DECISION No 190 of 20 February 2003
laying down the rules for placing on the market and using medical devices

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Pursuant to Article 107 of the Constitution and Article 5 of Law No 608/2001 assessing the conformity of products,
The Government of Romania has adopted this Decision.

CHAPTER I

General provisions, definitions, scope

Article 1

(1) This decision shall apply to medical devices and their accessories. For the purpose of this Decision, accessories shall be treated as medical devices in their own right. Both medical devices and their accessories shall be hereinafter referred to as *devices*.

(2) This Decision lays down the unitary legal framework regulating and assessing the conformity, for market surveillance and vigilance for medical devices and their accessories placed on the market and/or used in Romania, thus providing the levels of safety and performance of medical devices, as well as an adequate protection of patients', users' and other persons' health.

Article 2

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

1. *medical device* - means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software needed for its proper functioning, intended by the manufacturer to be used for human beings for the purpose of:
   a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
   b) diagnosis, surveillance, treatment or compensation of injury or handicap;
   c) investigation, replacement or modification of the anatomy or of a physiological process;
   d) control of conception, 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;
2. *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;
3. *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:
   a) concerning a physiological or pathological state, or
   b) concerning a congenital abnormality, or

c) to determine the safety and compatibility with potential recipients, or
d) 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.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

4. *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;

5. *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;

6. *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).

The obligations provided for in this Decision shall also apply to the natural or legal persons who assemble, package, process, refurbish and / or label products and / or assign to them the intended purpose of medical devices with a view to placing them on the market under their own name in order to be complied with by manufacturers.

This subparagraph shall not apply to the person who, while not being a manufacturer within the meaning of the first paragraph, assembles or adapts medical devices already on the market to fit an individual patient;

7. *intended purpose* - means the use for which the medical device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and / or in promotion materials;
8. *placing on the market* - means making available for the first time, for payment or free of charge, of a medical device, other than a device intended for clinical investigation or performance assessment, with a view to distributing and / or using it, regardless of whether it is new or fully refurbished;
9. *putting into service* – means the stage at which a medical device is ready for its first use on the market in accordance with its intended purpose;
10. *authorised agent* - means any legal or natural person established in Romania, specially assigned by the manufacturer, who acts on behalf of the manufacturer and who may be addressed by the authorities or by other bodies instead of the manufacturer in respect of the latter’s obligations under this Decision.

Article 3

(1) When a medical device is intended to administer a medicinal product, that device shall be subject to this Decision, without prejudice to the provisions governing medicinal products.
(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 medicinal product.
(3) The relevant essential requirements stated in Annex I shall apply to the medical device provided for in paragraph (2) only as regards its safety and performance.

Article 4

(1) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of the legislation on medicinal products and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorised in accordance with this Decision.

(2) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a constituent of a medicinal product or a medicinal product derived from human blood or human plasma (albumin, immunoglobulins, coagulants) and which is liable to act upon the body with action ancillary to that of the device, which shall be hereinafter referred to as “human blood derivative”, that device must be assessed and authorised in accordance with this Decision.

Article 5

This Decision shall not apply to:

a) in vitro diagnostic medical devices;

b) active implantable devices;

c) medicinal products governed by Government Emergency Ordinance No 152/1999 on medicinal products of human use, as subsequently amended and supplemented by Law No 336/2002 including also medicinal products derived from human blood and human plasma;

d) cosmetics;

e) 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 except for the medical devices provided for in Article 4 (2);

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

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

Article 6

(1) This Decision shall not apply to personal protection equipment.
(2) If it is decided that the provisions of this Decision shall apply to a product falling within the scope of paragraph (1), then the main intended purpose defined under Article 2 (7) shall be taken into account.

Article 7

This Decision constitutes a specific rule in the meaning of Article 1 (2) of Government Decision No 1.032/2001 establishing terms to place on the market and put into service electric and electronic devices as regards electromagnetic compatibility.

Article 8

This Decision shall not prejudice the implementation of provisions on carrying on safely nuclear activities.

CHAPTER II

Essential requirements medical devices must comply with, placing on the market and putting into service medical devices
Harmonised standards in the field of medical devices

SECTION 1
Placing on the market and putting into service medical devices

Article 9

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

The Ministry of Health and Family shall take all necessary steps to ensure that devices may be placed on the market, put into service and used provided that they comply with the requirements of this Decision and do not compromise the safety and health of patients, users or, where applicable, other persons when properly installed, maintained and used in accordance with the intended purpose.

(2) In case of doubt regarding the implementation of this Decision to a certain product, the Ministry of Health and Family shall take the final Decision.

SECTION 2
Essential requirements

Article 10

The devices must meet the essential requirements set out in Annex 1, taking account of the intended purpose of the devices concerned.

SECTION 3
Free movement of medical devices

Article 11

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

a) they bear the CE marking as provided for in Article 50 and in Annex 12, a marking complying with the essential requirements described in Annex 1, and they are registered in the database of the Ministry of Health and Family in accordance with Article 33;

b) they bear the national conformity marking CS provided for in Article 50 and in Annex 12, a marking certifying that the conformity of medical devices has been assessed by a notified body pursuant to Articles 18, 19, 20 and 21, where applicable, and are registered in the database of the Ministry of Health and Family in accordance with Article 33;

(2) Romania shall not create any obstacle to the free movement and placing on the market of:

a) medical devices intended for clinical investigation being made available authorised persons for that purpose if they meet the conditions laid down in Chapter VII and in Annex 9 and are registered in the database of the Ministry of Health and Family;

b) custom-made devices if they meet the conditions laid down in Article 22 and in Annex 8 and are registered in the database of the Ministry of Health and Family; Class IIa, IIb and III devices shall be accompanied by the statement of conformity referred to in Annex 8. These devices shall not bear the CE or CS marking.

(3) At trade fairs, exhibitions, demonstrations, scientific and technical meetings organised in Romania, devices which do not conform to this Decision may be exhibited, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply with this Decision.
(4) When a medical device reached the end user, the information provided in accordance with point 13 of Annex 1 shall be drawn up in Romanian, regardless of whether it is for professional or other use.
(5) Where the medical devices are subject to other technical regulations concerning other aspects and which also provide for the affixing of the CS or CE marking, the latter shall indicate that the device is in compliance with the provisions of the other technical regulations.
(6) Should one or more of the technical regulations provided for in paragraph (5) allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CS or CE marking shall indicate that the devices fulfil the provisions only of those technical regulations applied by the manufacturer.
(7) In the case provided for in paragraph (6), the particulars of the technical regulations applied by the manufacturer must be given in the documents, notices or instructions required by the technical regulations and accompanying such devices.

SECTION 4
Harmonised standards in the field of medical devices

Article 12

(1) Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the European harmonised standards. The list of Romanian standards adopting European harmonised standards concerning medical devices shall be approved by Order of the Ministry of Health and Family and shall be published in the Romanian Official Journal, Part I. The list of such standards is updated whenever necessary.
(2) For the purposes of this Decision, reference to European harmonised standards also includes the monographs of the European Pharmacopoeia notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products.
(3) If the Ministry of Health and Family considers that the harmonised standards adopted do not entirely meet the essential requirements referred to in Article 10, it shall take adequate measures with regard to these standards.

Article 13

The Ministry of Health shall take part in:
a) drafting national standardisation programmes to adopt as European harmonised standards on medical devices as Romanian standards;
b) the Technical Committees of ASRO to adopt European harmonised standards on medical devices.

CHAPTER 3
Committee on Medical Devices
Safety clause
Classification of medical devices

SECTION 1
Committee on Medical Devices

Article 14

(1) The Committee on Medical Devices is an advisory body made up of experts in various medical branches appointed by Order of the Minister of Health and Family in accordance with Law No 176/2000 on medical devices.
(2) The Committee on Medical Devices shall adopt its rules of procedure.
(3) The Ministry of Health and Family may consult the Committee on Medical Devices on matters related to the implementation and application of the provisions included in this Decision.

SECTION 2
Safeguard clause

Article 15

(1) Where the Ministry of Health and Family ascertains that the devices referred to in Article 11 (1) and (2) (b), when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Ministry of Health and Family shall immediately inform the parties concerned, such as the Public Health Departments or the National Health Insurance House of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Decision is due to:
a) failure to meet the essential requirements referred to in Article 10;
b) incorrect application of the standards referred to in Article 12, in so far as it is claimed that the standards have been applied;
c) shortcomings in the standards themselves.
(2) Where a non-complying device bears the CS or CE marking, the Ministry of Health and Family shall take appropriate action against whomsoever has affixed the mark and shall inform the parties concerned thereof.
4. The Ministry of Health and Family shall ensure that the parties concerned are kept informed of the progress and outcome of this procedure.

SECTION 3

Classification of medical devices

Article 16

(1) Medical devices shall be divided into Classes I, IIa, IIb and III. They are classified in accordance with Annex 9.
(2) In the event of a dispute between the manufacturer and the conformity assessment body assessing the conformity with respect to the classification of a medical device, resulting from the application of the classification rules, the matter shall be referred for decision to the Ministry of Health and Family.

CHAPTER 4
Vigilance procedure concerning incidents due to devices placed on the market

Article 17

The Ministry of Health and Family shall register and assess any information received in accordance with the provisions of this Decision as regards the incidents involving medical devices falling within Classes I, IIa, IIb and III which may concern:

a) any malfunction, failure/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 of other persons or to a serious deterioration in their state of health;
b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in point (a), leading to systematic recall of devices of the same type by the manufacturer.
(2) The obligation to notify the Ministry of Health and Family on any incidents in using medical devices lies with the medical practitioners, the medical institutions, other users, the manufacturer or the authorised agent established in Romania, the importer and the notified body. The Ministry of Health and Family shall inform the manufacturer or its authorised agent of any incidents.
(3) After carrying out an assessment, if possible together with the manufacturer, the Ministry of Health and Family shall inform the parties concerned of the incidents for which appropriate measures have been taken or are contemplated.

CHAPTER 5
Conformity assessment

SECTION 1
Conformity assessment procedures

Article 18

In the case of medical devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CS or CE marking, either:
a) follow the procedure relating to the CS or EC declaration of conformity set out in Annex 2; or
b) follow the procedure relating to the CS or EC type-examination set out in Annex 3, coupled with:
1. the procedure relating to the CS or EC verification set out in Annex 4;
2. the procedure relating to the CS or EC declaration of conformity set out in Annex 5.

Article 19

In the case of devices falling within Class IIa, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CS or CE marking, follow one of the following procedures:
a) the procedure relating to the CS or EC declaration of conformity set out in Annex 2; in this case the provisions of point 4 of Annex 2 is not applicable;
b) the procedure relating to the CS or CE declaration of conformity set out in Annex 7, coupled, where applicable, with
1. the procedure relating to the CS or EC verification set out in Annex 4;
2. the procedure relating to the CS or EC declaration of conformity set out in Annex 5;
3. the procedure relating to the CS or EC declaration of conformity set out in Annex 6.

Article 20

In the case of medical devices falling within Class IIb, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CS or CE marking, either:
a) follow the procedure relating to the CS or EC declaration of conformity set out in Annex 2; in this case, point 4 of Annex 2 is not applicable; or

b) follow the procedure relating to the CS or EC type-examination set out in Annex 3, coupled, where applicable, with:

1. the procedure relating to the CS or EC verification set out in Annex 4;
2. the procedure relating to the CS or EC declaration of conformity set out in Annex 5;
3. the procedure relating to the CS or EC declaration of conformity set out in Annex 6.

Article 21

In the case of medical devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CS or CE marking, follow the procedure set out in Annex 7 and draw up the CS or EC declaration of conformity required before placing each device on the market.

Article 22

(1) In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex 8 and draw up the statement set out in that Annex before placing each device on the market.

(2) The manufacturer shall submit to the Ministry of Health and Family a list of such devices as provided for in paragraph (1), which have been put into service in Romania.

Article 23

During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which have been carried out in accordance with this Decision at an intermediate stage of manufacture.

Article 24

The manufacturer may instruct his authorised agent established in the Romania to initiate the procedures provided for in Annexes 3,4,7 and 8.

Article 25

Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorised agent established in Romania, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

Article 26

The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

Article 27

Decisions taken by the notified bodies in accordance with Annexes 2 and 3 shall be valid for a maximum of 5 years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of 5 years.

Article 28

The records and correspondence relating to the procedures referred to in Articles 18 to 22 shall be drawn up in Romanian or in another language acceptable to the notified body.

Article 29

By way of derogation from Articles 18 to 22, the Ministry of Health and Family may authorize, on duly justified request, the placing on the market and putting into service, within the territory of Romania, of individual medical devices for which the procedures referred to

in Articles 18 to 22 have not been carried out and the use of which is in the interest of protection of health.

SECTION 2
Particular procedure for systems and procedure packs

Article 30

(1) By way of derogation from Articles 18 to 29, this Article shall apply to systems and procedure packs.

(2) Any natural or legal person who puts devices bearing the CS or CE marking together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:

a) he has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions;

b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers;

c) the whole activity is subjected to appropriate methods of internal control and inspection.

Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a CS or CE marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant procedure pursuant to Articles 18 to 29.

(3) Any natural or legal person who sterilized, for the purpose of placing on the market, systems or procedure packs referred to in paragraph (2) or other CS or CE-marked medical devices designed by their manufacturers to be sterilized before use, shall, at his choice, follow one of the procedures referred to in Annex 4, 5 or 6. The application of the procedures and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility. The person shall draw up a declaration stating that sterilization has been carried out in accordance with the manufacturer's instructions.

(4) The products referred to in paragraphs (2) and (3) themselves shall not bear an additional CS or CE marking but they shall be accompanied by the information referred to in point 13 of Annex 1 which resumes, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

(5) The declaration referred to in paragraphs (2) and (3) above shall be kept at the disposal of the Ministry of Health and Family for a period of 5 years.

SECTION 3
Decisions with regard to classification, derogation clause

Article 31

(1) Where Ministry of Health and Family considers that:

(a) application of the classification rules set out in Annex 9 requires a decision with regard to the classification of a given device or category of devices;

or

(b) a given device or family of devices should be classified, by way of derogation from the provisions of Annex 9, in another class;

or

(c) the conformity of a device or family of devices should be established, by way of derogation from the provisions of Articles 18 to 22, by applying solely one of the given procedures chosen from among those referred to in Articles 18 to 22,
it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures.
2. In the situations provided for in paragraph (1) above, the Ministry of Health and Family informs the parties concerned of the measurers taken.

CHAPTER 6

Registration and databank

SECTION 1

Registration of persons responsible for placing devices on the market

Article 32

(1) Any manufacturer who, under his own name, places medical devices on the market in accordance with the procedures referred to in Articles 21 and 22 and any other natural or legal person engaged in the activities referred to in Article 30 shall register to the Ministry of Family and Health the address of the registered place of business and the description of the devices concerned in order to be included into the national databank of the Ministry of Health and Family.
(2) For devices covered by Annexes IIb and III the Ministry of Health and Family may request to be informed of the data allowing identification together with the label and the instructions for use when such devices are placed on the market within the territory of Romania.
(3) Where a manufacturer who places devices referred to in paragraphs (1) and (2) on the market under his own name does not have a registered place of business in Romania, he shall designate an authorised agent. This authorised agent shall register to the Ministry of Health and Family the address of the registered place of business and the category of devices concerned in order to be included into the national databank of the Ministry of Health and Family.
(4) In case neither the manufacturer nor his authorised agent has his registered place of business in Romania, the importer, who must register to the Ministry of Health and Family, is responsible for keeping the documents certifying the conformity and producing them at the request of the Ministry of Health and Family.
(5) The Ministry of Health and Family shall inform the other authorities concerned of the data referred to in paragraphs (1) to (4).

SECTION 2

National databank

Article 33

(1) Data registered according to this Decision shall be stored in the national databank, accessible to the national authorities to enable them to carry out their tasks relating to this Decision on a well-informed basis.
(2) The national databank shall contain the following:
(a) data relating to registration of manufacturers and devices in accordance with Article 32;
(b) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedure as laid down in Annexes 2 to 7;

(c) data obtained in accordance with the vigilance procedure as defined in Article 17.
(3) Data provided for in paragraph (2) shall be forwarded in a standardised format.
(4) The procedures implementing this Article shall be adopted by Order of the Minister of Health and Family and shall be published in the Romanian Official Journal, Part I.

SECTION 3
SPECIAL HEALTH MONITORING MEASURES

Article 34

(1) The Ministry of Health and Family may adopt the necessary temporary measures justified as regards a certain device or group of devices when it deems that it/they should be prohibited, restricted or used under special terms in order to safeguard public health and safety and/or to ensure the observance of public health requirements pursuant Article 36 of the Treaty on the European Union.
(2) The Ministry of Health and Family shall inform the competent authorities concerned, stating the reasons on which the decisions adopted in accordance with paragraph (1) were based.

CHAPTER 7
Clinical investigation

Article 35

(1)In the case of devices intended for clinical investigations, the manufacturer, or his authorised agent established in Romania, shall follow the clinical investigation procedure referred to in Annex 8 and shall obtain the written agreement of the Ministry of Health and Family on the application of the clinical investigation procedure.

Article 36

The manufacturer or his authorised agent shall notify the Ministry of Health and Family about his intention to commence a clinical investigation in Romania.

Article 37

(1) In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the Ministry of Health and Family has notified him within that period of a decision to the contrary based on considerations of public health or public policy.

(2)Manufacturers may however be authorised to commence the relevant clinical investigations before the expiry of the period of 60 days, in so far as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question.

Article 38

In the case of devices other than those referred to in Article 37, manufacturers may be authorize to commence clinical investigations, immediately after the date of notification, provided that the ethics committee concerned has approved the investigational plan.

Article 39

The clinical investigations must be conducted in accordance with the provisions of Annex 10 and may be adjusted in accordance with the procedure laid down in Article 14 (3).

Article 40

The Ministry of Health and Family shall, if necessary, take the appropriate steps to ensure public health and public policy

Article 41

The manufacturer or his authorised agent established in Romania shall keep the report referred to in point 2.3.7 of Annex 10 at the disposal of the Ministry of Health and Family.

Article 42

The provisions of Articles 35, 36 and 36 do not apply where the clinical investigations are conducted using devices subject to the assessment procedures provided for in Articles 18 to 22 unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The provisions of Annex 10 remain applicable.

CHAPTER 8

Notified bodies

Article 43

(1) The Ministry of Health and Family shall notify the national authority that coordinates the quality infrastructure and product quality assessment field of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Articles 18 to 22 and the specific tasks for which the bodies have been designated.

(2) The method of assessing the bodies with a view to designating them shall be approved by order of the Minister of Health and Family within a period of 30 days from the publication of this Decision.

(3) By order of the Minister of Health and Family a list of the notified bodies assessing the conformity of medical devices, stipulating the tasks for which they have been notified, shall be published in the Romanian Official Journal, Part I.

Article 44

Ministry of Health and Family shall apply the criteria set out in Annex 11 for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant European harmonised standards shall be presumed to meet the relevant criteria.

Article 45

(1) If the Ministry of Health and Family finds that a notified body no longer meets the criteria specified on which the body has been designated, it shall withdraw the notification and shall publish the updated list of notified bodies in the Romanian Official Journal, Part I.

(2) The withdrawal of the notification shall not affect the validity of the conformity certificates prior to the date of the withdrawal unless there is available information that proves that the devices have serious deficiencies that can endanger patients, users or other persons.

Article 46

The notified body and the manufacturer, or his authorised agent established in Romania, shall lay down, by common accord, the deadlines for completion of the assessment and verification operations referred to in Annexes 2 to 6.

Article 47

The notified body shall inform the other notified bodies and the Ministry of Health and Family about all certificates suspended or withdrawn and, on request, about certificates issued or refused. It shall also make available, on request, all additional relevant information.

Article 48

(1) Where a notified body finds that pertinent requirements of this Decision have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on the manufacturer unless compliance with such requirements is ensured by the implementation of appropriate corrective measures.

(2) In the case of suspension or withdrawal of the certificate or of any restriction placed on the manufacturer or in cases where an intervention of the competent authority may become necessary, the notified body shall inform the Ministry of Health and Family thereof.

Article 49

The notified body shall, on request, supply all relevant information and documents, including budgetary documents, required to enable the Ministry of Health and Family and the national approval body to verify compliance with Annex 11 requirements

CHAPTER 9
Conformity markings

SECTION 1
CE or CS conformity marking

Article 50

Devices, other than devices for which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 10 must bear the CE or CS marking of conformity when they are placed on the market.

Article 51

(1) The CE or CS marking of conformity, as shown in Annex 12, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use.

(2) The CE or CS marking of conformity must also appear on the sales packaging.

(3) The CE or CS marking shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes 2, 3 and 4.

Article 52

(1) It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE or CS marking.

(2) Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE or CS marking is not thereby reduced.

SECTION 2
Wrongly affixed CE or CS marking

Article 53

In case the Ministry of Health and Family establishes that the CE or CS marking has been wrongly affixed, the manufacturer or his authorised agent established in Romania shall be obliged to end the infringement of the regulations in the field.

Article 54

Where the non-compliance provided for in Article 53 continues, the Ministry of Health and Family must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 15.

Article 55

The provisions stated in Articles 53 and 54 shall also apply where the CE or CS marking has been affixed in accordance with the procedures in this Decision, but inappropriately, on products that are not covered by this Decision.

CHAPTER 10
Implementation, transitional and final provisions

SECTION 1
Decisions in respect of refusal or restriction

Article 56

(1) Any decision taken pursuant to this Decision to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations or to withdraw devices from the market shall state the exact grounds on which it is based.

(2) The decisions provided for in paragraph (1) shall be notified without delay to the parties concerned, who shall at the same time be informed of the remedies available to them under the regulations in force and of the time limits to which such remedies are subject.

(3) In the event of a decision as referred to in paragraph (1), the manufacturer, or his authorised agent established in Romania, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken as justified in particular by public health requirements.

SECTION 2
Confidentiality

Article 57

(1) Without prejudice to the legislation in force and the national practice on medical secrecy, the natural and legal persons involved in the application of this Decision are bound to observe confidentiality with regard to information obtained in carrying out their tasks.

(2) The provisions of paragraph (1) shall not affect the obligations of Ministry of Health and Family and notified bodies with regard to mutual information and the dissemination of warnings.

SECTION 3
Final and transitional provisions

Article 58

The provisions of this Decision shall apply to legal and natural persons manufacturing , marketing, setting up, using, verifying, maintaining and restoring medical devices.

Article 59

Medical devices assessed, certified and registered pursuant to the rules and regulations in force in the field before the entry in force of this Decision may be placed on the market until the expiry of the validity date specified in the registration certificate or in the authorisation granted.

Article 60

The Ministry of Health and Family shall establish an assessment procedure for medical devices bearing the CE marking irrespective of the class they fall within which shall be applied by the notified body during the transitional period until Romania's accession to the European Union.

Article 61

The authorised specialists of the Ministry of Health and Family and of its technical and specialised entities as well as the notified bodies shall have access to all locations where medical devices are manufactured and/or used.

Article 62

Annexes 1 to 12 shall be an integral part of this Decision.

Article 63

Ministry of Health and Family establishes by order of the Minister the organisational scheme of the national databank referred to in Article 33, as well as the fees to be levied for registration in the databank.

Article 64

This decision enters into force 3 months after its publication in the Romanian Official Journal, Part I.

Article 65

Any provision contrary to this Decision shall be repealed as from the date this Decision enters into force.

PRIME MINISTER
ADRIAN NĂSTASE

Countersigned:

Minister of Health and Family,
Daniela Bartoş

Bucharest, 20 February 2003.
No 190.

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 article. In selecting the most appropriate solutions, the manufacturer must apply the following principles:

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

3. The devices must achieve the purpose intended by the manufacturer and be designed, manufactured and packed in such a way that they are suitable for one or more of the functions referred to in Article 2 (1), as specified by the manufacturer.

4. The characteristics and performances referred to in points 1 to 3 should not be adversely affected to such a degree that the health or safety of patients or users and, where applicable, of other persons, is compromised under clinical conditions during the device lifetime specified by the manufacturer, when the device is subject to an intensive use in normal operation conditions.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use are not adversely affected during transportation and storage done to 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. Requirements regarding design and construction

7. Chemical, physical and biological properties

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

a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;
b) 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 transportation, 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 use.

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.

Where a device incorporates as an integral part, a human blood derivative, the notified body shall seek the scientific opinion from the competent medical authority in Romania and/or, where necessary, from the European Agency for the Evaluation Medicinal Products (EMEA) on the quality and safety of the derivative. The usefulness of the derivative as part of the medical device will be checked taking into account the intended purpose of the device.

A sample from each batch of bulk or finished product of the human blood derivative shall be tested by a laboratory designated for that purpose by the competent medical authority in Romania.

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 use of the tissues.

The notified certification 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 transportation 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:

a) the risk of injury, in relation to their physical features, including the volume/pressure-size ratio, and, where appropriate, the ergonomic features;
b) the risks relating to environmental conditions, such as magnetic fields, external electrical influence, electrostatic charges, pressure, temperature or variations in pressure and acceleration;
c) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;
d) 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 use 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 use.

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 use. 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.

12.6. 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.

13. Information supplied by the manufacturer:

13.1. Each device must be accompanied by the information needed for its safe use and for the identification of the manufacturer, taking into account the training and knowledge of the potential users.

This information shall be present on the label and in the instructions for use.

As far as practicable and appropriate, the information needed for the safe use of the device must be present 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 comply with 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 particular indications:

a) the name or trade name and address of the manufacturer; for imported devices in view of their distribution in Romania, the label or 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 agent 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 that the device is for single use, in the case of single use devices;

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

h) if the device is intended for clinical investigations or performance assessment, the words 'exclusively for clinical investigations' or ‘exclusively for performance assessment’;

i) any special storage and/or handling conditions;

j) any special 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 contains a human blood derivative for devices provided for in Article 4 (2).

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.

The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:

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 pursuant to point 7.4;

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 10.

ANNEX 2

CS OR EC 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, ensures the examination of the product design pursuant to point 4 and is subject 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 Decision which shall apply to them.

The manufacturer must affix the CS or CE marking pursuant to Article 50 of this Decision and issue 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 notified body pursuant to Article 25 of the Decision.

The application must include:

a) the name and address of the manufacturer and any additional manufacturing site covered by the quality system;
b) all the relevant information on the product or product category covered by the procedure;
c) a written declaration that no application has been submitted to any other notified body for the same product in relation to the quality system;
d) the documentation on the quality system;
e) an undertaking by the manufacturer to meet all the requirements of the quality system;
f) an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,
g) 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 and Family 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, from the reasons stipulated in point (i), to the recall of such devices by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the provisions of this Decision which apply to them at every stage, from design to final inspection. All the provisions adopted by the manufacturer for his quality system must be systematically documented in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

a) the manufacturer's quality objectives;
b) the organization of the business and in particular:

1. the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned;
2. the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform;

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

1. a general description of the product, including any variants planned;
2. the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the

essential requirements which apply to the products if the standards referred to in Article 12 are not applied in full,;

3. the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed;

4. 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;

5. a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative as referred to in point 7.4 of Annex 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative taking account of the intended purpose of the device;

6. the clinical data referred to in Annex 10;

7. the draft label and, where appropriate, instructions for use;

d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

1. the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents;

2. the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used. It must be possible to trace back the calibration of the test equipment adequately.

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 harmonised 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 must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

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

3.4. The manufacturer shall inform the notified certification body which approved the quality system of any plan for substantial change to the quality system or the product-range covered. The notified certification 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 certification body shall notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. Examination of the design of the product

4.1. In addition to the obligations imposed by point 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in point 3.1.

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 of this Decision as specified in point 3.2 (c).

4.3. The notified body must examine the application and, if the product conforms to the relevant provisions of this Decision, issue the application with a CS or EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Decision. The certificate must contain the conclusions of the examination, the conditions of

validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the product.
In the case of devices referred to in Annex 1, point 7.4, first subparagraph the notified body shall, as regards the aspects referred to in that point, consult the competent bodies concerned in accordance with the legislation in force in the field of medicinal products before taking a decision.
The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.
In case of devices referred to in Annex 1, point 7.4, second subparagraph, the scientific opinion of the competent body established for that medicinal product must be included in the documentation concerning the device. The notified body shall give due consideration to the views expressed by the competent body established for the medicinal product when making its decision. The notified body may not deliver the certificate if the scientific opinion of the competent body established in the field of the medicinal product is unfavourable. It will convey its final decision to the competent body concerned.

4.4. Changes to the approved design must receive prior approval from the notified certification 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 certification 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 certification body to carry out all the necessary inspections and shall provide all relevant information, in particular:

a) the documentation regarding the quality system;
b) the quality system data the relating to design, such as the results of analyses, calculations, tests, etc.;
c) 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 certification 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 national competent authorities:

a) the declaration of conformity;
b) the documentation referred to in the fourth indent of point 3.1 (d);
c) the changes referred to in point 3.4;
d) the documentation referred to in point 4.2;
e) the decisions and reports from the notified certification body as referred to in points 3.3, 4.3, 4.4, 5.3 and 5.4.

6.2. In respect of devices subject to the procedure provided for in point 4, when neither the manufacturer nor his authorised agent 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 1, point 13.3 (a).

7. Applicability to devices in Class IIa and IIb:

Pursuant to the provisions of Articles 19 and 20, this Annex may be applied to the products in Class IIa and IIb, with the exception of point 4, which does not apply.

8. Applicability to devices referred to in Article 4 (2) of the Decision:

Upon completing the manufacture of each batch of devices referred to in Article 4 (2) of the Decision, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a laboratory designated for that purpose by the competent authority.

ANNEX. 3

CS OR CE TYPE-EXAMINATION

1. The CS or EC type-examination is the procedure whereby a notified certification body ascertains that a representative sample of the production covered fulfils the relevant provisions of this Decision.

2. The application shall include:

a) the name and address of the manufacturer and the name and address of the authorised agent, if the application is submitted by the agent;
b) 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 Decision. The applicant must make a *'type'* available to the notified certification body, while the notified certification body may request other samples as necessary;
c) 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) a general description of the type, including all variants planned;
b) drawings, methods of manufacture envisaged, in particular as regards sterilization, diagrams of components, sub-assemblies, circuits, etc.;
c) the descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the operation of the product;
d) a list of the standards referred to in Article 12 of the Decision, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements;
e) the results of calculations, risk analysis, investigations, technical tests carried out, etc.;
f) 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,
g) the clinical data referred to in Annex 10,
h) 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 Article 12 of the Decision, 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 to in Article 12 of the Decision 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 having the characteristics specified by the manufacturer;

4.3. carry out or have the appropriate inspections and tests carried out as are necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

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 Decision, the notified certification body shall deliver a CS or EC 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 1, point 7.4, first subparagraph the notified body shall as regards the aspects referred to in that point, consult one of the competent bodies established in the field of the medicinal product in accordance with the legislation on medicinal products before taking his final decision.

The notified body will give due consideration to the views expressed in the consultation with the competent body when making the final decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex 1, point 7.4, second subparagraph the scientific opinion of the competent body in the field of the medicinal product must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the competent body when making its decision. The notified body may not deliver the certificate if the scientific opinion of the competent body is unfavourable. It will convey its final decision to the competent body.

6. The applicant shall inform the notified body having delivered the CS or EC 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 CS or EC 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 CS or EC type-examination certificate.

7. Administrative provisions:

7.1. Other notified bodies may obtain a copy of the CS or EC 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.

7.2. The manufacturer or his authorised agent must keep the technical documentation copies of CS or EC type-examination certificates and their additions, for a period of at least 5 years after the last device has been manufactured.

7.3. When neither the manufacturer nor his authorised agent 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 4

CS OR EC VERIFICATION

1. The *CS or EC verification* is the procedure whereby the manufacturer or his authorised agent 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 CS or EC type-examination certificate and meet the requirements of this Decision.

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 CS or EC type-examination certificate and to the requirements of this Decision. 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 CS or EC type-examination certificate and with the requirements of this Decision. In this respect, the manufacturer shall affix the CS or EC marking in accordance with Article 50 of the Decision and issue a CS or EC declaration of conformity for this purpose.

In addition, in the case of sterile products, the manufacturer must apply the provisions of Annex 5, points 3 and 4 regarding sterilization security and preservation.

3. The manufacturer shall establish and keep up to date a systematic procedure to review experience gained from devices in the postproduction phase and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the specialised department of the Ministry of Health and Family 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 which, for the reasons referred to in point (i), led to the systematic recall of such devices by the manufacturer.

4. The notified certification body shall carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of this Decision, 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 the safety of sterilization.

5. Verification by examination and testing of every product:

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

5.2. The notified body must affix, or have affixed, its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification:

6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.

6.2. A random sample is taken from each batch. The products which make up the sample are examined and the appropriate tests defined in the relevant standard(s) referred to in Article 12 or equivalent tests must be carried out to verify the conformity of the products with the type described in the CS or EC type-examination certificate and with the requirements of this Decision which apply to them in order to determine whether to accept or reject the batch.

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 harmonised standards referred to in Article 12, taking into account the specific nature and the class of the product concerned.

6.4. If the batch is accepted, the notified certification 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 certification 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 agent shall, for at least 5 years after manufacture of the last product, make available to the competent body the following documents:

a) the declaration of conformity;
b) the documentation referred to in point 2;
c) the certificates referred to in points 5.2 and 6.4;
d) where appropriate, the type-examination certificate referred to in Annex 3.

8. Applicability of procedure to devices in Class IIa:

Pursuant to Article 19, the provisions of this Decision may apply to products in Class IIa, with the following exceptions:

8.1. by way of 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 7 and meet the requirements of this Decision;

8.2. by way of 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 7.

9. Applicability of procedure to devices referred to in Article 4 (2) of the Decision:

In the case of point 5, upon completing the manufacture of each batch of devices referred to in Article 4 (2), and in the case of verification under point 6, the manufacturer shall inform the notified body of the release of this batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a laboratory designated for that purpose by the Ministry of Health and Family.

ANNEX 5

CS OR EC DECLARATION OF CONFORMITY
Production quality assurance

1. The manufacturer must ensure the application of the quality system approved for the manufacture of the products concerned and carry out the final inspection 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 comply with the type described in the CS or EC type-examination certificate and meet the provisions of this Decision which apply to them.

The manufacturer must affix the CS or CE marking in accordance with Article 50 of the Decision and draw up a 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 shall submit to a notified body an application for assessment of his quality system.

The application shall include:

a) the name and address of the manufacturer;
b) all the relevant information on the product or product category covered by the procedure;
c) a written declaration that no application has been submitted to any other notified body for the same products;
d) the documentation on the quality system;
e) an undertaking to fulfil the obligations imposed by the approved quality system;
f) an undertaking to maintain the approved quality system;
g) where appropriate, the technical documentation on the types approved and a copy of the CS or EC type-examination certificates;
h) an undertaking by the manufacturer to establish and keep up to date a systematic procedure to review experience gained from devices in the postproduction phase and to implement appropriate means to apply any necessary corrective action whenever an inadequacy is found. This undertaking must include an obligation for the manufacturer to notify the Ministry of Health and Family 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 performance of a device which for the reasons referred to in point (i) above leading to a systematic 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 CS or EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures.

This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.

It must include in particular an adequate description of:

a) the manufacturer's quality objectives;

b) the organization of the business and in particular:

1. the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned;

2. the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform;

c) the inspection and quality assurance techniques at the manufacturing stage and in particular:

1. the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents;

2. the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

3.3. The notified body shall 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 harmonised standards comply with these requirements.

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

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

The decision shall be notified to the manufacturer after completion of the final inspection and shall 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 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 decision shall 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:

a) the documentation regarding the quality system,
b) 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 to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. Administrative provisions:

5.1. The manufacturer or his authorised agent shall, for at least 5 years after the last product has been manufactured, make available to the specialised department of the Ministry of Health and Family, the following documents:

a) the declaration of conformity;
b) the documentation referred to in point 3.1 (d);
c) the changes referred to in point 3.4;
d) the documentation referred to in point 3.1 (g);
e) the decisions and reports from the notified body as referred to in points 4.3 and 4.4;
f) the type-examination certificate referred to in Annex 3, if the case be.

6. Applicability to devices in Class IIa:

In line with Article 19, this Annex may apply to products in Class IIa, subject to the following exemption:

6.1. 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 7 and meet the requirements of this Decision which apply to them.

7. Applicability to devices referred to in Article 4 (2) of the Decision:

Upon completing the manufacture of each batch of devices referred to in Article 4 (2), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a laboratory designated for that purpose by the Ministry of Health and Family.

ANNEX 6

CS OR EC DECLARATION OF CONFORMITY
Product quality assurance

1. The manufacturer must ensure the 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 point 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 5, 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 CS or EC type-examination certificate and meet the applicable provisions of this Decision.

The manufacturer affixes the CS or CE marking in accordance to Article 50 of the Decision and draws up a written declaration of conformity. This declaration must cover a given number of identified specimens and must be kept by the manufacturer. The CS or CE marking must be accompanied by the identification number of the notified body which fulfils the tasks provided for in this Annex.

3. Quality system:

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

The application must include:

a) the name and address of the manufacturer;
b) all the relevant information on the product or product category covered by the procedure;
c) a written declaration specifying that no application has been submitted to any other notified certification body for the same products;
d) the documentation on the quality system;
e) an undertaking by the manufacturer to fulfil the obligations imposed by the approved quality system;
f) an undertaking by the manufacturer to keep the approved quality system adequate and efficacious;
g) where appropriate, the technical documentation on the types approved and a copy of the CS or EC type-examination certificates;
h) an undertaking by the manufacturer to establish and keep up to date a systematic procedure to review experience gained from devices in the postproduction 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. In accordance with the quality system, each product or a representative sample of each batch shall be examined and shall be subject to appropriate tests, as defined in the relevant harmonised standards, or to equivalent tests to ensure that the products comply with the type described in the CS or EC type-examination certificate and fulfil the provisions of this Decision. 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:

a) the quality objectives and the organisational structure, responsibilities and powers of the managerial staff with regard to product quality;
b) 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;
c) the efficient methods of monitoring the operation of the quality system;
d) 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 certification 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 harmonised 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 certification body access for inspection purposes to the inspection, testing and storage facilities and supply it with all relevant information, in particular:

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

4.3. The notified body must carry out periodical 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 Decision. 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 referred to in Article 12 or equivalent tests must be carried out. Where one or more of the samples fail to comply, 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 at least 5 years after the last product has been manufactured, make available to the specialised department of the Ministry of Health, the following documents:

a) the declaration of conformity;
b) the documentation referred to in point 3.1 (g);
c) the changes referred to in point 3.4;
d) the decisions and reports from the notified body as referred to in the final paragraph of points 3.4, 4.3 and 4.4;
e) the certificate of conformity referred to in Annex 3, where appropriate.

6. Applicability to devices in Class IIa

In accordance with Article 19, this Annex may apply to products in Class IIa, subject to this derogation:

6.1. By way of derogation from points 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and states that the products are manufactured in conformity with the technical documentation referred to in point 3 of Annex 7 and meet the applicable requirements of this Decision.

ANNEX 7

CS OR EC DECLARATION OF CONFORMITY

1. The declaration of conformity is the procedure whereby the manufacturer or his authorised agent 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 Decision.

2. The manufacturer must prepare the technical documentation described in point 3. The manufacturer or his authorised agent must make this documentation, including the declaration of conformity, available to the competent authorities for inspection purposes for at least 5 years after the last product has been manufactured. Where neither the manufacturer nor his authorised agent is established in Romania, the obligation to keep the technical documentation available shall 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 this Decision.

It must include in particular:

a) a general description of the product, including any variants planned;
b) design drawings, manufacturing methods and diagrams of components, sub-assemblies, circuits;
c) the descriptions and explanations necessary to understand the above-mentioned drawings and diagrams and the operation of the product;

d) the results of the risk analysis and a list of harmonised standards referred to in Article 12, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Decision, if the standards referred to in Article 12 have not been applied in full;
e) in the case of products placed on the market in a sterile condition, a description of the sterilization methods used;
f) 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;
g) the test reports and, where appropriate, clinical data in accordance with Annex 10;
h) 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 postproduction 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 Ministry of Health and Family 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 4, 5 or 6. Application of the provisions of the above-mentioned Annexes and the intervention by the notified body shall be limited to:

a) in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions,
b) 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 6.1. of this Annex shall apply.

6. Applicability to devices in Class IIa:

In accordance to Article 19, this Annex may apply to products in Class IIa, subject to the following derogation:

6.1. where this Annex is applied in conjunction with the procedures referred to in Annexes 4, 5 or 6, a single declaration of conformity 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 Decision.

ANNEX 8

STATEMENT
CONCERNING DEVICES FOR SPECIAL PURPOSES

1. For custom-made devices or for devices intended for clinical investigations, the manufacturer or his authorised agent 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:

a) data allowing identification of the device in question;
b) a statement that the device is intended for the exclusive use by a particular patient, stating the name of the patient;
c) the name of the medical practitioner or other authorised person who made out the prescription and the name of the clinic concerned;
d) the particular features of the device as specified in the relevant medical prescription;
e) a statement that the device in question conforms to the essential requirements set out in Annex 1 and, where applicable, indicating which essential requirements have not been met.

2.2. for devices intended for the clinical investigations covered by Annex 10:

a) data allowing identification of the device in question;
b) an investigation plan stating in particular the purpose, scientific, technical or medical grounds, scope and number of devices concerned;
c) the detailed opinion of the ethics committee concerned;
d) the name of the medical practitioner or other authorised person and of the institution responsible for the investigations;
e) the place, starting date and scheduled duration for the investigations,
f) 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 Ministry of Health and Family:

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 Decision.

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) a general description of the product;
b) design drawings, methods of manufacture, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits;
c) the descriptions and explanations necessary to understand the above-mentioned drawings and diagrams and the operation of the product,
d) the results of the risk analysis and the list of harmonised standards referred to in Article 12, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Decision if the above-mentioned standards have not been applied;
e) 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 documentation referred to in point 3.1.

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 9

CLASSIFICATION CRITERIA

I. DEFINITIONS

1. Definitions for the classification rules

1.1. Duration

a) Transient - normally intended for a less than 60 minutes continuous use;
b) Short term - normally intended for continuous use, but not for more than 30 days;
c) 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 Decision, 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:
  a) to be totally introduced into the human body or,
  b) 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 Decision, central nervous system means brain, meninges and spinal cord.

II. Implementing Rules

1. Implementing rules

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

1.2. 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.

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

1.4. 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.

1.5. 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 shall be 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 shall be included in Class IIa:

a) if they may be connected to an active medical device in Class IIa or a higher class;
b) 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 shall:

a) be in Class I, if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
b) be 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;
c) 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 shall:

a) be in Class I, if they are intended for transient use;
b) be 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;
c) be 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 included in Class IIa.

2.2. Rule 6

All surgically invasive devices intended for transient use shall be in Class IIa unless they are:

a) 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;
b) reusable surgical instruments, in which case they are in Class I;
c) intended to supply energy in the form of ionising radiation in which case they are in Class IIb;
d) intended to have a biological effect or to be wholly or mainly absorbed in which case they shall be in Class IIb;
e) 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:

a) 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;
b) or specifically for use in direct contact with the central nervous system, in which case they are in Class III;
c) or to supply energy in the form of ionising radiation in which case they are in Class IIb;
d) or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III;
e) 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 shall be in Class IIb unless they are intended:

a) to be placed in the teeth, in which case they are in Class IIa;
b) 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;
c) to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III;
d) 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 shall be 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 shall be 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 shall be in Class IIa :

a) 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,
b) if they are intended to image *in vivo* distribution of radio-pharmaceuticals,
c) 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 shall be 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, shall be 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 shall be 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.

All devices incorporating, as an integral part, a human blood derivative, 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 shall in Class III.

4.3. Rule 15

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses shall 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 10

CLINICAL INVESTIGATION

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 1 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 harmonised 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 in accordance with article 57 of the Decision.

2. Clinical investigations

2.1. Objectives

The objectives of clinical investigation are:

a) to verify that, under normal conditions of use, the performance of the devices conform to those referred to in point 3 of Annex 1, and

b) 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 light 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 Article 17 must be fully recorded and notified to the competent authority.

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.

ANNEX 11

CRITERIA
for the designation of notified certification bodies

1. The notified certification body, its manager 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 agent 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 Decision and, in particular, of this Annex. The notified certification 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 2 to 6, 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.

This includes the availability of sufficient scientific staff within the organisation who possess adequate experience and knowledge necessary to assess the biological and medical functionality and performance of devices for which it has been notified, in relation to the requirements of this Decision and, in particular, with Annex 1 requirements.

4. The notified certification body must have:

a) sound vocational training covering all the assessment and verification operations which the body has been designated for;
b) satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections;
c) 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 notified body must take out civil liability insurance, unless the liability is assumed by the State under domestic legislation.

7. The staff of the notified certification 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 Decision or any other legal provisions in the Romanian legislation in force. The staff of the notified body shall not keep professional secrecy vis-à-vis the competent administrative authorities of Romania in the field in which its activities are carried out.

ANNEX 12

GENERAL RULES

to affix and use the CS marking of conformity

1. The CS conformity marking affixed to medical devices show that the legal person having affixed it or liable for its affixation has checked the conformity of the medical device with all essential requirements applicable and that the medical device has been subject to the conformity assessment procedure provided for in this Decision.

2. For medical devices subject to different technical regulations which provide for the affixation of the CS conformity marking, this means that the medical devices comply with the provisions of all the technical regulations concerned; in case one or more technical regulations allow the manufacturer to opt for a certain arrangement to be applied to the medical device in a transitional period, the CS conformity marking means only conformity with the provisions of the technical regulations applied by the manufacturer; in this case, the documents, notices or instructions accompanying the medical devices or, where appropriate, the plates comprising the main technical specifications shall include the identification data of the technical regulations applied.

3. The CS conformity marking is formed of the initials C and S taking the form below; it must comply with the following characteristics: Times New Roman fonts, size 36, diameter of the circle 20 mm, initial C stands for the essential requirement, initial S stands for security.

CS

If the marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.

The components C and S of the CS marking must have substantially the same vertical dimension, which may not be less than 5 mm.

4. Any medical device must bear the CS/CE marking unless otherwise stipulated in this Decision.

5. The CS/CE marking shall be affixed at the end of the last production control phase.

6. The CS/CE marking shall be followed by the identification number of the notified body involved in the production control phase.

7. The notified body is liable for affixing his identification number either by himself or by the manufacturer or his authorised agent, which is a legal person established in Romania.

8. The CS/CE marking and the identification number of the body may be followed by an icon or any other mark indicating, for instance, the using category, if it is necessary to specify the purpose of medical devices. These shall be approved by Order of the Minister of Health and Family.

9. A medical device may bear different marks, for instance marks indicating the conformity with national or European standards or with any other regulations provided these marks are not mistaken for the CS/CE marking; these marks may be affixed only on the medical device, on the packing or on the documents accompanying the medical device provided the legibility and visibility of the CS/CE marking is not affected.

10. The CE conformity marking shall consist of the initials 'CE' taking the form specified in Annex 3 to Law No 608/2001 assessing the conformity of products; it has the following characteristics:

a) the graduated drawing must be observed;
b) if the marking is reduced or enlarged, the proportions given in the graduated drawing must be respected;
c) the C and E components of the CE conformity 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.