufacturer shall draw up a written declaration of conformity. This declaration shall cover a given number of identified specimens of the products manufactured and shall be kept by the manufacturer.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- the name and address of the manufacturer;

- all the relevant information on the product or product category covered by the procedure;
- a written declaration that no application has been submitted to any other notified body for the same products;
- the documentation on the quality system;
- an undertaking to fulfil the obligations imposed by the approved quality system;
- an undertaking to maintain the approved quality system;
- where appropriate, the technical documentation on the types approved and a copy of the type-examination certificates;
- an undertaking by the manufacturer to establish and keep up to date a systematic procedure to review experience gained from devices in the production phase and to implement appropriate means to apply any necessary corrective action whenever an inadequacy is found, such as:

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

ii) any technical or medical reason connected with the characteristics or performance of a device leading to the recall of such devices by the manufacturer.

3.2. The implementation of the quality system must ensure that the products conform to the type described in the type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in the quality manual.

The quality manual must include in particular:

a) a description of the manufacturer's quality objectives;

b) a description of production and in particular:

- the departments, the responsibilities of the managerial staff and of the quality assurance system responsible;
- the methods used to monitor the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including the handling of nonconforming products;

c) a description of the inspection and quality assurance techniques in the manufacturing stage and in particular:

- the processes and procedures used, particularly regarding sterilization, procurement of materials and other relevant documents,
- the product identification procedures with respect to updated drawings, specifications or other relevant documents at every manufacturing stage;

d) a description of the appropriate tests and trials to be carried out before, during and after manufacturing, their frequency and the testing equipment used; it must be possible to trace back the calibration of the testing equipment.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in point 3.2. It is presumed that quality systems implementing the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned.

The assessment procedure must include an inspection of the manufacturing processes on the manufacturer's premises and, in duly substantiated cases, on the premises of suppliers.

The decision must be notified to the manufacturer after completion of the final inspection and must include the inspection conclusions and a reasoned assessment.

3.4. The manufacturer shall inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether, after the changes, the quality system still meets the requirements referred to in point 3.2.

The decision must be notified to the manufacturer and include the inspection conclusions and a reasoned assessment.

4. Surveillance

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

4.2. The manufacturer shall authorise the notified body to carry out all the necessary inspections and shall provide all relevant information, in particular:

- the documentation regarding the quality system,
- the quality system data relating to manufacturing, such as inspection reports and test data, calibration data, qualification certificates of the personnel concerned.

4.3. The notified body shall carry out periodical inspections and assessments to make sure that the manufacturer applies the approved quality system and shall supply the manufacturer with an assessment report.

4.4. The notified body may pay unannounced visits on the manufacturer's premises and carry out or ask that tests be carried out in order to check the adequate operation of the quality system. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. Administrative provisions

5.1. The manufacturer or his authorised representative shall, for at least five years after the last product has been manufactured, make available to the specialised department of the Ministry of Health , the following documents:

- the declaration of conformity;
- the documentation referred to in the fourth indent of point 3.1;
- the changes referred to in point 3.4;
- the documentation referred to in the seventh indent of point 3.1;
- the decisions and reports from the notified body as referred to in points 4.3 and 4.4;
- the type-examination certificate referred to in Annex III, if the case be.

5.2. The notified body shall make available to the other notified bodies, on request, all relevant information concerning the quality system approvals issued, refused or under assessment.

6. Verification of manufactured products covered by Annex XIII, List A

6.1. In the case of products listed in Annex XIII, List A, the manufacturer shall forward to the notified body without delay after the conclusion of the controls and tests the relevant reports on the tests carried out on the manufactured devices or batches of manufactured devices. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities.

6.2. The manufacturer shall place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but no later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

7. Applicability to devices in Class IIA and IIB:

The provisions in this Annex may apply to the products in Class IIA, with the following exceptions:

7.1. by way of derogation from points 2, 3.1 and 3.2, by virtue of the declaration of conformity, the manufacturer ensures and declares that the products in Class IIA are manufactured in conformity with the technical documentation referred to in point 3 of Annex VII and meet the requirements of this Annex.

ANNEX VI

DECLARATION OF CONFORMITY
Product quality assurance

1. The manufacturer must ensure application of the quality system approved for the final inspection and testing of the product, as specified in point 3, and is subject to the surveillance referred to in Section 4.

In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Annex V, points 3 and 4.

2. The *declaration of conformity* is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by point 1 above ensures and declares that the products concerned conform to the type described in the type-examination certificate and meet the applicable provisions of this Annex.

The manufacturer draws up a written declaration of conformity. This declaration must cover a given number of identified specimens and must be kept by the manufacturer.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- the name and address of the manufacturer;
- all the relevant information on the product or product category covered by the procedure;
- a written declaration specifying that no application has been submitted to any other notified body for the same products;
- the documentation on the quality system;
- an undertaking by the manufacturer to fulfil the obligations imposed by the approved quality system;
- an undertaking by the manufacturer to keep the approved quality system adequate and efficacious, the technical documentation on the types approved and a copy of the type-examination certificates;
- an undertaking by the manufacturer to establish and keep up to date a systematic procedure to review experience gained from devices in the production phase and to implement appropriate means to apply any necessary corrective action.

This undertaking must include the manufacturer's obligation to notify the competent specialised department of the Ministry of Health of the following incidents, immediately on learning of them:

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

(ii) any technical or medical reason connected with the characteristics or the performance of a device leading to a systematic recall of devices by the manufacturer.

3.2.Each product or a representative sample of each batch shall be examined and shall be subject to appropriate tests, as defined in the relevant harmonized standards, or to equivalent tests to ensure that the products comply with the type described in the type-examination certificate and fulfil the provisions of this Annex. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit uniform interpretation of the quality programmes, quality plans, quality manuals and quality records.

It should include in particular an adequate description of:

- the quality objectives and the department, responsibilities and powers of the managerial staff with regard to product quality;
- the examinations and tests that will be carried out after manufacture; it must be possible to trace back the calibration of the testing equipment adequately;
- the efficient methods of monitoring the operation of the quality system;
- the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned.

The aforementioned checks shall not apply to those aspects of the manufacturing process designed to secure sterility.

3.3. The notified body audits the quality system to determine whether it meets the requirements referred to in point 3.2. It is presumed that quality systems implementing the relevant harmonized standards comply with these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes.

The decision shall be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body must assess the changes proposed and verify whether, after these changes, the quality system still meets the requirements referred to in point 3.2. After receiving the above-mentioned information, the notified body notifies the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

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

4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, testing and storage facilities and supply it with all relevant information, in particular:

- the documentation on the quality system;
- the technical documentation;
- the quality records, such as inspection reports, test data, calibration data, qualification reports of the staff concerned.

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

4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask that tests be carried out in order to check that the quality system is working properly and that the production conforms to the applicable requirements of this Annex. To this end, an adequate sample of the final products, taken on site by the notified body, must be examined and the appropriate tests defined in the relevant standards or equivalent tests must be carried out. Where one or more of the samples fail to conform, the notified body must take the appropriate measures. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. Administrative provisions

5.1. The manufacturer must, for a period ending at least five years after the last product has been manufactured, make available to the specialised department of the Ministry of Health, the following documents:

- the declaration of conformity;

- the documentation referred to in the seventh indent of point 3.1;
- the changes referred to in point 3.4;
- the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4;
- where appropriate, the certificate of conformity referred to in Annex III.

5.2. The notified body must make available to the other notified bodies, on request, all relevant information concerning the quality system approvals issued, refused or withdrawn.

6. Applicability to devices in Class IIA

This Annex may apply to products in Class IIA, subject to this derogation:

6.1. by derogation from points 2.3.1 and 3.2, by virtue of the declaration of conformity, the manufacturer ensures and declares that the products in Class IIA are manufactured in conformity with the technical documentation referred to in point 3 of Annex VII and meet the requirements of this Annex.

ANNEX VII

DECLARATION OF CONFORMITY

1. The *declaration of conformity* is the procedure whereby the manufacturer or his authorised representative established in Romania who fulfils the obligations imposed by point 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by point 5, ensures and declares that the products concerned meet the applicable provisions of this Annex.

2. The manufacturer must prepare the technical documentation described in point 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the specialised department of the Ministry of Health for inspection purposes for a period ending at least five years after the last product has been manufactured. Where neither the manufacturer nor his authorised representative is established in Romania, the obligation to keep the technical documentation available must fall to the person who places the product on the market.

3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Annex.

It must include in particular:

- a general description of the product, including any variants planned;
- design drawings, manufacturing methods and diagrams of components, sub-assemblies, circuits;
- the descriptions and explanations necessary to understand the above-mentioned drawings and diagrams and the operation of the product,
- the results of the risk analysis and a list of harmonized standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements;
- in the case of products placed on the market in a sterile condition, a description of the sterilization methods used;
- in case of devices containing human origin tissues or other substances derived from such tissues, information on the origin of the materials and the conditions in which it was collected;
- the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other devices in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such devices having the characteristics specified by the manufacturer;
- the test reports and, where appropriate, clinical data in accordance with Annex X;

- adequate 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, the known reference values, the accuracy and measurement units used; such information should originate from studies in a clinical environment or result from relevant biographical references;
- the label and instructions for use.

4. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the specialised body of the Ministry of Health of the following incidents, immediately on learning of them:

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

(ii) any technical or medical reason connected with the characteristics on the performance of a device, for the reasons referred to in point (i) leading to systematic recall of devices of the same type by the manufacturer.

5. With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in Annex IV, V or VI. Application of the provisions of the above-mentioned Annexes and the intervention by the notified body shall be limited to:

- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions,
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements. The provisions of point 7.1. of this Annex shall apply.

6. In the case of the devices for self-testing, the manufacturer should submit an application to a notified body in order to have a design examination.

6.1. The application, accompanied by the technical documentation, should enable the assessment of the design conformity with the essential requirements referred to in Annex I. This application shall include in particular:

- test reports, results of the studies carried out on the persons who used the devices concerned;
- data showing the handling possibilities of the device in view of intended purpose for self-testing;
- information to be provided with the device on its label and its instructions for use.

6.2. The notified body must examine the application and, if the product complies with the relevant provisions of this Annex, shall issue a EC design-examination certificate. The notified body may require the application to be completed by further tests or proofs to allow assessment of its conformity with the requirements of this Annex I. The certificate must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the device.

6.3. The applicant shall inform the notified body which issued the CE design-examination certificate of any significant change in the approved design. Changes to the approved design must receive later approval from the notified body which issued the CE design-examination certificate wherever the changes could affect conformity with the essential requirements or with the conditions prescribed for use of the product. This additional approval must take the form of a supplement to the CE design-examination certificate.

7. Applicability to devices in Class IIA

This Annex may apply to products in Class IIA, subject to the following derogation:

7.1. where this Annex is applied in conjunction with the procedures referred to in Annexes IV, V or VI, a single declaration shall be issued. As regards the declaration issued in accordance with this Annex, the manufacturer must ensure and declare that the product design meets the applicable provisions of this Annex.

ANNEX VIII

STATEMENT
CONCERNING DEVICES FOR SPECIAL PURPOSES

1. For custom-made devices or for devices intended for clinical investigations, the manufacturer or his authorised representative established Romania must draw up the statement in accordance with the provisions of point 2.

2. The statement must contain the following information:

2.1. for custom-made devices:

- data allowing identification of the device in question;
- a statement that the device is intended for the exclusive use by a particular patient, stating the name of the patient;
- the name of the medical practitioner or other authorised person who made out the prescription and the name of the clinic concerned;
- the particular features of the device as specified in the relevant medical prescription;
- a statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been met.

2.2. for devices intended for the clinical investigations covered by Annex X:

- data allowing identification of the device in question;
- an investigation plan stating in particular the purpose, scientific, technical or medical grounds, scope and number of devices concerned;
- the detailed opinion of the ethics committee concerned;
- the name of the medical practitioner or other authorised person and of the institution responsible for the investigations;
- the place, starting date and scheduled duration for the investigations,
- a statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

3. The manufacturer must also undertake to keep available for the specialised department of the Ministry of Health:

3.1. for custom-made devices, a documentation allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Annex.

The manufacturer must take all the measures necessary to ensure that the manufacturing process results in products which are manufactured in accordance with the above-mentioned documentation;

3.2. for devices intended for clinical investigations, the documentation must contain:

- a general description of the product;
- design drawings, methods of manufacture, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits;
- the descriptions and explanations necessary to understand the above-mentioned drawings and diagrams and the operation of the product,

- the results of the risk analysis and a list of harmonized standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements;
- the results of the design calculations, and of the inspections and technical tests carried out.

The manufacturer must take all the measures necessary to ensure that the manufacturing process results in products which are manufactured in accordance with the appropriate documentation.

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

4. The information contained in the declarations concerned by this Annex should be kept for at least 5 years.

ANNEX IX

CLASSIFICATION CRITERIA

I. DEFINITIONS

1. Definitions for the classification rules

1.1. *Duration*

- Transient - normally intended for continuous use for less than 60 minutes;
- Short term - normally intended for continuous use for not for more than 30 days;
- Long term - normally intended for continuous use for more than 30 days.

1.2. *Invasive devices*

Invasive device - a device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice - any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening.

Surgically invasive device - an invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

For the purposes of this Annex, devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as *surgically invasive devices*.

Implantable device - any device which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain in place after the procedure. Any device intended to be introduced into the human body through surgical intervention and intended to remain in place after the procedure, for at least 30 days is also considered an *implantable device*.

1.3. *Reusable surgical instrument* - instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping (fastening) or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

1.4. *Active medical device* - any medical device used in operation, depending on a source of electrical energy or any source of power, other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

1.5. *Active therapeutical device* - any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological

functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

1.6. *Active device for diagnosis* - any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

1.7. *Central circulatory system*

For the purposes of this Annex, *central circulatory system* means the following vessels: arteriae pulmonales, aorta ascendens, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachicephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.

1.8. Central nervous system

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

II. IMPLEMENTING RULES

2. Implementing rules

2.1. Application of the classification rules shall be governed by the intended purpose of the devices.

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

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

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

2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

III. CLASSIFICATION

1. Non-invasive devices

1.1. *Rule 1*

All non-invasive devices are included in Class I, unless one of the rules set out hereinafter applies.

1.2. *Rule 2*

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are included in Class IIA:

- if they may be connected to an active medical device in Class IIA or a higher class;
- if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues;
- in all other cases they are in Class I.

1.3. *Rule 3*

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIB, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIA.

1.4. *Rule 4*

All non-invasive devices, which come into contact with injured skin:

- are in Class I, if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
- are in Class IIB, if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent;
- are in Class IIA in all other cases, including devices principally intended to manage the micro-environment of a wound.

2. Invasive devices

2.1. *Rule 5*

All invasive devices with respect to body orifices, others than the surgically invasive devices and which are not intended for connection to an active medical device:

- are in Class I, if they are intended for transient use;
- are in Class IIA, if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I;
- are in Class IIB, if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIA.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIA or a higher class, shall be in Class IIA.

2.2. *Rule 6*

All surgically invasive devices intended for transient use are in Class IIA unless they are:

- intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III;
- reusable surgical instruments, in which case they are in Class I;
- intended to supply energy in the form of ionising radiation in which case they are in Class IIB;
- intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIB;
- intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class IIB.

2.3. *Rule 7*

All surgically invasive devices intended for short-term use are in Class IIB unless they are intended:

- either specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III;
- or specifically for use in direct contact with the central nervous system, in which case they are in Class III;
- or to supply energy in the form of ionising radiation in which case they are in Class IIB;
- or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III;
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIB.

2.4. *Rule 8*

All implantable devices and long-term surgically invasive devices are in Class IIB unless they are intended:
- to be placed in the teeth, in which case they are in Class IIA;
- to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III;
- to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III;
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

3. Additional rules applicable to active devices

3.1. *Rule 9*

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

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

3.2. *Rule 10*

Active devices intended for diagnosis are in Class IIA :
- if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,
- if they are intended to image *in vivo* distribution of radiopharmaceuticals,
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS, in which case they are in Class IIB.

Active devices intended to emit ionising radiation and intended for diagnosis and therapeutic interventional radiology, including devices that control or monitor such devices, or which directly influence their performance, are in Class IIB.

3.3. *Rule 11*

All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body shall be in Class IIA, unless this is done in a manner that it is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIB.

3.4. *Rule 12*

All other active devices shall be included in Class I.

4. Special Rules

4.1. *Rule 13*

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

4.2. *Rule 14*

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIB, unless they are implantable or long term invasive devices, in which case they are in Class III.

4.3. *Rule 15*

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

All devices intended specifically to be used for disinfecting medical devices are in Class IIA.

This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

4.4. *Rule 16*

Non-active devices specifically intended for recording of X-ray diagnosis images are in Class IIA.

4.5. *Rule 17*

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

5. *Rule 18*

By way of derogation from other rules, blood bags are included in Class IIB.

ANNEX X

DECLARATIONS AND PROCEDURES

on the devices intended for clinical investigation or performance evaluation

1. General provisions

1.1. As a general rule, conformity with the requirements concerning the characteristics and performances referred to in points 1 and 3 of Annex I under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data, in particular in the case of implantable devices and devices in Class III. Taking account of any relevant harmonized standards, where appropriate, the adequacy of the clinical data must be based on:

1.1.1. either a compilation of the relevant scientific literature currently available on the intended purpose of the device and the techniques employed as well as, if appropriate, a written report containing a critical evaluation of this compilation;

1.1.2. or the results of all the clinical investigations made, including those carried out in conformity with point 2.

1.2. All the data must remain confidential.

2. Clinical investigations

2.1. Objectives

The objectives of clinical investigation are:

- to verify that, under normal conditions of use, the performance of the devices conform to those referred to in point 3 of Annex I, and
- to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the patient’s benefits and in relation to intended performance of the device.

2.2. Ethical considerations

Clinical investigations must be carried out in accordance with the Romanian standard SR – EN 540, identical to the European standard EN 540, drawn up on the basis of the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989.

It is mandatory that all measures relating to the protection of human subjects be carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

2.3. Methods

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

2.3.2. The procedures used to perform the investigations must be appropriate to the device under examination.

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

2.3.4. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients must be examined.

2.3.5. All adverse incidents such as those specified in Chapter VI of this Law must be fully recorded and notified to the specialised department of the Ministry of Health.

2.3.6. The investigations must be performed under the responsibility of a medical practitioner or other authorised qualified person in a specific environment.

The medical practitioner or other authorised person must have access to the technical and clinical data regarding the device.

2.3.7. The written report, signed by the medical practitioner or other authorised person responsible, must contain a critical evaluation of all the data collected during the clinical investigation.

3. Statements and procedures on the performance evaluation devices

3.1. For devices for performance evaluation, the manufacturer or its authorised representative shall draw up a statement including the data specified under point 3.2. below:

3.2. The said statement shall include the following information:

- data allowing the identification of the concerned device ;
- an evaluation plan establishing the purpose, technical and scientific medical grounds and the number of devices to be assessed;
- a list with the laboratories or other institutions participating in the evaluation study;
- starting date and the scheduled duration of 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 meets the requirements of this Law apart from the aspects covered by the evaluation and apart from those specifically itemized in the statement, and that every precaution has been taken to protect the health and safety of the patient, user and other persons.

3.3. The manufacturer must also undertake to keep available for the specialised department of the Ministry of Health the documentation allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Law. The said documentation shall be kept for at least 5 years after the end of the performance evaluation.

The manufacturer must take all the measures necessary to ensure that the manufacturing process results in products which are manufactured in accordance with the documentation mentioned in the first paragraph.

ANNEX XI

CRITERIA
for the designation of notified bodies

1. The notified body, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorised representative of any of these persons.

The notified body may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This shall in no way preclude the possibility of technical information exchanges between the manufacturer and the body.

2. The notified body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection,

especially from persons or groups of persons having an interest in the results of the verifications.

Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of this Law and, in particular, of this Annex. The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor.

3. The notified body must be able to carry out all the tasks assigned to such bodies under Annexes II to VI, whether these tasks are carried out by the body itself or on its responsibility; in particular, it must have the necessary staff and possess the facilities needed to properly perform the technical and administrative tasks entailed in assessment and verification. It must also have access to the equipment necessary for the verifications required.

4. The notified body must have:

- sound vocational training covering all the assessment and verification operations for which the body has been designated;
- satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections;
- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of the notified body must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

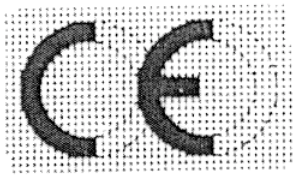
6. The body must take out civil liability insurance, unless it is a budgetary undertaking.

7. The staff of the notified body are bound to observe professional secrecy with regard to all information gained in the course of their duties, under the strict observance of this Law or any other legal provisions in the Romanian legislation in force, except vis-à-vis the competent administrative authorities of Romania in the field in which its activities are carried out.

ANNEX XII

CE MARKING OF CONFORMITY

The CE conformity marking shall consist of the initials 'CE' taking the following form:



- the graduated drawing must be observed;
- if the marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.
- the various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

This minimum dimension may be waived for small-scale devices.

ANNEX XIII

LIST
of *in vitro* diagnostic medical devices

LIST A

- reagents and reagent products, including calibrators and control materials for the determination of the following blood groups: ABO system, Rhesus (C, c, D, E, e) anti-Kell**;**
- reagents and reagent products, including calibrators and control materials for detecting, confirming and quantifying, in the samples taken from the human body, the infections markers of the HIV (HIV 1 and HIV 2), HTL V, I and II and B, C and D hepatitis;

LIST B

- reagents and reagent products, including calibrators and control materials for the determination of the following blood groups: anti – Duffy and anti-Kid;
- reagents and reagent products, including calibrators and control materials for the determination of the irregular anti-erythrocytes anti-bodies:
- reagents and reagent products, including calibrators and control materials for detecting, confirming and quantifying in the samples taken from the human body the following congenital infections: rubella and toxoplasmosis;
- reagents and reagent products, including calibrators and control materials for the diagnosis of phenylketonuria inherited disease;
- reagents and reagent products, including calibrators and control materials for the determination of the following infections in humans: cytomegalovirus, chlamydia;
- reagents and reagent products, including calibrators and control materials for the determination of the following groups of tissues: HLA: DR, A and B;
- reagents and reagent products, including calibrators and control materials for the determination of the PSA tumoral markers;
- reagents and reagent products, including calibrators and control materials and software, mainly intended to evaluate the trisomy 21 risk;
- self-diagnosis devices, including calibrators and control materials for measuring the blood sugar contents.