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REGULATION
From: The Ministry of Health

MEDICAL DEVICE REGULATION

CHAPTER ONE
Objective, Scope, Basis and Definitions

Objective and Scope

ARTICLE 1- (1) The present Regulation is intended to define and lay down procedures and terms applicable to the design, classification, production, market release, commissioning and inspection of medical devices and accessories to define basic requirements that they should carry and to protect the patients, users and third parties against such risks or hazards that may arise in terms of health and safety in the course of their use.

(2) The present Regulation covers all operations and acts by public agencies and bodies in relation to the design, manufacturing, market release, commissioning, use and audit of medical devices and accessories.

(3) Where a device is manufactured for the purpose of the application of a medical product within the scope of the Regulation on the Licensing of Medicine Products for Human Use published in the Official Gazette issued on 19/1/2005 under no 25705, the said device shall be treated to fall within the scope of this Regulation. This shall not prevent the application of the provisions on the Licensing of Medicine Products for Human Use.

(4) Where this device is released to the market as a single product in combination with a medical product and is for one-off use, this single product shall be subject to the provisions of the Licensing of Medicine Products for Human Use. In this case, in case of issues related to the safety and performance of the medical device, such provisions in Annex 1 hereto covering basic requirements shall be applicable.

(5) Where the device is used in integration with a substance in order to help its function on the human body and this substance is considered as a medical product on the Regulation on the Licensing of Medicine Products for Human Use in its independent use, the said device is treated to fall within the scope hereof.

(6) Where the device is used in integration with a substance in order to help its function on the human body and this substance is considered as a medical product derived from human blood or plasma on the Regulation on Licensing of Medicine Products for Human Use, the said device is treated to fall within the scope hereof.

(7) The present Regulation shall not be applicable to the following:

(a) In vitro medical diagnosis devices;
(b) Active medical devices implantable into the body that fall within the scope of Active Implantable Medical Devices Regulation published in the Official Gazette dated 9/1/2007 under no 26398;
(c) Medical products falling within the scope of the Regulation on the Licensing of Medicine Products for Human Use published in the Official Gazette issued on 19/1/2005 under no 25705;
(d) Cosmetic products falling within the scope of Cosmetic Law dated 24/3/2005 (law no 5324);
(e)Except for human blood derivatives, human blood, blood products, plasma or blood cells of human origination, human cells, tissue, transplant organs or any products produced from them;
(f)Tissues and cells of animal origination excluding medical devices incorporating inorganic animal tissues and products made of them.

(8) The primary function of a product is checked when it is decided if a product is within the scope of the Regulation on Licensing of Medicine Products for Human Use or the present Regulation.
(9) Whenever a device is intended to be used in line with this Regulation or on the Personal Protection Equipment Regulation published in the Official Gazette issued on 29/11/2006 under no 26361, basic health and safety requirements in both regulations are fulfilled.
(10) For devices that undergo a compliance evaluation under this Regulation, the provisions of Electromagnetic Compatibility Regulation published in the Official Gazette issued on 24/10/2007 under no 26680 shall not be sought.
(11) The provisions of this Regulation shall not affect the enforcement of regulations related to the radiation safety and medical irradiation.

Basis

ARTICLE 2- (1) The present Regulation is based on the Law on the Preparation and Implementation of the Technical Legislation dated 29/6/2011 (Law no 4703), item (c) of the first paragraph of Article 9 and item (k) of the first paragraph of Article 3 of the Basic Healthcare Services Law dated 7/5/1987 (Law no 3359) and Article 43 of the Decree-law on the Organization and Tasks of the Ministry of Health dated 13/12/1983 (the Law no 181).

Definitions

ARTICLE 3- (1) Terms used in this Regulation are defined as follows:

a) Accessory: refers to such part(s) which are not considered as a medical device on their own but which are manufactured to be used in combination with it to ensure the intended use of a medical device;

b) the Ministry: refers to the Ministry of Health;

c) Device subcategory: refers to such medical devices with a common technology or common intended use;

ç) Market release: refers to the release of a medical device in a ready for intended use by the end user for the first-time;

d) Customized device: refers to such medical device manufactured based on the recipe issued by a qualified medical applicator (doctor) intended for use in a specific patient and which comes up with specific design characteristics except for medical devices customized according to the wishes of the doctor and which may be manufactured in bulk;

e) Manufacturer: refers to a natural or legal person which designs, manufactures, packages and labels a medical device before releasing it under its own name irrespective of whether it is manufactured by or on behalf of it except for such persons which customize medical devices available in the market in line with the patient's condition pursuant to the present Regulation; or a natural or legal person which combines, packs, processes, fully restores and or labels one or more than one product and/ or which markets as medical devices under its name and in line with its intended use.

f) Blood human derivative: refers to such substances which may be used as a blood product component or blood product as defined in the Regulation on Licensing of Medicine Products for Human Use when it is derived from human blood and plasma and which may assist the impact of the medical device on the human body;

g) In vitro medical diagnosis device: refers all medical devices which may be reactive, reactive product, calibrator, control material, kit, tools, gadgets, instruments, equipment or system designed by the manufacturer for the in vitro review of samples picked from the human body, including the blood and tissue donations, irrespective of their single or combined use, in order:

1- to get information about the physiological or pathological circumstances;
2- to get information about congenital abnormalities;
3- to identify safety or conformity for potential buyers; or
4- to monitor the treatment

and to vacuumed or non-vacuumed sample containers used to preserve those samples;

ğ) generic device group: refers to those medical devices which are classified as generic ones and which do not display specific characteristics and which have common technology or identical or similar purpose of use;

h) the Law: refers to the Law on the Preparation and Implementation on the Drafting of Technical Legislation for Products (no 4703);

ı) Clinical-research purpose device: refers to such device(s) covered by the clinical research to be conducted by a qualified doctor or a competent person licensed to conduct clinical researches in line with Article (2.1) of the Annex X on human beings in a satisfactory clinic environment;

i) Clinical data: refer to such safety and/ or performance data derived from the following as a result of the use of such data:

1. Clinical researches related to the said device; or
2. Clinical studies or other studies covered in the scientific literature related to a similar device which may be proven to be equivalent of this one;
3. Published and/ or unpublished reports related to other clinical experience related to a similar device which may be proven to be equivalent of this one;

j) the Commission: refers to the European Union Commission;

k) Intended Use: refers to the purpose of use which is described by the manufacturer in detail in the technical file and which is stated on operating use manual, promotional material or label of the medical device;

l) Shoulder, Knee and Hip Joint Replacement Device: refers to a medical device which is the component of the implantable joint replacement system in order to function as a natural shoulder, knee or hip joint except for auxiliary plants such as screw, nail or plate;

m) Market launch: refers to the offer of a new or renovated medical device to the market free or at a price for the first-time distribution and/ or use after the completion of its manufacture except for clinical purpose devices;

n) Disposable device: refers to a medical device which may be used for one patient only for once;

o) Medical device: refers to all kinds of devices, tools, instruments, software, accessories or other materials including such software necessary for their intended use and which are manufactured by the manufacturer for diagnosis and/ or treatment purpose in particular to be used use alone or in combination with others for the following purposes for human beings and which do not fulfill their primary function when used on human beings by means of pharmacological, immunological or metabolic impacts but somehow supported by them in the course of their operation:

1) Diagnosis, prevention, tracking, treatment or alleviation of diseases; or
2) Diagnosis, monitoring, alleviation or remedial of injury or disability; or
3) Research, change or replacement of an anatomic or physiological function; or
4) Birth control;

ö) Authorized representative: refers to a natural or legal person based in Turkey and explicitly authorized by the manufacturer and who shall be the contact point for entities and institutions and act on behalf of the Manufacturer in order to fulfill its obligations set out herein.

CHAPTER TWO
Market Launch and Release, Basic Requirements, Free Movement, Special Purpose Devices, Compliance with Harmonized Standards and Protective Measures

Market Launch and Release

Article 4- (1) Medical devices meeting the provisions of this Regulation shall be launched or released to the market upon their duly supply, installation, protection and intended use.

Basic Requirements

Article 5- (1) Medical devices and accessories should be in compliance with the basic requirements set out in Annex 1 as applicable to them, taking into consideration their intended use.

(2) In circumstances where devices covered by the present Regulation fall within the scope of the Machinery Safety Regulation published in the Official Gazette issued on 3/3/2009 under no 27158, they should also meet specific basic requirements of the said Regulation about the health and safety.

Free Movement, Special Purpose Devices

Article 6- (1) Medical devices that undergo conformity assessment procedures in accordance with the provisions hereof and bear CE mark may be released or launched to the market without any barrier.

(2) CE mark may not be attached on the following devices and no barrier is set for these circumstances:

a) The use by a doctor or a person licensed to do clinical research of clinical purpose devices which are in compliance with such terms set out in Article 15 and Annex VIII;

b) On the condition that they have been certified with such declaration stated in Annex VIII, the market launch and release of medical devices in Class IIa, IIb and III offered for the use of a certain patient with a name or identifying number and customized medical devices in line with the provisions hereof;

(3) Medical devices which do not comply with the provisions hereof may be exhibited at commercial exhibits and shows on the condition that they bear a mark clearly stating that they shall not be released or launched to the market until the provisions of the Regulation are met;

(4) Such information, operating manuals, labels and maintenance and repair books as well as other descriptions which are referred to in Article (13) of Annex 1 and which should be provided by the manufacturer for patients, users and doctors together with the medical device should be in Turkish when the medical device is released to the market.

Conformity with harmonized standards

ARTICLE 7- (1) Medical devices manufactured in line with harmonized standards published by the European Union shall be considered to have met the relevant provisions of basic requirements referred to in Article 5.

(2) Conformity with harmonized standards particularly extends to European Pharmacopoeia monographs in:
a) interaction between medical devices and materials used in those devices incorporating medical product;
b) surgical yarns.

(3) Where it is determined that basic requirements of harmonized standards are not fully met, this shall be reported to the Ministry. The Ministry shall forward such information to the Commission in electronic media or through the Foreign Trade Undersecretariat.

Protective Measures

Article 8 – (1) Where the Ministry determines that except for clinical research purpose devices referred to in paragraph (a) of the second paragraph in Article 6, the use of medical devices which are installed, used and maintained in use in line with its intended use pose a danger for the purposes of the health and/ or security of the patient, doctor, user or third parties, it may adopt all measures to ensure that these devices are recalled from the market, to prevent or restrict their market launch or release. It shall report to the Commission its decision backed by justification and whether the non-compliance in relation to medical devices are attributable to the following and this reporting shall be made either by means of Undersecretariat of Foreign Trade or in electronic media:

a) Failure to meet basic requirements set out in Article 5;
b) Misapplication of standards in Article 7;
c) Weaknesses in the standards themselves;

(2) When a medical device which is not in conformity with the present regulation bears a CE marking, the Ministry shall adopt such measures against those ones attaching it and shall give information to the Commission in electronic media or by virtue of the Foreign Trade Undersecretariat.

CHAPTER THREE
Classification, Warning System, Conformity Assessment Procedures, Systems, Special Methods for Transaction Packages and Sterilization, and Exceptions Report

Classification

ARTICLE 9- (1) Medical devices shall be categorized into four classes, namely, Class I, IIa, IIb and III according to such criteria set out in Annex IX.

(2) With respect to the implementation of the classification rules, disputes that may subsequently arise between the manufacturer and certified body shall be reported to the competent authority which appoints the institution approved by the parties.

(3) Where the Ministry deems it necessary that classification rules described in Annex IX should be rescheduled in light of technical developments or the information derived from negative happenings falling within the scope of Article 10 following the market launch of the medical device, it shall report its decision with justification to the Commission via Foreign Trade Undersecretariat or in electronic media.

Warning System

ARTICLE 10- (1) The Ministry shall ensure that the following information submitted to it hereunder for the devices in Class I, IIa, IIb and III are recorded, evaluated and necessary measures are adopted. The information shall be as follows:

a) 1) Deterioration and/ or deviation in the specifications and/ or performance of the medical device;
2) insufficient details in operating manual and label which may lead to a severe decline in the health condition of the patient or the user or his death;
b) Technical and medical causes based on the specifications and performance of the medical device which cause its manufacturer to recall the devices of the same type from the market in a systematic way due to the reasons set out in item (a) in this paragraph.

(2) The relevant health personnel and/ or institution shall immediately give information to the Ministry about the circumstances described in the first paragraph. The Ministry shall give information to the manufacturer or its authorized representative about the said event so that necessary measures are adopted.

(3) The Ministry shall evaluate the circumstances together with the manufacturer or its authorized representative, if possible, and provided that provisions in Article 8 remain reserved, it shall urgently update the Commission electronically or by virtue of Foreign Trade Undersecretariat about the negative events referred to in the first paragraph hereof and present and future measures to minimize the likelihood of their recurrence.

Conformity Evaluation Procedures

ARTICLE 11- (1) The points defined herein shall be taken into consideration in the conformity declaration procedures.

(2) Except for customized manufactured devices and clinical research purpose devices, the manufacturer shall follow up the procedure defined in Annex VII only to attach CE marking on Class I medical devices, and issue the attached declaration of conformity;

(3) Except for customized manufactured devices and clinical research purpose devices, the manufacturer shall follow up the following procedures in order to attach CE marking on Class IIa medical devices:

a) Conformity declaration procedure related to the full quality assurance system set out in Annex II [except for Article (4) in that Annex];
b) Together with the conformity declaration referred to in Annex VII, the conformity declaration related to:
1) verification referred to in Annex IV; or
2) production quality assurance referred to in Annex V; or
3) product quality assurance referred to in Annex VI.

(4) Except for customized manufactured devices and clinical research purpose devices, the manufacturer shall follow up the following procedures in order to attach CE marking on Class IIb medical devices:

a) Conformity declaration procedure related to the full quality assurance system set out in Annex II [except for part (4) in that Annex];
b) Together with the conformity declaration referred to in Annex III, the conformity declaration related to:

1) verification referred to in Annex IV; or
2) production quality assurance referred to in Annex V; or
3) product quality assurance referred to in Annex VI.

(5) Except for customized manufactured devices and clinical research purpose devices, the manufacturer shall follow up the following procedures in order to attach CE marking on Class III medical devices:

a) Conformity declaration procedure related to the full quality assurance system set out in Annex II;
b) Together with the conformity declaration referred to in Annex III, the conformity declaration related to:
1) verification referred to in Annex IV; or
2) production quality assurance referred to in Annex V.

(6) The manufacturer shall issue the attached Declaration by following up the procedure defined in Annex VIII for each customized device before it releases it to the market. It shall send a list of those customized devices which are released to the market to the Ministry.

(7) The manufacturer and/ or certified body shall take into consideration the results of the evaluation and verification during the interim phase of the production in line with this Regulation;

(8) The manufacturer may assign authorized representative to initiate the procedures defined in Annexes III, IV, VII and VIII.

(9) In circumstances where the certified body should be involved in the conformity evaluation procedure, the manufacturer or its authorized representative shall select either of those institutions certified for the evaluation.

(10) Certified body shall require all kinds of information and documents that may be necessary to verify the conformity in line with the selected procedure.

(11) Decisions adopted by a certified body in line with Annexes II, II, V and VI shall be valid for a maximum term of 5 (five) years; however, the validity of the decision may be extended for maximum 5 (five) year terms upon the application filed within the term defined in the contract executed between the manufacturer and the certified body.

(12) Records and correspondence related to the methods defined in the second, third, fourth fifth and sixth paragraphs shall be made in either of the official languages of the European Community acceptable to the certified body and/ or in Turkish.

(13) The Ministry may permit the market launch or release of an individual medical device within the Turkish territory upon a request backed by its reasons if the procedures defined in the second, third, fourth, fifth and sixth paragraphs are not applied but the device is decided to be helpful to maintain the healthcare of the people if used.

Systems, special methods for transaction packages and sterilization

ARTICLE 12- (1) The provisions of this article shall be applicable when medical devices attached with CE marking in line with Article 11 are combined together in the form of a transaction package or device system for the purposes of market launch. A natural or legal person who undertakes this operation shall issue a transaction package or device system declaration showing:

(a) that the mutual compatibility between medical devices combined in line with the manufacturer instructions are secured and that the combination is done according to those instructions;
(b) that operating manuals in line with the manufacturer instructions are provided to the users in the market launch of a transaction package or device system;
(c) that the internal control and inspections of the entire process are done by means of new methods.

(2) Where those requirements set out in the first paragraph of this article are not fulfilled, and if the combination of a transaction package or a device system with such devices lacking CE marking or the selected device combination is not in compliance with its actual intended use, such device combinations shall be treated as a single medical device and the applicable provisions of Article 11 shall be applied.

(3) In the course of the sterilization:

a) a natural or legal person sterilizing medical devices designed to be sterilized prior to use in order to release them to the market shall follow up the procedures set out in Annex II or Annex V.

b) In procedures to ensure sterilization, Annex II or Annex V with the intervention by the certified body shall be applied until the sterilized package is unpacked or damaged;

c) A natural or legal person issues a statement showing that it carries out the sterilization in accordance with the manufacturer’s instructions.

(4) Medical devices referred to in the first and third paragraphs shall not bear an additional CE marking. These devices shall bear such details referred to in Annex I/13 as provided by their manufacturers. Statements set out in the first and third paragraphs shall be kept for five (5) years for submission to the Ministry.

Classification and Notices related to exceptional cases

ARTICLE 13- (1) The Ministry shall submit its request to the Commission electronically or by means of Foreign Trade Undersecretariat together with the underlying reasons to ensure that necessary measures are adopted:

a) where there is a doubt and a specific decision should be issued in the course of the application of the classification rules set out in Annex IX to a specific medical device or a medical device group;

b) where a medical device or a group of medical devices should be treated within another class as an exception to the provisions of Annex IX;

c) where the conformity of the medical device or a group of medical devices should be secured by means of applying only one of the methods defined in Article 11 as an exception to that article;

ç) where a decision should be taken as to whether a medical device or a group of medical devices should fall within the scope of any of the definitions set out in subparagraphs (a), (d), (g) (ı) or (o) of the first paragraph in Article 3.

CHAPTER FOUR
Registry System, Clinical Researches, Certified body and CE Marking

Registry System

ARTICLE 14- (1) The Ministry shall keep the registration of medical devices launched to the market in accordance with the terms set out herein and those persons who are responsible for it.

(2) The manufacturer that launches the medical device to the market under its own name in accordance with the procedures set out in the second, third, fourth, fifth and sixth paragraphs of Article 11 and a natural or legal person who commits the actions defined in Article 12 shall provide the Ministry with such necessary information and documents related to the business and medical device.

(3) The Ministry shall require such descriptive information for any medical device in Class IIa, IIb and III together with its label and operating manual in the event that such device is launched to the market.

(4) Where the manufacturer which launches the medical device to the market under its own name is based outside the country, its authorized representative shall be notified to the Ministry. The authorized representative shall notify to the Ministry such registered addresses of the company in the territory as well as such information related to medical devices as set out in the second paragraph.

(5) The Ministry shall notify to the Commission such information provided by the manufacturer or its authorized representative in relation to medical devices in the third paragraph electronically or by virtue of the Foreign Trade Undersecretariat upon request, and the Ministry may require information from the Commission if and when necessary.

(6) Regulatory data related to this Regulation shall be kept in medical device data bank to ensure that certified bodies shall fulfill their tasks hereunder. Data bank shall consist of the following:

(a) Data related to records of manufacturers, authorized representatives and medical devices referred to in paragraph three herein;
(b) Data related to such issued, changed, added, suspended, withdrawn or rejected documents in line with the method set out in Annexes II, III, IV, V, VI or VII;
(c) Data related to the warning system defined in Article 10;
(ç) Data related to clinical researches defined in Article 15;

(7) The Ministry shall adopt all necessary measures where a medical device or a group of medical devices is to be recalled from the market or it is banned or restricted from release or launch to the market or it is held subject to specific conditions in order to protect health and safety and / or to observe the requirements of the public health. In this case, it shall notify its decision backed up by its reasons to the Commission electronically or by virtue of the Foreign Trade Undersecretariat.

Clinical Researches

ARTICLE 15- (1) The manufacturer or its authorized representative shall take those actions defined in Annex VIII for the clinical research purpose vehicles, and shall provide the Ministry with such necessary information about the future clinical research together with the statement set out in Article (2.2) of Annex VIII.

(2) The manufacturer shall notify to the Ministry its clinical research request in accompaniment of the relevant Ethical Committee approval about the implant and long-term invasive devices included in Class IIa or IIb or medical devices in Class III. The Ministry shall decide on the request 60 (sixty) days following the notice date.

(3) Where the relevant Ethical Committee gives its consenting opinion to the research plan by attaching its reasons, the Ministry may permit the manufacturer to start up the said clinical research before waiting for the expiry of 60 (sixty) day term.

(4) In case of medical devices other than the ones referred to in paragraph two, where the relevant Ethical Committee gives its consenting opinion to the research plan by attaching its reasons, the Ministry may permit the manufacturer to immediately start up the research.

(5) Clinical researches shall be conducted in line with Annex X.

(6) If necessary, the Ministry shall adopt such necessary and appropriate measures in order to protect the public health and public benefit for clinical researches. When the Ministry rejects, suspends, ceases, or demands a significant change for, a clinical research, it shall notify its decision backed by its reasons to the Commission electronically or through the Foreign Trade Undersecretariat.

(7) The Manufacturer or its authorized representative shall provide the Ministry with the outcome of the clinical research. In the event that the clinical research is terminated early, its reasons shall be further notified. Where the early termination is for the security purposes, the Ministry shall notify this to the Commission electronically or through the Foreign Trade Undersecretariat. The report referred to in Annex X/2.3.7 shall be kept ready by the manufacturer or its authorized representative to be submitted to the Ministry.

(8) If the clinical research is intended for the purpose defined in the conformity evaluation procedures for a medical device bearing CE marking by using that device, the relevant provisions of Annex X only shall be applicable for this.

Certified Body

ARTICLE 16- (1) A body which is competent enough to perform those tasks set out in Article 11 and other special tasks assigned to it shall apply to the Ministry. The Ministry shall evaluate the certified body candidates in line with the provisions in this article and shall notify the eligible ones to the Foreign Trade Undersecretariat, which shall in turn submit them to the Commission. After the Commission assigns an identification number, the decision by the Ministry to assign the certified body shall be published in the Official Gazette and the certified body shall start up its operations.

(2) When choosing a certified body, such compliance with the requirements set out in Annex XI shall be sought. Notwithstanding the foregoing, the provisions of the Law as well as the provisions of the Conformity Evaluation Bodies and Certification Bodies Regulation published in the Official Gazette issued on 17/1/2002 under no 24643 shall also be applicable. Moreover, a body which meets the harmonized standards applicable for certified bodies shall also be deemed to have met the requirements in Annex XI.

(3) Upon request, the certified body shall provide the Ministry with all documents and information that shall allow to audit the compliance with terms set out in Annex XI, including budget documents.

(4) Where the Ministry determines that the certified body does not comply with such terms referred to in the second paragraph, it shall declare the approval as null and void, and this decision shall be published in the Official Gazette. Moreover it shall notify the decision to the Foreign Trade Undersecretariat to be notified to the Commission.

(5) The certified body and the manufacturer or its authorized representative shall mutually set such period of time to complete the evaluation and validation procedures defined in Annexes II, III, IV, V and VI.

(6) The certified body shall update the Ministry about each and every document issued, changed, added, suspended, cancelled or withdrawn by it. Moreover, it shall provide other certified bodies which operate hereunder with information about these issues and documents issued by it upon request. The certified body shall also submit all additional information that may be requested from it.

(7) Where the certified body determines that the relevant provisions hereof are not complied by the manufacturer or the document was inadvertently issued, it may suspend, cancel or impose restrictions on the issued document, taking into consideration the proportionality principle, until the manufacturer adopts corrective measures and ensures compliance with necessary requirements. In such circumstances or where the Ministry's intervention is required, the certified body shall give information to the Ministry. The Ministry shall notify this to the Commission electronically or through the Foreign Trade Undersecretariat.

CE Marking

ARTICLE 17- (1) For the purpose of attaching the CE marking the following shall be taken into consideration:

a) All medical devices other than customized ones and clinical research purpose ones should bear such CE marking along with the identification number of the certified body responsible for the completion of the procedures defined in Annexes II, IV, V and VI.

b) CE marking set out in Annex XII shall be attached on the medical device, sterilized packaging, operating manual and sales package in a easily visible, readable and inerasable way.

c) It is prohibited to affix any marking or sign which may lead to misunderstanding about the meaning or form of CE marking. Another mark may be affixed on the medical device, its packaging or its operating manual in a manner that it will not block the visibility and reading of the CE marking.

(2) Moreover, relevant parties shall be obliged to comply with the provisions of the Law and the "Regulation on the Attachment and Use of "CE" Conformity Mark on the Product" as to the use and attachment of the CE marking.

Unduly attached CE Marking

ARTICLE 18- (1) In the event that the CE marking is unduly attached on the product or is not attached at all, the manufacturer or its authorized representative shall be obliged to terminate the breach in accordance with such terms defined by the Ministry provided that Article 8 shall remain reserved. In case the breach is not stopped, the Ministry shall ensure that the medical device shall be recalled from the market by taking all measures that may restrict or ban the market release of the medical device.

(2) Products which are not covered by the present Regulation but on which CE marking is attached according to the provisions hereof shall be subject to the first paragraph.

CHAPTER FIVE
Miscellaneous

Rejection or Restriction Decisions

ARTICLE 19- (1) The Ministry may adopt the following decisions clearly backed up by their reasons in the course of the implementation of this Regulation:

a) Rejection or restriction decisions for the market release or launch of a medical device or any clinical research;
b) Decisions for recalling medical devices.

(2) For all decisions referred to in the first paragraph, the manufacturer or its authorized representative shall have the right to give its opinion in advance, if possible, depending on the urgency of the measure to be adopted.

(3) With respect to the rejection or restriction or market recalls for medical device(s), the provisions of the Law as well as the "Regulation on the Procedures and Terms for Market Watch and Audit by the Ministry of Health" published in the Official Gazette issued on 25/6/2007 under no 26563.

Confidentiality

ARTICLE 20- (1) The Ministry, the certified body and all parties involved in the application of the present Regulation shall ensure the confidentiality of all information that they may come to know during the performance of their tasks. However, the Ministry's obligations with respect to mutual information exchange and warning system with other national competent authorities and certified bodies remain reserved. Moreover, such confidential information may be disclosed with prior notice to the Ministry upon the request by the judicial and other higher authorities in circumstances required by the public health and order.

(2) The following shall not be treated as confidential:

a) Registration details of such persons in charge of the market launch of the medical devices according to Article 14;
b) Such information sent by the manufacturer, its authorized representative or distributor to the user in line with measures described in the third paragraph of Article 10;
c) Such information described in the issued, corrected, amended, added, suspended or cancelled certificates.

Advisory Commissions

ARTICLE 21- (1) The Ministry may set up new advisory commissions about medical devices and standards in case its internal technical regulation and advisory commissions turn out to be incompetent. A Directive to be enacted by the Ministry shall define the set-up, composition and functions of such advisory commissions.

Compliance with other legislation

ARTICLE 22- (1) Where a medical device falls within the scope of another legislation applicable to the attachment of CE marking, the provisions of such other legislation should also be complied.

(2) Where one or more than other relevant legislation grants the manufacturer an optional right as to the implementation during the transition period, CE marking shall only signify the compliance with the provisions of such legislation that the manufacturer chooses to apply, in which case the legislation to be applicable shall be stated on such documents, warnings, labels or operator's manual given together with the medical device.

CHAPTER SIX
Final Provisions

Safety of Use

ARTICLE 23- (1) A medical device shall be used by taking into consideration its intended use defined by its manufacturer and, if any, other recommendations in its operating manual.

(2) For a medical device which requires installation, quality control tests, calibration and repair and maintenance works, such operations shall be done in the way described by the manufacturer.

(3) Provisions applicable to the breaches

ARTICLE 24- (1) Any person who acts in breach of the present Regulation shall be subject to the provisions of the Law, Turkish Criminal Code dated 26/9/2004 under no 5237 and other applicable legislation.

Aligned European Union legislation

ARTICLE 25- (1) The present Regulation is drafted and enacted in parallel with the following legislation in order to ensure compliance with the European Union legislation applicable to medical devices:

a) The Medical Devices Directive 93/42/EEC;
b) In Vitro Medical Diagnostic Devices Directive 98/79/EC;
c) Directive 2000/70/EC covering medical devices incorporating stable derivates of human blood or human plasma;
ç) Directive 2001/104/EC amending Council Directive 93/42/EEC concerning medical devices;
d) Commission Directive 2003/12/EC on the reclassification of breast implants in the framework of Directive 93/42/EEC;
e) Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements in the framework of the Directive 93/42/EEC concerning medical devices;
f) Directive 2007/47/EC amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

References

ARTICLE 26- (1) References made to the Medical Devices Regulation published in the Official Gazette issued on 9/1/2007 under no 26398 in other previous regulations shall be deemed to have been made to the present Regulation.

Abolished Regulation

ARTICLE 27- (1) The Medical Device Regulation published in the Official Gazette issued on 9/1/2007 under no 26398 is hereby revoked.

Effectiveness

ARTICLE 28- (1) This Regulation shall come in force upon its publication.

Enforcement

ARTICLE 29- The provisions of this Regulation shall be enforced by the Ministry of Health.

ANNEX I
BASIC REQUIREMENTS

1. GENERAL REQUIREMENTS

1) Medical devices should be designed and manufactured in a manner that will not cause a danger to the clinical status or safety of patients, and the health and security of the other persons, if necessary, when they are used in line with their intended purpose and conditions of use.

Risks related to the utilization purpose of medical devices should be acceptable compared to their benefits to the patients and they should secure a high level of protection for health and safety.

For the design of a medical device:

- the erroneous use risk that may be attributable to the environment where the device is to be used and to the device's ergonomic features should be minimized as much as possible (design for patient safety); and
- the technical knowledge, experience, educational background, and if possible, medical and physical condition of the person who will potentially use the device should be taken into consideration (design for professional, handicapped or other users).,

2) Solutions adopted by the manufacturer for the design and manufacturing of medical devices should contain generally accepted technical methods and should be in compliance with safety principles. The manufacturer should apply the following in selecting the most appropriate solutions:

- It should make a safe design and manufacturing in order to minimize and eliminate dangers as much as possible;

- Where dangers cannot be eliminated, certain and adequate measures such as alarms should be taken;

- Where all measures taken are not enough to eliminate all risks, those ones still applicable should be notified to the user.

3) A medical device should attain such performance prescribed by its manufacturer and should be designed, manufactured and packaged in a way that would be fit for more or more than one function described in subparagraph (o), the first paragraph, Article 3 of the present Regulation.

4) Adverse conditions that may arise in the course of regular conditions during the life of the medical device defined by the manufacturer should not be likely to change specifications set out in Articles (1), (2) and (3) hereof, its performance and clinical conditions or to ruin the health and safety of the patient, user and third persons.

5) Medical devices shall be designed, manufactured and packaged in a way that when they are shipped and stored in accordance with instructions set out in the operator's manual provided by the manufacturer their specifications and performance shall not be adversely affected during their lifetimes.

6) The risk that may be caused by the unwanted side effects of the medical device should be at acceptable level compared to the performance expected from it.

6.a) The compliance of the medical device with the basic requirements should involve a clinical evaluation done according to Annex X.

II. REQUIREMENTS RELATED TO DESIGN AND CONSTRUCTION

7) Chemical, Physical and Biological Properties:

7.1 A medical device should be designed and manufactured in a way to warrant the properties and performance defined in the "General Requirements" of this Annex, in particular, taking into consideration the following:

- Toxicity and inflammability, in particular, when choosing the material to be used;
- Taking into consideration the intended purpose of a medical device, the compliance between the material used and the biological tissue, cell and body fluids;
- Where necessary, biophysical or modeling research results whose validity should be proven in advance.

7.2 Medical devices should be designed, manufactured and packaged in a manner to minimize dangers with respect to residuals and contaminants for patients, users or other persons who store and transport them in line with its intended purpose. Tissues exposed to medical device and the time and frequency of exposure should be particularly given attention.

7.3 A medical device should be designed and manufactured in a way that it may be safely used with materials, substances and gases it is in contact during its regular use or routine operations. If the medical device is intended to yield a

medical product, these devices should be designed and manufactured in accordance with such measures and restrictions applicable to the said products, and the performance of both should continue in line with their intended purposes.

7.4 In order to measure the safety, quality or benefits of a substance which is treated to be a medical product covered by the Regulation on the Licensing of Medicine Products for Human Use when it is used alone, a comparison should be made by means of appropriate methods defined in the said Regulation when it is used as a complementary part supporting the function of a medical device on human body.

With respect to the substances referred to in paragraph one, the certified body shall seek a scientific opinion from the European Medicines Agency (EMEA) or the Ministry for the clinical benefit/ risk profile to be displayed by the use of device and whether the said substance is high quality and safe, taking into consideration the intended purpose of the device and evaluating whether the use of that substance as a part of a medical device is beneficial. The said scientific opinion shall use such data to be drafted by the certified body with respect to the potential benefit from the attachment of the said substance to the medical device as well as to the manufacturing process.

Where a medical device contains a human blood derivative as a part of the whole, the certified body shall seek a scientific opinion from the European Medicines Agency (EMEA) with respect to the clinical benefit/ risk profile based on the use of the device and whether this derivative is safe and high quality, taking into consideration the intended purpose of the device and evaluating whether the use of that substance as a part of a medical device is beneficial. The said scientific opinion shall use such data to be drafted by the certified body with respect to the potential benefit from the attachment of the said substance to the medical device as well as to the manufacturing process.

Whenever a change is introduced to the complementary articles in a medical device, in particular, with respect to the manufacturing process, it is notified to the certified body. In order to confirm that the said article maintains its high quality and safe status, the certified should apply to the Ministry or the European Medicines Agency (EMEA) once again for an opinion. The institution which issues an opinion takes into consideration the data gathered by the certified body for the potential benefit from the attachment of the said article to the medical device in order to confirm that such change shall not adversely affect the previously drawn benefit/ risk profile.

When the consulted institution has access to an information likely to affect the known benefit/ risk profile of the said complementary article in case it is used in a medical device, it shall give its opinion to the certified body about whether there is such effect. The certified body shall take into consideration the most current scientific opinion to evaluate the conformity evaluation process.

7.5 A medical device should be designed and manufactured to minimize such potential dangers caused by substances leaking from it. According to the Regulation on the Classification, Packaging and Labeling of Hazardous Substances and Preparations published in the Official Gazette issued on 26/12/2008 under bis no 27092, special emphasis shall be placed on such carcinogenic, mutagen substances or substances with toxic effect on reproduction.

In the event that a medical device, or a part thereof, whose intended use is to administer pharmaceuticals, body fluids or other substances to the body and/ or to expel them from the body or a medical device with an intended use to carry and store this kind of body fluids or substances contain Category 1 or 2 group phthalates which are carcinogenic, mutagenic or have toxic effects on reproduction according to the Regulation on the Classification, Packaging and Labeling of Hazardous Substances and Preparations, a label signifying that the medical device contains phthalates should be affixed on the medical device and/ or the package of each component or, where necessary, on the sales pack.

In the event that the intended use of the said medical device is for the treatment of pregnant or nursing women or children, certain information related to the special reason of the use of such substances and the risks they pose in relation to said patient groups, and if necessary, the appropriate causal measures should be stated in the technical file or operating manual of the device in order to ensure compliance with the basic requirements in this paragraph, in particular.

7.6 A medical device should be designed and manufactured in a style likely to minimize the dangers associated with such unwanted objects that are accidentally mixed with it, taking into consideration the device itself and the environmental conditions where it shall be used.

8) Infection and microbiological contamination

8.1 A medical device and its manufacturing process should be designed in a way to eliminate or minimize the infection risk for the patient, the user and third parties as much as possible. The design should be an easy-to-implement one and when necessary the contamination between the patient and the device should be minimized during the use.

8.2 Tissues of animal origin should be derived from such animals controlled by veterinary and inspected for its intended use.

Certified bodies should hide the details in relation to the geographical origins of animals.

Cells and substances of animal origin should be processed, protected, tested and used at the most appropriate safety conditions, In particular, the safety with respect to viruses and other contagious agents should be secured by applying such valid elimination or viral inactivation methods applicable in the course of manufacturing.

8.3 When sterilized medical devices are launched to the market in disposable packs, they should be designed, manufactured and packaged in accordance with such appropriate methods ensuring that they remain sterilized until the protective package is unpacked or deformed.

8.4 Sterilized medical devices should be manufactured and sterilized by means of a proper and applicable method.

8.5 A medical device in need of sterilization should be duly manufactured in controlled environments (for instance environmental conditions).

8.6 Packaging systems of non-sterile medical devices should be likely to protect the prescribed cleanness level without any deformation to the medical device, and where the medical device is to be sterilized before its use, then in a manner to minimize the microbiological contamination risk.

The packaging system should be in compliance with the sterilization by means of the sterilization method designated by the manufacturer.

8.7 The package and/ or label of the medical device should permit the user to discern between sterile and non-sterile identical or similar medical devices.

9) Manufacturing and Environmental Features

9.1 Where a medical device is to be used in combination with another medical device or equipment, all combinations including connection systems should be safe, and should not pull down the performance of the said device. Restrictions applicable to the use should be stated on the label or operating manual.

9.2 A medical device should be designed and manufactured in a manner to eliminate, or if this is not possible, to minimize the following dangers:

- Risk of getting injured depending on the physical features of the medical device, including the volume/ pressure rate as well as dimensional and ergonomic features;

- Dangers that may arise from estimated environmental conditions such as magnetic field, external electrical impact, electrostatic discharge, pressure, heat or acceleration or pressure changes;

- Reciprocal interaction dangers with other medical devices regularly used in the course of applied treatment or after clinical researches;

- Dangers that may arise when any measurement or control mechanism loses its effectiveness or the material used gets older and wears away and the maintenance or calibration is not possible (just like in implants).

9.3 A medical device should be designed and manufactured in order to minimize the inflammation or explosion risk in the course of regular use and even in a simple error. In particular, when it is necessary to use a medical device together with inflammable, explosive or ignitable substances, these points should be paid attention.

10) Medical devices with measurement function

10.1 Medical devices with measurement function should be designed and manufactured in a way which shall ensure necessary sensitivity and which shall remain within appropriate measurement sensitivity limits, taking into consideration the prescribed purpose of the medical device. Sensitivity limits should be defined by the manufacturer.

10.2 Measurement, monitoring and gauge scale should be designed according to ergonomic principles, taking into consideration the intended use of the medical device.

10.3 Measurements carried out by a medical device with measurement function should be expressed in such measurement units defined in the Regulation for International Units System published in the Official Gazette issued on 21/6/2006 under no 24792.

11) Protection against radiation

11.1 In general:

11.1.1 For the design and manufacturing of a medical device, such measures that would minimize the impact on patients, users and third parties exposed to the radiation should be taken. Notwithstanding the foregoing a medical device

should be designed and manufactured in a way that would not prevent the application of required doses for treatment and diagnosis purposes.

11.1.2 Required radiation:

11.2.1 When a medical device which emits a dangerous level of radiation is designed for a special medical purpose where the benefits of radiation prevail its risks, the user should be given the means to control the emission. These medical devices should be designed and manufactured in a way to allow the tolerance and re-productivity of relevant permanently variable parameters.

11.2.2 A medical device should be equipped with sound and visual alarm systems that would be triggered off when a medical device causes an invisible and/ or visible potential radiation.

11.3 Unwanted radiation:

11.3.1 A medical device should be designed and manufactured in a manner that would minimize the exposure of patients, users and third persons against the radiation emission which is unwanted, deviates from its purpose or in the form of a fallout.

11.4 Operating manuals:

11.4.1 Operating manual of a device emitting radiation should contain detailed information about the nature of the emitted radiation, measures for the protection of the patient and user, the avoidance of misuse and the elimination of dangers that may arise from the installation of the medical device.

11.5 Ionizing Radiation:

11.5.1 Medical devices that emit ionizing radiation should be designed and manufactured, as far as possible, in a way to allow the adjustment and control of the emitted radiation's quantity, quality and geometry depending on its intended use.

11.5.2 A medical device emitting ionizing radiation for radiodiagnostic purpose should be designed and manufactured in a way which would minimize the exposure of the patient and user to radiation to ensure a high quality image and/ or printout commensurate for the desired medical purpose.

11.5.3 A medical device emitting ionizing radiation for radiotherapy purpose should be designed and manufactured in a way to allow a reliable observation and control of the applied dose, the type and energy of beam and, where necessary, the quality of beam.

12) Requirements for a medical device equipped with or connected t an energy resource:

12.1 A medical device incorporating programmable electronic systems should be designed to ensure the continuity, reliability and performance of these systems in line with the intended use. A medical device should be equipped with appropriate means which will minimize or eliminate the potential dangers whenever an error occurs in the system.

12.1.a The software of a medical device which contains a software or which itself is a medical software should be a state-of-the-art one, taking into consideration the development phases, risk management, validation and verification principles.

12.2 Where the patient safety depends on an internal energy source, a medical device should be equipped with a gadget showing the status of the power source.

12.3 Where the patient safety depends on an external energy source, a medical device should be equipped with an alarm system which emits a signal when the power source is cut off.

12.4 A medical device with the intended use of monitoring one or multiple clinical parameters of a patient should be equipped with such appropriate alarm system which alarms the user in circumstances that may cause the death or a serious deterioration in the health condition of the patient.

12.5 A medical device should be designed and manufactured to minimize the risk to create an electromagnetic field which could the operation of another medical device or equipment deployed in the same environment.

12.6 Protection against electrical dangers:

A medical device which is correctly installed should be designed and manufactured in a manner which would not cause an electrical shock risk in the course of regular use, or even, in case of a simple mistake.

12.7 Protection against mechanical and heat dangers:

12.7.1 A medical device should be designed and manufactured in a manner to protect the user and the patient against mechanical dangers which are attributable to strength, stability, moving parts and similar items.

12.7.2 A medical device should be designed and manufactured in a manner to minimize those dangers attributable to its vibrations or oscillations, taking into particular consideration the instruments and technical developments which restrict the vibrations at its source unless those vibrations are part of the defined performance.

12.7.3 A medical device should be designed and manufactured to minimize dangers arising from sounds emitted by the medical device, taking into particular consideration those instruments and technical developments restricting the sound at its source unless such sound is a part of the defined performance.

12.7.4 Terminals that should be manually used by the user and connections to electrical, gas, hydraulic and pneumatic energy sources should be designed and manufactured in a manner to minimize potential risks.

12.7.5 Except for parts and areas for heat supply or to reach specific temperatures, those had-contact parts of the medical devices and the area encircling them should not reach such level of heat that would pose danger under regular conditions of use.

12.8 Protection against dangers for patients in the administration of substances or power supply:

12.8.1 A medical device whose intended use is to administer substances or supply energy to the patient should be designed and manufactured in a manner to ensure appropriate flow rate at sustainable adequate sensitivity in order to warrant the safety of the user and the patient.

12.8.2 A medical device should be equipped with such gadgets which prevent and/ or show any irregularity in the flow rate.

A medical device should be equipped with an appropriate system which would prevent the energy and/ or the energy from the substance source from accidentally reaching a dangerous level.

12.9 Control and gauge functions should be explicitly stated on the medical device. When such information necessary for function or function and setting parameters are stated on the medical device with the help of an imaging system, such data should be understandable by the user, and if necessary, by the patient.

13) Information provided y the manufacturer:

13.1 Along with each medical device such details defining the manufacturer and allowing a safe and proper use should be given, taking into consideration the education and knowledge level of the potential users.

Such information should be stated in detail in the operating manual and on the label.

Information necessary to ensure the safe operation of the medical device should be also stated on the medical device and/ or on the package of each component thereof or whenever necessary on the commercial package. If it is not possible to pack each component, then such information should be on the brochures of one or more than one medical device.

There should be an operating manual in the package of each medical device. If it is possible to safely use a Class I or IIa medical device without reference to the operating manual, then operating manual may be omitted.

13.2 Such information may be expressed in the form of symbols. Symbols and descriptive colors should be in accordance with harmonized standards. Symbols and colors without any standard should be described in the documents provided with the medical device.

13.3 Label information:

a) Name or trade name and address of the manufacturer: for an import medical device, furthermore, the name or trade name and address of its authorized representative and/ or the imported should be stated on the label or sales package or operating manual.

b) Detailed information describing the contents of the package and the medical device particularly intended for the user.

c) The word “STERILE” if necessary;

ç) Lot code or serial number together with the word “LOT” if necessary;

d) The best-before-date in terms of month and year, if necessary;

e) The word “disposable”, if necessary;

f) Where the medical device is manufactured upon an order, then the words “medical device manufactured for customized purpose”;

g) The words “specific for clinical research” for clinical research purpose devices;
ğ) Special storage and/ or operating conditions;
h) Special operating manual;
ı) Warnings and/ or measures to be adopted;
i) For active medical devices in addition to the item (d), manufacturing date to be inserted into batch/ lot or serial number;
j) Sterilization method, if necessary;
k) Information as to the certificate of permission obtained from Turkish Atom Energy Agency for carrier containers and medical devices incorporating radioactive substances;
l) Words evidencing that a medical device contains a human blood derivative.

13.4 If the intended use of the medical device is not easily understandable by the user, then the manufacture should clearly describe such use on the label and operating manual.

13.5 Where necessary and if possible, all circumstances that may cause any potential danger attributable to medical devices and their components in the same batch/ lot should be clearly stated in the operating manual.

13.6 If necessary, an operating manual should contain the following information:

a) All details other than the ones in items (ç) and (d) below, as set out in Article (13.3) of this Annex;
b) Performance and unwanted side effects described in Article (3) of this Annex;
c) Where a medical device should be placed with or connected to other medical devices or equipment in order to operate it in line with its intended use, all features and adequate information that may be necessary to ensure a safe integration;
ç) All information necessary to validate if the medical device is correctly installed and it would operate in the right and safe way; and any information about the nature and frequency of such maintenance and calibration works required for the safe and proper operation of the medical device at all times;
d) When necessary, any information that would allow to avoid serious dangers that may arise from the implantation of the medical device;
e) Information as to the reciprocal interaction dangers attributable to the medical device in the course of specific treatment or research;
f) Necessary information for the reapplication of sterilization methods if necessary or the package ensuring the sterilization is deformed;
g) If the medical device is a reusable one and its cleansing, disinfection and resterilization is necessary, then information about necessary methods including the sterilization method and about how many times it may be reused;

Where a medical device should be sterilized before its use, when such cleansing and sterilization instructions provided by the manufacturer are correctly applied, the medical device should still meet the “General Requirements” in this Annex.

In disposable medical devices, such information related to technical elements and features that the manufacturer is aware of about risks that may arise if the medical device is reused should be stated in the operating manual. Where no operating manual is required in line with such Article (13.1) of this Annex, said information should be provided to the user upon request.

ğ) Details related to all operations or function that may be required before the medical device is ready for use (for instance sterilization, last installation).

h) In a medical device emitting radiation for medical purpose radiation, detailed information about its intensity, type and nature.

An operating manual should also contain details in order to raise the awareness of healthcare personnel and patients about contraindications and measures to be adopted, These details should particularly cover the following:

ı) Measures to be adopted in case of a change in the medical device’s performance;
i) Measures to be taken in case of changes to magnetic fields, external electrical impacts, electrostatic discharge or pressure, or any change to the predictable environmental conditions such as acceleration, thermal igniting sources.
j) All information related to medical product which contains restrictions as to the selection of the substance to be introduced in case of a medical device which gives off a medical product or products;
k) Measures to be taken against special or unexpected dangers that may arise in the course of the disposal of the medical device;
l) Medical devices or human blood derivatives likely to be implemented as an integrated part according to Article (7.4) of this Annex
m) Accuracy degree set for medical devices with measurement function;
n) Printing date of the operating manual and latest updates.

ANNEX II
EU DECLARATION OF CONFORMITY
(Full Quality Assurance System)

1) The manufacturer shall ensure the implementation of a certified quality control system set out in Article 3 of this Annex for the design, manufacturing and final controls of medical devices; it shall be further subject to the procedures defined in Articles 3.3, 4 and 5 of this Annex with respect to the supervision and inspection.

2) EC Declaration of Conformity is a process that shows that the manufacturer which fulfils those requirements set out in Article (1) of this Annex assures and declares that the said products are in compliance with the provisions hereof.

Accordingly, the manufacturer shall attach a CE marking and issue a written declaration of conformity according to Article 17 of the Regulation. This statement to be kept by the manufacturer should cover all manufactured medical devices, which should be explicitly described with a product name, product code or other words.

3) Quality system:
3.1 The manufacturer shall apply to the certified body for the assessment of its quality system and this application covers the following points:

- The name and address of the manufacturer, the names and addresses of all other manufacturing sites covered by the manufacturer;
- All information related to the medical device or the group of medical devices in question;
- A written declaration that no application is filed with any other certified body for the same medical devices;
- Documents evidencing quality system;
- The manufacturer's undertaking to fulfill the requirements of the certified quality system;
- The manufacturer's undertaking that the certified quality system shall be maintained in full and effectively;
- The manufacturer's undertaking that data derived from medical devices during the post-production stage shall be reviewed, including the provisions in Annex X; that a system shall be set up in order to apply necessary corrective actions and that this system shall be maintained current and updated. This undertaking also extends to the obligation that the manufacturer shall give notice to the Ministry as soon as it becomes aware of the following situations:

a) 1) Deterioration and/ or deviation in the specifications and/ or performance of the medical device;
2) Insufficient details in operating manual and label which may lead to a severe decline in the health condition of the patient or the user or his death;
b) Technical and medical causes based on the specifications and performance of the medical device which cause its manufacturer to recall the devices of the same type from the market in a systematic way due to the reasons set out in item (a) in this paragraph.

3.2 Quality System Application should guarantee that at all stages from the design to the final control, medical devices shall be in conformity with the provisions hereof. For the quality system, all conditions adopted by the manufacturer, requirements and elements, quality records, completed works, plans and programs should be set out in a document in a written, orderly and systematic manner.

This quality system certification should particularly cover all documents and data derived from the processes set out in item (c) in addition to the following:

a) The manufacturer's quality targets;
b) The business' organizational structure, and in particular:

- Responsibilities of the officers and employees in charge of the design quality and manufacturing of the medical device, their authorities and corporate organization;
- Methods intending to control the effective operation of the quality system to ensure that the medical devices and their designs, including the control of non-conforming medical devices shall be at the desired level;
- Where a medical device or its parts are designed, manufactured and/ or finally inspected and tested by third parties, a description of the effective operation of the quality system, in particular, those methods to monitor the scope and method of the control applied to the said third party;

c) Processes to monitor and validate the design of the medical devices; related documents, and in particular, the following:

- A general description of the medical device and its intended use, including any potential change;
- Design features including risk analysis results and applicable standards, including the definition of the solutions adopted to ensure that a medical device shall meet basic requirements even if the standards defined in Article 7 of this Regulation are not entirely met;
- Systematic measures and processes and design control and verification techniques applicable in the course of the design of medical devices;

- Where a medical device is to be connected to another one in order to function in line with its intended use, the evidence that these medical devices with necessary features defined by their respective manufacturers shall meet basic requirements when they are interconnected;
- A statement referred to in Annex 1/7.4 and which shows that the medical device, as a part of the whole, incorporates human blood derivative or a substance and data related to the test results necessary to assess the availability, quality and safety of the human blood derivative or substance, taking into consideration the intended use of the medical device;
- A declaration whether tissues of animal origin are used in the manufacturing of the medical device in line with the regulations applicable to tissues of animal origin;
- Solutions adopted in line with Article (2) of Annex I;
- Preclinical assessment;
- Clinical assessment set out in Annex X;
- Draft label, and if necessary, the operating manual.

ç) Inspection and quality assurance techniques during the manufacturing:

- In particular, processes to be used for sterilization and purchasing methods and the related documents;
- Processes to define and describe a medical device which should be kept updated and which shall be issued by using the drawings, specifications and other related documents at every stage of the manufacturing.

d) Appropriate tests and trials to be done before, during and after the manufacturing; their frequency; the test devices to be used and those points that would allow a backwards monitoring of the calibration of the test device

3.3 The certified body shall carry out its audit in order to ensure that the quality system is in conformity with such requirements in Article (3.2) of this Annex. Quality systems to which the applicable harmonized standards are applied shall be accepted to be in conformity with the said requirements.

At least one member in the assessment committee should have an experience in assessments about the relevant technology. The assessment should cover the assessment of the documents related to the medical device's design on a sampling basis and the on-site inspection of the manufacturer, its supplier and/ or its contractor, if necessary, to audit the manufacturing processes.

The decision shall be served on the manufacturer along with the results of the audit and an assessment with explanations.

3.4 The manufacturer shall provide the certified body certifying the quality system with such information about all designs related to significant changes that it plans to introduce to the quality system or the medical device type. The certified body shall assess the proposed changes to review if they are in conformity with the requirements in Article (3.2) of this Annex and shall notify its decision to the manufacturer. This decision also covers the audit results and an assessment with explanations.

4) Review of the medical device's design:

4.1 The manufacturer shall provide the certified body with its design file of the medical device that it plans to manufacture according to Article (3.1) of this Annex in addition to those requirements set out in Article 3 above.

4.2 The application should describe the design, manufacturing and performance of the said medical device and should cover all documents necessary to review the conformity of the medical device with the requirements hereof as set out in item 'c) in Article 3.2 of this Annex.

4.3 The certified body shall review the application and if the said device is in conformity with the provisions hereof, it shall issue an EC Design-Examination certificate to the applicant. The certified body may require additional evidence and tests in the course of the application to assess the conformity with the requirements hereof. The certificate shall also cover the purpose of the medical device. If necessary, and such data required to define the certified design, the results of the audit and conditions of validity.

In case of a medical device set out in the second paragraph of Annex I/7.4, the certified body shall consult the Ministry or the European Medicines Agency (EMEA) before adopting a decision about the situation referred in that article. The Ministry or the European Medicines Agency (EMEA) shall submit its opinion within 210 (two hundred and ten days) from the date of the delivery of the valid documents to it. The said scientific opinion shall be included in the assessment of the said device. The certified body shall take into consideration those points raised in the scientific opinion before it makes its decision, and shall report its final decision to the Ministry or the European Medicines Agency (EMEA).

In case of a medical device referred to in the third paragraph of Annex I/7.4, the scientific opinion of the European Medicines Agency (EMEA) should also be stated in the documents related to the medical device. The European Medicines Agency (EMEA) shall issue its opinion within 210 (two hundred and ten days) from the date of the delivery of the valid documents to it. The certified body shall take into consideration the opinion by the European Medicines Agency (EMEA)

before it makes its decision. If the scientific opinion of the European Medicines Agency (EMEA) is not favorable, the certified body may refuse to issue the certificate. The certified body shall report its final decision to the European Medicines Agency (EMEA).

In case of medical devices manufactured by using tissues of animal origin, the certified body shall proceed with the regulations applicable to them.

4.4 Where in case of design changes the compliance with the basic requirements hereof or the conditions for the operation of the medical device are affected, an additional certification should be received from the certified body that has issued the EC Design-Examination certificate. The applicant shall notify all changes related o the design to the certified body, and receive an "additional certification" in addition to the EC Design-Examination certificate.

5.5 Supervision and Audit

5.1 The purpose of the supervision and audit is to ensure that the requirements of an approved quality system are fully fulfilled.

5.2 The manufacturer shall permit the certified body to carryout all necessary audits and shall provide it with all necessary information. This information includes the following:

- Quality system documents;
- Results of analyses, calculations and tests foreseen in the relevant part of the quality system about the design, solutions set forth in Article 2 of Annex 1, preclinical and clinical assessments, clinical watch plan following the launch to the market and the results;
- Inspection reports, reports about test data and calibration data and qualifications of the relevant personnel set out in the relevant part of the quality system concerning the manufacturing.

5.3 The certified body shall conduct periodic audits and assessments to assure that the manufacturer remains in conformity with the approved quality system. It issues and gives an assessment report to the manufacturer.

5.4 The certified body may pay unscheduled visits to the manufacturer. If it deems it necessary during these visits, it may conduct or have third parties conducted tests to audit if the quality system works well. The manufacturer shall be given an audit report, and if conducted, a test report.

6) Administrative Provisions

6.1 The manufacturer shall retain the following documents, for submission to the Ministry, for minimum five (5) years with effect from the manufacturing date of the last manufactured medical device, and minimum 15 (fifteen) years for implantable devices:

- Declaration of conformity;
- Quality system documents referred to in Article (3.1) of this Annex, and in particular, such documents, data and records shown in the second paragraph of Article (3.2);
- Changes referred to in Article (3.4) of this Annex;
- Documents referred to in Article (4.2) of this Annex;
- Decisions and reports by the certified body as referred to in Articles (3.3), (4.3), (4.4), (5.3) and (5.4) of this Annex.

7) Application for Class IIa and IIb medical devices:

7.1 Except for Article (4) of this Annex, this Annex shall be applicable to such Class IIa and IIb medical devices referred to in Article 11 of the present Regulation.

7.2 For Class IIa medical devices, the certified body shall assess the technical documents set out in subparagraph (c) of Article (3.2) for at least one sample from each device subcategory in terms of compliance with the provisions hereof as a part of the assessment set out in Article (3.3) of this Annex.

7.3 For Class IIa medical devices, the certified body shall assess the technical documents set out in subparagraph (c) of Article (3.2) of this Annex for at least one sample from each generic device group in terms of compliance with the provisions hereof as a part of the assessment set out in Article (3.3).

7.4 The certified body shall take into consideration technological innovations, similarities in the design, technology, manufacturing and sterilization methods, intended purpose and the results of the past assessments done in line with the present Regulation (for instance in terms of physical, chemical and biological features). The certified body shall make ready and available the reasons underlying the samples picked by it so that it can submit them to the Ministry.

7.5 The certified body shall inspect other samples under its supervision and audit assessment referred to in Article (5) of this Annex.

8) Application for medical devices incorporating human blood derivative:

When the manufacturing of each batch/ lot of the medical devices incorporating human blood derivative is completed, the manufacturer shall give information to the certified body about the market launch of the medical device batch/ lot and shall send to the certified body the official certificate issued by a state laboratory in relation to the market launch of them or by another laboratory designated by the Ministry according to the Regulation on the Licensing of Medicine Products for Human Use.

ANNEX III
EC TYPE REVIEW

1) EC Type Review means the certification by the certified body that a sample representing the production is in conformity with the provisions of the present Regulation.

2) The application covers the following:

- The manufacturer's name and address; if the application is done by an authorized representative then the name and address of the authorized representative;
- For the conformity assessment of the sample representing the production defined as "type" in the provisions of the present Regulation, those documents listed in Article 3 of this Annex; and other samples to be provided upon the request of the certified body and a "type" prepared to be delivered to the certified body;

- A written declaration that there is no other application filed with another certified body for the same type.

3) Documents provided should ensure that the design, manufacturing and performance of the medical device shall be easily understood, and should include the following:

- A general definition and intended use of the type, including scheduled changes;
- Design drawings, in particular, manufacturing methods projected for the sterilization, and a detailed chart showing components, subgroups and circuits;
- Definitions and explanations necessary to ensure that the functioning of the medical device, the drawings and chart are understood;
- A list of those standards referred to in Article 7 of this Regulation which are partly or fully implemented, and the definition of solutions adopted in order to meet basic requirements of the present Regulation when these standards are not implemented;
- Results of certain operations such as design calculations, risk analyses, examinations and technical tests;
- Taking into consideration the intended use of the medical device, a statement that a substance or human blood derivative referred to in Annex I/7.4 is in the structure of the medical device as a whole; and data related to the tests conducted to assess the safety, quality and viability of such substance or human blood derivative;
- A statement on whether or not tissues of animal origin are used in the manufacturing of the medical device pursuant to the regulations governing the tissues of human origin;
- Solutions adopted in accordance with Article (2) of Annex I;
- Preclinical assessment;
- Clinical assessment referred to in Annex X;
- Draft label, and if necessary, operating manual.

4) Certified Body

4.1 It reviews if the documents submitted are in conformity with the type and if the type is manufactured in conformity with the documents; and if the applicable provisions of the standards referred to in Article 7 of the present Regulation are complied with. It assesses its findings and records the results.

4.2 It conducts or requires third parties to conduct necessary inspections and tests to verify if the manufacturer's solutions meet the basic requirements hereof for such medical devices to which the standards referred to in Article 7 of this Regulation are not applied. If medical device is to be connected to other medical device(s), it should be proven that it shall still meet the basic requirements hereof when it is connected to a medical device with the features designated by the manufacturer.

4.3 In the event that the manufacturer selects applicable standards currently in force, it conducts or requires third parties to conduct necessary to assess that these standards are truly complied with.

4.4 It shall designate, together with the applicant, the site where necessary inspections and tests shall be applied.

5) The certified body shall issue an EC Type-Examination Certificate to the manufacturer that fulfils the provisions of the present Regulation. The certificate shall contain data necessary to define the approved type, the manufacturer's name

and address, the audit results and validity terms. The relevant parts of the document are attached to the certificate and a copy shall be retained by the certified body.

In case of a medical device set out in the second paragraph of Annex I/7.4, the certified body shall consult the Ministry or the European Medicines Agency (EMEA) before adopting a decision about the situation referred in that article. The Ministry or the European Medicines Agency (EMEA) shall submit its opinion within 210 (two hundred and ten days) from the date of the delivery of the valid documents to it. The said scientific opinion shall be included in the assessment of the said device. The certified body shall take into consideration those points raised in the scientific opinion before it makes its decision, and shall report its final decision to the Ministry or the European Medicines Agency (EMEA).

In case of a medical device referred to in the third paragraph of Annex I/7.4, the scientific opinion of the European Medicines Agency (EMEA) should also be stated in the documents related to the medical device. The European Medicines Agency (EMEA) shall issue its opinion within 210 (two hundred and ten days) from the date of the delivery of the valid documents to it. The certified body shall take into consideration the opinion by the European Medicines Agency (EMEA) before it makes its decision. If the scientific opinion of the European Medicines Agency (EMEA) is not favorable, the certified body may refuse to issue the certificate. The certified body shall report its final decision to the European Medicines Agency (EMEA).

In case of medical devices manufactured by using tissues of animal origin, the certified body shall proceed with the regulations applicable to them.

Where a design change affects the conditions described for the use of the product or conformity with the basic requirements hereof, an additional certification should be received from the certified body that has issued the EC Type-Examination Certificate for such changes. If necessary, the applicant shall obtain an additional approval in addition to the first EC Type-Examination Certificate.

7) Administrative Provisions

7.1 Other certified institutions may receive a copy of the EC Type-Examination Certificate and/ or its annexes. Annexes to the certificate shall be given to other certified bodies upon a request backed by its reasons within the knowledge of the manufacturer.

7.2 The manufacturer or its authorized representative shall retain one copy of the EC Type-Examination Certificate and the complementary annexes thereto for a minimum term of 5 (five) years from the manufacturing of the last medical device. The term for retaining such certificate shall be minimum 15 (fifteen) years from the manufacturing of the last medical device for implantable devices.

ANNEX IV
EC VERIFICATION

1) EC verification is an operation whereby the manufacturer or its authorized representative represents and guarantees that medical devices subject to the procedures defined in Article 4 of this Annex are in conformity with the type defined in the EC Type-Examination Certificate and that it acts in compliance with such provisions hereof governing them.

2) The manufacturer shall adopt necessary measures about the manufacturing method to ensure that its medical devices are in full conformity with the provisions hereof and all specifications of the type defined in the EC Type-Examination Certificate. The manufacturer shall issue, if possible, such documents evidencing the conformity of the medical device with the requirements of the Regulation and with the type defined in the EC Type-Examination Certificate as well as the provisions prescribed to ensure homogenous production as well as all routine procedures, the manufacturing process, and in particular, the necessary sterilization before it starts the manufacturing. The manufacturer shall attach a CE marking and issue a declaration of conformity according to Article 17 of this Regulation.

In addition, the manufacturer shall apply such provisions of Articles (3) and (4) of Annex V for the manufacturing processes in order to assure and maintain the sterilization only in medical devices launched to the market in sterile form.

3) The manufacturer shall be responsible to set up and maintain a system in current form in order to review such data derived from the medical devices following their manufacturing, including the provisions in Annex V and to implement necessary corrective actions. In this respect, the manufacturer is also under the obligation to immediately give notice to the Ministry as soon as it becomes aware of the following:

a) 1) Deterioration and/ or deviation in the specifications and/ or performance of the medical device;
2) insufficient details in operating manual and label which may lead to a severe decline in the health condition of the patient or the user or his death;
b) Technical and medical causes based on the specifications and performance of the medical device which cause its manufacturer to recall the devices of the same type from the market in a systematic way due to the reasons set out in item (a) in this paragraph.

4) The certified body shall verify the products in statistical terms as defined in Article (6) or by controlling and testing each medical device as defined in Article (5) of this Annex, depending on the manufacturer's decision and shall conduct appropriate tests and reviews to verify if requirements set out herein are fulfilled.

Controls above shall not be applicable to a manufacturing process designed to assure the sterilization.

5) Verification of each medical device by tests and controls

5.1 Each medical device shall be separately reviewed. If possible, such tests defined in the applicable standards in Article 7 of this Regulation or equivalent tests are done to verify the conformity of the medical device with the type defined in the EC Type-Examination Certificate and the relevant requirements of the Regulation.

5.2 The certified body shall affix its own identification number on each certified medical device or have it affixed, and issue a written declaration of conformity for all tests completed.

6) Statistical Verification

6.1 The manufacturer shall submit the final products together with homogenous batch/ lot numbers.

6.2 Random samples are picked from each batch/ lot. These samples are separately reviewed. If possible, to determine if the batch/ lot is accepted or refused, such tests defined in the applicable standards in Article 7 of this Regulation or equivalent tests are done to verify the conformity of the medical device with the type defined in the EC Type-Examination Certificate and the relevant requirements of the Regulation.

6.3 The statistical control of the medical device shall be made on the basis of such qualifications and/ or variables that need the functional sampling charts that provide high level of safety and performance in line with the state-of-the-art technology. This sampling chart shall be created according to the relevant standards in Article 7 of the Regulation, taking into consideration the special nature of the said device category.

6.4 If the batch/ lot is accepted, the certified body shall affix its own identification number on each certified medical device or have it affixed, and issue a written declaration of conformity for all tests completed. All medical devices in the accepted batch/ lot except for non-conforming samples may be launched to the market.

If a batch/ lot is rejected, then the certified body shall adopt necessary measures to prevent the market launch of the said batch/ lot. In the event that batches/ lots are frequently rejected, the certified body may suspend the statistical verification.

The manufacturer may affix the identification number of the certified body in the course of the manufacturing works under the certified body's responsibility.

7) Administrative Provisions

The manufacturer or its authorized representative shall keep the following documents, for submission to the Ministry, for a minimum term of 5 (five) years from the manufacturing date of the last medical device and for a minimum term of 15 (fifteen) years for implantable devices.

- Declaration of conformity;
- Documents referred to in Article (2) of this Annex;
- Documents referred to in Articles (5.2) and (6.4) of this Annex
- If necessary, the EC Type-Examination Certificate referred to in Annex III.

8) Application for Class IIa medical devices

This Annex may be applicable to such Class IIa medical devices referred to in Article 11 of the Regulation by taking into consideration the following:

8.1 The manufacturer shall guarantee and announce by virtue of the declaration of conformity that except for Articles (1) and (2) of the present Annex, it manufactures Class IIa products in accordance with the technical documents referred to in Article (3) of the present Annex and that they meet the requirements of the present Regulation.

8.2 Except for Articles (1), (2), (5) and (6) of the present Annex, verifications done by the certified body by virtue of technical documents referred to in Article (3) of Annex VII are for the purposes of the confirmation of the conformity of Class IIa products.

9. Application for medical devices incorporating human blood derivative

In case of medical devices incorporating human blood derivative if the manufacturing of each batch/ lot of a medical device is to be verified according to Article (6), the manufacturer shall give information to the certified body about

the market launch of the medical device batch/ lot and shall send to the certified body the official certificate issued by a state laboratory in relation to the market launch of them or by another laboratory designated by the Ministry according to the Regulation on the Licensing of Medicine Products for Human Use.

ANNEX V
EC DECLARATION OF CONFORMITY
(Production Quality Assurance)

1) The manufacturer shall implement the quality system approved for the manufacturing and shall carry out the final controls of the said medical devices as described in Article (3 of this Exhibit; moreover, it shall be subject to the supervision and audit referred to in Article 4 of the present Annex.

2) The EC Declaration of Conformity is an operation whereby the manufacturer fulfilling the requirements set out in the Article (1) of the present Annex guarantees and reports that its said products are in conformity with the type defined in the EC Type-Examination Certificate and the applicable provisions of this Regulation.

The manufacturer shall affix the CE marking and issue a written declaration of conformity in accordance with Article 17 of the present Regulation. This declaration shall cover all medical devices which are clearly defined by way of product name, product code or other remarks and shall be kept and retained by the manufacturer.

3) Quality system

3.1 The manufacturer shall apply to the certified body for the assessment of its quality system. This application shall consist of the following:

- The manufacturer's name and address;
- All information related to the medical device or the group of medical devices covered by the transaction;
- A written statement confirming that the manufacturer has not filed any application with any other notified body for the same medical devices;
- Quality system documents
- An undertaking to fulfill all requirements of a certified quality system;
- An undertaking to maintain the certified quality systems in full and in an effective way;
- When necessary, a technical certificate for the approved type and a copy of the EC Type-Examination Certificate;
- The manufacturer's undertaking that data derived from medical devices during the post-production stage shall be reviewed, including the provisions in Annex X; that a system shall be set up in order to apply necessary corrective actions and that this system shall be maintained current and updated. This undertaking also extends to the obligation that the manufacturer shall give notice to the Ministry as soon as it becomes aware of the following situations:

a) 1) Deterioration and/ or deviation in the specifications and/ or performance of the medical device;
2) Insufficient details in operating manual and label which may lead to a severe decline in the health condition of the patient or the user or his death;
b) Technical and medical causes based on the specifications and performance of the medical device which cause its manufacturer to recall the devices of the same type from the market in a systematic way due to the reasons set out in item (a) in this paragraph.

3.2 The implementation of the quality system should ensure the conformity of the products with the type referred to in the EC Type-Examination Certificate.

All provisions, requirements and prescriptions adopted by the manufacturer for the quality system shall be systematically and regularly certified in the form of written policies and procedures. This documentation of the quality system should allow that the quality plans, programs, manuals, records and similar quality policies and procedures should be construed in the same way.

This certificate shall particularly include the following:

a) The manufacturer's quality targets;
b) The business' organizational structure, and in particular:

- Responsibilities of the officers and employees in charge of the design quality and manufacturing of the medical device, their authorities and corporate organization;
- Methods intending to control the effective operation of the quality system to ensure that the medical devices and their designs, including the control of non-conforming medical devices shall be at the desired level;
- Where a medical device or its parts are designed, manufactured and/ or finally inspected and tested by third parties, a description of the effective operation of the quality system, in particular, those methods to monitor the scope and method of the control applied to the said third party;

c) Inspection and quality assurance techniques during the manufacturing:

- In particular, processes to be used for sterilization and purchasing methods and the related documents;
- Processes to define and describe a medical device which should be kept updated and which shall be issued by using the drawings, specifications and other related documents at every stage of the manufacturing.

ç) Appropriate tests and trials to be done before, during and after the manufacturing; their frequency; the test devices to be used and those points that would allow a backwards monitoring of the calibration of the test device.

3.3 The certified body shall carry out its audit in order to ensure that the quality system is in conformity with such requirements in Article (3.2) of this Annex. Quality systems which apply the applicable harmonized standards shall be accepted to be in conformity with the said requirements.

At least one member in the assessment committee should have an experience in assessments about the relevant technology. The assessment should cover the assessment of the documents related to the medical device's design on a sampling basis and the on-site inspection of the manufacturer, its supplier and/ or its contractor, if necessary, to audit the manufacturing processes. The decision shall be served on the manufacturer along with the results of the audit and an assessment with explanations.

The manufacturer shall provide the certified body certifying the quality system with such information about all designs related to significant changes that it plans to introduce to the quality system or the medical device type.

The certified body shall assess the proposed changes to review if they are in conformity with the requirements in Article (3.2) of this Annex. After the said information is received the decision consisting of the audit results and an assessment backed by explanations shall be sent to the manufacturer.

4) Supervision and Audit

4.1 The purpose of the supervision and audit is to ensure that the requirements of an approved quality system are fully fulfilled.

4.2 The manufacturer shall permit the certified body to carryout all necessary audits and shall provide it with all necessary information. This information includes the following:

- Quality system documents;
- Technical documents;
- Inspection reports, reports about test data and calibration data and qualifications of the relevant personnel set out in the relevant part of the quality system concerning the manufacturing.

4.3 The certified body shall carry out periodic audit and assessment to ensure that the manufacturer complies with the approved quality system and give an assessment report to the manufacturer.

4.4 Moreover, the certified body may pay unscheduled visits to the manufacturer. If it deems it necessary during these visits, it may conduct or have third parties conducted tests to audit if the quality system works well. The manufacturer shall be given an audit report, and if conducted, a test report.

5) Administrative Provisions

5.1 The manufacturer shall retain the following documents, for submission to the Ministry, for minimum five (5) years with effect from the manufacturing date of the last manufactured medical device, and minimum 15 (fifteen) years for implantable devices:

- Declaration of conformity;
- Quality system documents referred to in Article (3.1) of this Annex;
- Changes referred to in Article (3.4) of this Annex;
- A copy of the EC Type-Examination Certificate referred to in Article (3.1) of the present Annex and technical documents related to the approved type;
- The decision and reports of the certified body referred to in Articles (4.3) and (4.4) of the present Annex;
- If necessary, the EC Type-Examination Certification referred to in Annex III.

6) Application for Class IIa medical devices:

This Annex may be applicable to such Class IIa medical devices referred to in Article 11 of the Regulation by taking into consideration the following:

6.1 The manufacturer shall guarantee and announce by virtue of the declaration of conformity that except for Articles (2), (3.1) and (3.2) of the present Annex, it manufactures Class IIa products in accordance with the technical documents referred to in Article (3) of the Annex VII and that they meet the requirements of the present Regulation.

6.2 For Class IIa medical devices, the certified body shall assess the technical documents set out in Article (3) of Annex VII for at least one sample from each device subcategory in terms of compliance with the provisions hereof as a part of the assessment set out in Article (3.3).

6.3 The certified body shall take into consideration technological innovations, similarities in the design, technology, manufacturing and sterilization methods, intended purpose and the results of the past assessments done in line with the present Regulation (for instance in terms of physical, chemical and biological features). The certified body shall make ready and available the reasons underlying the samples picked by it so that it can submit them to the Ministry.

6.4 The certified body shall examine other samples under the supervision and audit assessment set out in Article (4.3).

7) Application for medical devices incorporating human blood derivative:

When the manufacturing of each batch/ lot of the medical devices incorporating human blood derivative is completed, the manufacturer shall give information to the certified body about the market launch of the medical device batch/ lot and shall send to the certified body the official certificate issued by a state laboratory in relation to the market launch of them or by another laboratory designated by the Ministry according to the Regulation on the Licensing of Medicine Products for Human Use.

ANNEX VI
EC DECLARATION OF CONFORMITY
(Product Quality Assurance)

1) The manufacturer shall implement the quality system approved for the production and shall carry out the inspection and test procedures of the said medical devices as described in Article (3) of this Annex; moreover, it shall be subject to the supervision and audit referred to in Article (4) of the present Annex.

In addition, the manufacturer shall implement the provisions of Articles (3) and (4) of Annex V for manufacturing processes which are intended for the assurance and maintenance of the sterility only in medical devices launched to the market in sterile form

2) The EC Declaration of Conformity is an operation whereby the manufacturer fulfilling the requirements set out in the Article 1 of the present Annex guarantees and reports that its said products are in conformity with the type defined in the EC Type-Examination Certificate and the applicable provisions of this Regulation.

The manufacturer shall affix the CE marking and issue a written declaration of conformity in accordance with Article 17 of the present Regulation. This declaration shall cover all medical devices which are clearly defined by way of product name, product code or other remarks and shall be kept and retained by the manufacturer. The CE marking shall be next to the identification number of the certified body implementing the procedures defined in this Annex.

3) Quality system

3.1 The manufacturer shall apply to the certified body for the assessment of its quality system. This application shall consist of the following:

- The manufacturer’s name and address;
- All information related to the medical device or the group of medical devices covered by the transaction;
- A written statement confirming that the manufacturer has not filed any application with any other notified body for the same product;
- Quality system documents
- An undertaking by the manufacturer to fulfill all requirements of a certified quality system;
- An undertaking by the manufacturer to maintain the certified quality systems in full and in an effective way;
- When necessary, a technical certificate for the approved type and a copy of the EC Type-Examination Certificate;
- The manufacturer’s undertaking that data derived from medical devices during the post-production stage shall be reviewed, including the provisions in Annex X; that a system shall be set up in order to apply necessary corrective actions and that this system shall be maintained current and updated. This undertaking also extends to the obligation that the manufacturer shall give notice to the Ministry as soon as it becomes aware of the following situations:

a) 1) Deterioration and/ or deviation in the specifications and/ or performance of the medical device;
2) Insufficient details in operating manual and label which may lead to a severe decline in the health condition of the patient or the user or his death;
b) Technical and medical causes based on the specifications and performance of the medical device which cause its manufacturer to recall the devices of the same type from the market in a systematic way due to the reasons set out in item (a) in this paragraph.

3.2 Under the quality system, the sample from each medical device or batch/ lot shall be examined and such tests defined in the applicable standards in Article 7 of this Regulation or equivalent tests are done to ensure the conformity of the medical device with the type defined in the EC Type-Examination Certificate and the relevant requirements of the Regulation. All provisions, requirements and prescriptions adopted by the manufacturer for the quality system shall be systematically and regularly certified in the form of written policies and procedures. This documentation of the quality system should allow that the quality plans, programs, manuals, records and similar quality policies and procedures should be construed in the same way.

This document particularly includes the following definitions:

- Quality targets, organizational structure, responsibilities and powers of the employees in the company with respect to the quality of medical devices;
- Post-manufacturing examinations and tests as well as those points that would allow a backwards monitoring of the calibration of the test device;
- Methods to monitor the effective operation of the quality system;
- Reports related to the inspection, test and calibration as well as records in relation to the quality such as relevant personnel;
- Where a medical device or its parts are designed, manufactured and/ or finally inspected and tested by third parties, a description of the effective operation of the quality system, in particular, those methods to monitor the scope and method of the control applied to the said third party.

Examinations above shall not be applicable to a manufacturing process designed to assure the sterilization.

3.3 The certified body shall carry out its audit to determine if the quality system is in conformity with the requirements defined in Article (3.2) of the present Annex. Quality systems to which applicable harmonized standards are applied shall be accepted to be in conformity with the said requirements.

At least one member in the assessment team should have assessment experience about the relevant technology. In order to control the manufacturing process for the purposes of the assessment, the manufacturer, and where necessary, its supplier shall undergo an on-site audit. The decision shall be notified to the manufacturer together the audit results and an assessment with explanations.

3.4 The manufacturer shall provide the certified body which certifies its quality system with information about all its projections for significant changes to its quality system.

The certified body shall assess the proposed changes to review if they are in conformity with the requirements in Article (3.2) of this Annex. After the said information is received the decision consisting of the audit results and an assessment backed by explanations shall be sent to the manufacturer.

4) Supervision and Audit

4.1 The purpose of the supervision and audit is to ensure that the requirements of an approved quality system are fully fulfilled.

4.2 The manufacturer shall authorize the certified body to audit the inspection, test and storage sites and shall supply to the certified body all required information including the following in full:

- Quality system documents;
- Technical documents;
- Inspection reports, test and calibration data as well as records related to quality such as the qualifications of the relevant personnel.

4.3 In order to assure that the manufacturer implements the quality system, the certified body shall carry out periodical audits and assessments and shall give an assessment report to the manufacturer.

4.4 Certified body may pay unscheduled visits to the manufacturer. If it deems it necessary during these visits, it may conduct or have third parties conducted tests to audit if the quality system works well and the product is in conformity with the requirements of the present Regulation. For this purpose, it picks up and examines a sample from the final products and conducts such tests defined in the applicable standards in Article 7 of this Regulation or equivalent ones. Where one or more than one sample is in deviation of the requirements, the certified body shall adopt necessary measures.

The certified body shall give the manufacturer an audit report, and if conducted, a test report.

5) Administrative provisions

The manufacturer shall retain the following documents, for submission to the Ministry, for minimum five (5) years with effect from the manufacturing date of the last manufactured medical device, and minimum 15 (fifteen) years for implantable devices:

- Declaration of conformity;
- A copy of the EC Type-Examination Certificate referred to in Article (3.1) of the present Annex and technical documents related to the approved type;
- Changes referred to in Article (3.4) of this Annex;
- The decision and reports of the certified body referred to in the second paragraph of Article (3.4) of the present Annex and also in Articles (4.3) and (4.4) of it;
- If necessary, the declaration of conformity referred to in Annex III, EC Type-Examination Certification referred to in Annex III.

6) Application for Class IIa medical devices:

This Annex may be applicable to such Class IIa medical devices referred to in Article 11 of the Regulation by taking into consideration the following:

6.1 The manufacturer shall guarantee and announce by virtue of the declaration of conformity that except for Articles (2), (3.1) and (3.2) of the present Annex, it manufactures Class IIa products in accordance with the technical documents referred to in Article (3) of the Annex VII and that they meet the requirements of the present Regulation.

6.2 For Class IIa medical devices, the certified body shall assess the technical documents set out in Article (3) of Annex VII for at least one sample from each device subcategory in terms of compliance with the provisions hereof as a part of the assessment set out in Article (3.3).

6.3 The certified body shall take into consideration technological innovations, similarities in the design, technology, manufacturing and sterilization methods, intended purpose and the results of the past assessments done in line with the present Regulation (for instance in terms of physical, chemical and biological features). The certified body shall make ready and available the reasons underlying the samples picked by it so that it can submit them to the Ministry.

6.4 The certified body shall examine other samples under the supervision and audit assessment set out in Article (4.3).

ANNEX VII
EC CONFORMITY OF DECLARATION

1) The EC Declaration of Conformity is a process whereby the manufacturer or its authorized representative which fulfils the obligations set out in Article 2 of the present Annex and those obligations referred to in Article (5) of this Annex for medical devices launched to the market in a sterile form as well as for medical devices with the measurement functions declares and guarantees that it fulfils such requirements and that said devices are in conformity with the relevant provisions of this Regulation.

2) The manufacturer should issue the technical certificate described in Article (3) of the present Annex. The manufacturer or its authorized representative shall retain such technical document consisting of the declaration of conformity for minimum 5 (five) years from the date of the manufacturing of the last medical device in order to submit it in case of an audit by the competent authorities. This document shall be kept for minimum 15 (fifteen) years for the implantable devices from the date of the manufacturing of the last medical device.

3. This technical document should allow the assessment of the medical device's conformity to the requirements of the Regulation. This document shall show the following;:

- A general definition and intended use of the type, including scheduled changes;
- Design drawings, manufacturing methods projected, and a detailed chart showing components, subgroups and circuits;
- Definitions and explanations necessary to ensure that the functioning of the medical device, the drawings and chart are understood;
- Risk analysis results and a list of those standards referred to in Article 7 of the present Regulation which are partly or fully implemented, and the definition of solutions adopted in order to meet basic requirements of the present Regulation when these standards are not implemented;
- Definition of methods employed for medical devices launched to the market in a sterile form and the validation reports;
- Results of the applied audits and design calculations; where a medical device is to be connected to another one in order to function in line with its intended use, the evidence that these medical devices with necessary features defined by their respective manufacturers shall meet basic requirements when they are interconnected;
- Solutions adopted in accordance with Article (2) of Annex I;
- Pre-clinical assessment;

- Clinical assessment issued in accordance with Annex X;
- Label and operating manual.

4) The manufacturer shall be responsible to set up and maintain a system in current form in order to review such data derived from the medical devices following their manufacturing, including the provisions in Annex X and to implement necessary corrective actions. In this respect, the manufacturer is also under the obligation to immediately give notice to the Ministry as soon as it becomes aware of the following:

a) 1) Deterioration and/ or deviation in the specifications and/ or performance of the medical device;
2) Insufficient details in operating manual and label which may lead to a severe decline in the health condition of the patient or the user or his death;
b) Technical and medical causes based on the specifications and performance of the medical device which cause its manufacturer to recall the devices of the same type from the market in a systematic way due to the reasons set out in item (a) in this paragraph.

5) With respect to medical devices launched to the market in sterile form and medical devices with measurement function included in Class I, the manufacturer should act in accordance with not only the requirements set out in this Annex but also either of the procedures defined in Annex II, Annex IV, Annex V or Annex VI.

The application of the Annexes above and the intervention by the certified body shall be limited to the following:

- In medical devices launched to the market in sterile form, manufacturing issues related to the assurance and maintenance of the sterilization only;
- For medical devices with measurement function, manufacturing issues related to the conformity of the products with metrological requirements.

Moreover, the second paragraph of Article (6) in this Annex shall be applicable to them.

6) Application for Class IIa medical devices

This Annex may be applicable to Class IIa medical devices referred to in Article 11 of the Regulation, taking into consideration the following exception:

When the provisions of this Annex are implemented together with procedures set out in Annex IV, Annex V or Annex VI, the declaration of conformity set out in the relevant Annexes shall be made in the form of a single declaration. With respect to the declaration based on this Annex, the manufacturer declares and guarantees that the product design meets the relevant provisions of this Regulation.

ANNEX VIII
DECLARATION FOR SPECIAL PURPOSE DEVICES

1) The manufacturer or its authorized representative shall issue a declaration incorporating the information referred to in Article 2 of the present Article for the customized devices or clinical research purpose devices.

2) This declaration sets forth the following information:

- The manufacturer’s name and address;
- Descriptive information about the medical device;
- A declaration that the medical device shall be used by a specific patient, along with the patient’s name;
- The prescribing doctor or the name of any other competent person, and where necessary, the name of the polyclinic;
- Specific specifications of the prescribed medical device;
- A declaration confirming that the said medical device meets basic requirements set out in Annex 1 and, where it fails to meet these requirements in full, stating the reasons underlying it.

2.2 For clinical research purpose devices referred to in Annex X:

- Descriptive information about the device;
- Clinical research plan;
- Researcher brochure;
- Confirmation that the subjects of the research are insured;
- An informed volunteer consent form;
- The declaration if a substance or human blood derivative referred to in Annex 1/7.4 will not be included in the structure of the device as a part of the whole;
- The declaration about whether or not tissues of animal origin are used in the manufacturing of the device in line with the regulations applicable to them;
- Opinions of the relevant ethical opinion and detailed explanations in relation to these opinions;

- The name of the institution, the medical applicator and other competent personnel in charge of the research;
- The place, commencement date and planned term of the research;
- A declaration confirming the conformity of the devices with basic requirements in addition to the subject matters covered by the research and describing all measures adopted for the patient's safety and the protection of his health.

3) The manufacturer shall also keep ready the following document in order to submit it to the Ministry when necessary:

3.1 A certificate related to the design, manufacturing, expected performance and actual performance and the manufacturing site(s) of a customized medical device in a way allowing an assessment if it meets the requirements of the present Regulation.

The manufacturer shall adopt all measures to ensure that the manufacturing method shall allow the manufacturing of medical devices in line with the certificate referred to in the first paragraph of this Article.

3.2 Documents related to clinical research purpose devices should have the following information:

- A general description and intended use of the device;
- Design drawings, in particular, manufacturing methods projected for the sterilization, and a detailed chart showing components, subgroups and circuits;
- Definitions and explanations necessary to ensure that the functioning of the medical device, the drawings and chart are understood;
- Risk analysis results and a list of those standards referred to in Article 7 hereof which are partly or fully implemented, and the definition of solutions adopted in order to meet basic requirements of the present Regulation when these standards are not implemented;
- A statement referred to in Annex 1/7.4 and which shows that the medical device, as a part of the whole, contains human blood derivative or a substance and data related to the test results necessary to assess the availability, quality and safety of the human blood derivative or substance, taking into consideration the intended use of the medical device;
- Where tissues of animal origin are used in the manufacturing of the device in line with the regulations applicable to the use of such tissues, risk management measures to pull down the infection risk;
- Results such as design calculations, applied audits and technical tests.

The manufacturer shall adopt all necessary measures in the course of its manufacturing to ensure that devices shall be manufactured in accordance with the certificate referred to in the first paragraph of this Article.

The manufacturer agrees and undertakes that the effectiveness of these measures shall be assessed or, when necessary, shall be audited.

4) Documents and information referred to in this Annex shall be kept for minimum 5 (five) years. This term shall be minimum 15 (fifteen) years for implantable devices.

5) For customized medical devices, the manufacturer shall be responsible to review the post-manufacturing data derived from the medical devices, including the provisions set out in Annex X and to introduce necessary corrective actions. In this respect, the manufacturer is also under the obligation to immediately give notice to the Ministry as soon as it becomes aware of the following:

a) 1) Deterioration and/ or deviation in the specifications and/ or performance of the medical device;
2) insufficient details in operating manual and label which may lead to a severe decline in the health condition of the patient or the user or his death;
b) Technical and medical causes based on the specifications and performance of the medical device which cause its manufacturer to recall the devices of the same type from the market in a systematic way due to the reasons set out in item (a) in this paragraph.

ANNEX IX
CLASSIFICATION RULES

I. DEFINITIONS

1) Definitions used in classification rules:

1.1 Medical devices by period of time:

- **Temporary:** medical devices with the intended use for less than 60 minutes under regular circumstances and on a continuous basis;
- **Short-term:** medical devices with the intended use for less than 30 days minutes under regular circumstances and on a continuous basis;

- Long-term: medical devices with the intended use for more than 30 days minutes under regular circumstances and on a continuous basis.

1.2 Invasive devices: These are medical devices fully or partly permeating, entering or implanted into the body through bodily cavities or by going through the body surface.

- Bodily cavity: Any natural cavity in the body, including the outer surface of the eye socket as well as permanent artificial cavities (such as stoma);
- Surgically invasive device: This kind of devices are invasive medical devices implanted into the body by passing through the body by means of a surgical operation or with the help of instruments;

In addition to medical devices above which are defined in line with the purpose of the present Regulation, medical devices used by implanting them in a place in the body other than its cavities are also defined as surgical invasive devices.

- Implant devices: These are medical devices which are implanted in the human body in full by means of surgical operation or instead of eye surface or epithelial surface which are meant to stay there after the implantation.

A medical device which is partly implanted into the human body by surgical operation and which is meant to stay there for minimum 30 (thirty) days following the operation are also defined as an implant device.

1.3 Reusable surgical instruments: These are medical devices used for cutting, boring, scraping, peeling, uniting, pulling, fixing, bonding and similar surgical operations without any connection to any active medical device and which may be used again after the completion of such operations.

1.4 Active medical devices: These are those medical devices which are run by electricity or other power source or by means of the conversion of this energy other than the gravity force or the energy naturally created by human body. A device which allows the passage of energy, substances and other elements between the medical device and the patient without any significant change in the form of energy shall not be classified as an active medical device. A software which alone is a medical device shall be deemed an active medical device.

1.5 Active treatment devices: These are medical devices which, either alone or in combination with other medical devices, support, change, replace or renew biological structures or functions in order to treat or alleviate a disease, injury or disability.

1.6 Active diagnostics devices: These are active medical devices which, either alone or in combination with other medical devices, provide information to identify or diagnose, watch or treat physiological conditions, healthcare condition, diseases or genetic disorders.

1.7 Central cardiovascular system: The central cardiovascular system shall cover the following veins for the purposes of this Regulation.

Arteriaepulmonalis, aorta ascendens, arcus aorta, aorta descendens up to aortic bifurcation arteriaecoronariae, arteriacarotiscommunis, arteriacarotisexterna, arteriacarotisinterna, arteriaecerebralis, truncusbrachicephalicus, venaecordis, venaepulmonalis, vena cava superior and vena cava inferior.

1.8 Central nervous system: The central nervous system shall consist of brain, meninges and spinal cord for the purposes of this Regulation.

1I. APPLICATION RULES

2) Application rules:

2.1 The application of the classification rules shall be determined according to the projected intended use of medical devices.

2,2 Where a medical device is to be used in combination with another medical device, the classification rule shall be applied to each medical device individually whereas accessories shall be classified separate from the medical devices even though they are used in combination.

2.3 A software which affects the use of a medical device or runs it shall be included in the same class.

2.4 Unless a medical device shall not be used in a specific part of the body only, it is classified based on the most critical place of use.

2.5 Where several rules are applicable to the same medical device based on the performance defined by its manufacturer, a medical device shall be treated within the strictest rule under the highest classification out of them.

2.6 For the calculation of the time period referred to in Article (1.1) in section 1, a “continuous use” shall mean an “actual use of the medical device in line with its intended use without any interruption whatsoever”. Notwithstanding the foregoing, the interruption in use of a medical device to be immediately replaced by an identical or similar device shall also be treated as the continuous use of that medical device.

III. CLASSIFICATION

1) Non-invasive devices

1.1. Rule 1:

All non-invasive devices shall be included in Class I unless they fall within the scope of following rules:

1.2. Rule 2:

If all non-invasive devices for the supply and receipt of or storing blood, body fluids or tissues or the infusion or application of liquids or gases into the body;

- can be connected to active medical devices in Class IIa or a higher class;

- and are for the purpose of supply and receipt of or storing blood, body fluids or storage of bodies, organ parts or body tissues, then they are included in Class IIa. In all other circumstances, they fall within the scope of Class Ia.

1.3 Rule 3:

All non-invasive devices which change the chemical or biological compounds of the blood, other body fluids or other fluids which are intended to be infused to the body shall be within Class IIb; however, if the treatment includes the filtration, centrifugal operation or replacement of the gas or heat, then they will be within Class IIa.

1.4 Rule 4:

All non-invasive devices which are in contact with the injured skin shall be within:

- Class I if they are used as a mechanical barrier for the depression or absorption of secretions.
- All medical devices which are intended for use in wounds which essentially arise as a result of a destroyed dermis shall fall within Class IIb.
- All medical devices used in all other circumstances, including medical devices for the essential purpose of healing the micro-surrounding of the wound shall fall within Class IIa.

2) Invasive devices:

2.1: Rule 5:

Except for surgical invasive devices, all invasive devices related to bodily cavity connected to a Class I active medical device only:

- shall fall within Class I in case of temporary use.

- Medical devices intended for a short-term use shall fall within Class IIa; however, those ones used in oral cavity up to pharinx and in ear canal up to tympana or nasal cavity shall fall within Class I.

- Medical devices intended for a long-term use shall fall within Class IIb; however, those ones which are not fit for absorption through mucous membrane or are used in oral cavity up to pharinx and in ear canal up to tympana or nasal cavity shall fall within Class IIa.

Except for surgical invasive devices, all invasive devices related to bodily cavities which are to be used when connected to an active medical device in Class IIa or a higher class shall fall within Class IIa.

2.2 Rule 6:

All surgical invasive devices for temporary use shall fall within Class IIa except that:

- surgical invasive devices which control, diagnose, monitor or correct any disorder in the heart or central cardiovascular system, in particular, by direct contact with them shall fall within Class III.
- surgical instruments that may be reused shall fall within Class I.

- surgical invasive devices which are used by direct contact with central nervous system in particular shall fall within Class III.
- surgical invasive devices with the intended use to supply energy in the form of ionizing radiation shall fall within Class IIb.
- surgical invasive devices which have biological effects and the majority or entirety of which is absorbed shall fall within Class IIb.
- surgical invasive devices used to administer drugs to the body shall fall within Class IIb if they pose a potential danger for the manner of administration.

2.3 Rule 7:

Except for the following circumstances, all surgical invasive devices for short term use shall fall within Class IIa:

- surgical invasive devices which control, diagnose, monitor or correct any disorder in the heart or central cardiovascular system, in particular, by direct contact with them shall fall within Class III;
- surgical invasive devices which are used by direct contact with central nervous system in particular shall fall within Class III;
- surgical invasive devices with the intended use to supply energy in the form of ionizing radiation shall fall within Class IIb;
- surgical invasive devices which have biological effects and the majority or entirety of which is absorbed shall fall within Class III;
- Except for those ones implanted in teeth, medical devices which undergo a chemical change in the body or which are used to administer drugs shall fall within Class IIb.

2.4 Rule 8:

Except for the following circumstances, all implant devices and long-term surgical invasive devices shall fall within Class IIb:

- Medical devices implanted in teeth shall fall within Class IIa.
- Medical devices which are used in direct contact with the heart, central cardiovascular system or central nervous system shall fall within Class III.
- Medical devices with biological effects or the majority or entirety of which is absorbed shall fall within Class III;
- Except for those ones implanted in teeth, medical devices which undergo a chemical change in the body or which are used to administer drugs shall fall within Class III.
- Breast implants shall fall within Class III.
- Shoulder, knee and hip replacement devices shall fall within Class III.

3. Additional rules applicable to active devices

3.1 Rule 9:

All active treatment devices intended for the supply or conversion of energy shall fall within Class IIa. However, if the medical device poses a potential risk in the supply or receipt of energy or in ensuring the energy conversion with the human body, taking into consideration its structure, density and energy application area, it shall within Class IIb.

A medical device monitoring or controlling the performance of an active treatment device included in Class IIb or all active devices with a direct effect on the performance of such devices shall fall within Class IIb.

3.2 Rule 10:

Diagnostic active devices shall fall within Class IIa:

- Medical devices supplying the energy to be absorbed by the human body, other than the ones used to light the patient's body, in a visible spectrum;
- Medical devices used to view in vivo distribution of radiopharmaceuticals;
- Medical devices allowing the direct diagnosis or monitoring of vital physiological functions.

However, medical devices intended to monitor the changes in the structure that may pose a sudden risk for the patient's condition such as central nervous system activities, changes in respiratory system or heart functions shall fall within Class IIb.

Devices which emit ionizing radiation and whose intended use is interventional radiological diagnosis and treatment as well as all active devices with the intended use to monitor and control those active devices or with a direct impact on their performance shall fall within Class IIb.

3.3 Rule 11:

All active devices that supply and/ or receive pharmaceuticals, body fluids or other substances to or from the body shall fall within Class IIa. That said, if the way of administration poses a potential risk, given the relevant part of the body and the characteristics of the supplied substance, then these devices shall fall within Class IIb.

3.4 Rule 12:

All other active devices shall fall within Class I.

4) Special rules:

4.1 Rule 13:

All medical devices which are, when used alone, treated as a medical product according to the Regulation on the Licensing of Medicine Products for Human Use and which contain a substance supporting the effect of the medical device on the human body shall fall within Class III.

All medical devices incorporating human blood derivative shall fall within Class III.

4.2 Rule 14:

All medical devices which are used to prevent the infection of venereal diseases or for birth control shall fall within Class IIb. However, where a device is an implant or long-term invasive one, it falls within Class III.

4.3 Rule 15:

All medical devices that are used to disinfect, clean, rinse or, when necessary, moist the contact lenses shall fall within Class IIb.

Medical devices which are particularly used to disinfect medical devices shall fall within Class IIa. Medical devices used to disinfect invasive devices shall fall within Class IIb.

This rule shall not be applicable to other products which clean medical devices other than contact lenses by means of physical effect.

4.4 Rule 16:

Medical devices which are used in particular to record X-ray diagnostic images shall fall within Class IIa.

4.5 Rule 17:

Except for medical devices which are intended to contact with intact skin only, all medical devices manufactured by using animal tissues or dead tissue parts shall fall within Class III.

5) Rule 18:

Different from other rules, blood bags shall fall within Class IIb.

ANNEX X
CLINICAL ASSESSMENT

1) General Provisions

1.1 As a general rule, a confirmation that a medical device meets the requirements in terms of performance and specifications set out in Articles 1 and 3 of Annex I under the conditions of regular use and an assessment as to the side effects and acceptability of benefit-risk ratio referred to in Article 6 of Annex 1 should be based on clinical data. The assessment as to such data shall be hereinafter referred to as the "clinical assessment" and they may be methodologically accepted by taking into consideration, if necessary, the applicable harmonized standards and they should follow up a defined procedure which is based on either of the following:

1.1.1 The said procedure may be based on the following:

- Where the medical device for which there are related data is equivalent of the assessed medical device; or
- Where said data are in full conformity with the applicable basic requirements, then a critical assessment of the relevant scientific literature about the safety, performance, design characteristics and intended use of the medical device.

1.1.2 The said procedure may rely on the critical assessment of results coming from all completed clinical researches.

1.1.3 The said procedure may be based on a critical assessment to be made by combining clinical data set out in Articles (1.1.1) and (1.1.2).

1.1a Unless the fact that implantable devices and Class II medical devices are based on available clinical data may be justified in full, clinical researches shall be done for these devices.

1.1b. Clinical assessment and the results shall be documented. Such documents and/ or data identifying them in full shall be included in the technical file of the medical device.

1.1c Clinical assessment and the related documents should be constantly updated in line with the data coming from the supervision and audit after the market launch. In circumstances where post-market launch clinical follow-up is not deemed necessary under the supervision and audit plan of the medical device following its launch, this shall be backed up and documented with its reasons in full.

1.1d In circumstances where the indication of conformity with basic requirements based on clinical data is not appropriate, an appropriate reason is given based on the risk management outputs and taking into consideration the characteristics of the interaction between medical device and body, the intended clinical performance and the manufacturer's arguments. If the conformity of the medical device with basic requirements is to be proven in reliance of performance assessment, comparison test and pre-clinical assessment only, then it should be fully justified.

1.2 All such data should remain confidential according to Article 20 of the present Regulation.

2) Clinical researches:

2.1 Their objectives:

- An assessment of the performance of the medical device under regular conditions of use according to Article (3) of Annex 1;

- An assessment whether it causes an unwanted side effect under regular conditions of use or to see if that effect poses an acceptable risk compared to the intended performance of the medical device.

2.2 Ethical Assessments

Clinical researches should be conducted according to the Declaration of Helsinki which was adopted in the 18th WMA (World Medicine Association) General Assembly held in Helsinki, Finland in 1964 and which was last revised in the WMA General Assembly. All measures intended to protect human health should be applied subject to the Declaration of Helsinki. This Declaration covers all stages of a clinical research from the time when the need is identified to the time when the study's reasons are laid down until the results are published.

2.3 Methods

2.3.1 Clinical researches should be implemented against a plan which reflect scientific and technical data which are current and they should either verify or reject the manufacturer's claims about the medical device. These researches should come up with a sufficient number of observations which guarantee the scientific validity of results.

2.3.2 Methods used to conduct researches should be commensurate with the researched medical device.

2.3.3 Clinical researches should be conducted under conditions that are comparable to the use of the medical device under regular conditions.

2.3.4 All appropriate features and their impact on the patient, including those ones related to the performance and safety of medical device should be examined.

2.3.5 All serious adverse conditions should be fully recorded and should be immediately reported to the country/ countries of the clinical research and to the Ministry together with the name(s) of such country/ countries.

2.3.6 Researches should be conducted by the relevant medical applicator or a competent person in his field in an acceptable environment.

The relevant medical applicator or the competent person with specialism in the relevant field should have technical and clinical data related to the device.

2.3.7 The resultant report should contain a critical assessment of all data gathered throughout the clinical research and should be signed by the relevant medical applicator or other competent person.

ANNEX XI
MINIMUM REQUIREMENTS FOR THE APPOINTMENT OF CERTIFIED BODY

1) The manager of the certified body as well as its personnel who carries out the verification may not also be those persons, or their authorized representatives, who design, manufacture, supply, use or install the medical devices audited by them. Such persons should not be directly involved in the design, manufacturing, marketing or maintenance of the medical devices or should not represent those parties that are directly involved. This should not prevent the exchange of technical information between the manufacturer and the body.

2) Certified body and the relevant personnel should have sufficient knowledge in the field of medical devices and should carry out the assessment and verification in line with the professional ethical rules. They should be particularly isolated from all pressures and monetary incentives from persons and groups who have an interest in the verification results as they may effect the audit results.

A certified body may delegate a part of conformity assessment tasks for which it is assigned to a contractor/ subcontract which meets the requirements of this Annex, in particular, and the Regulation. The certified body shall retain all such documents assessing the qualifications of the contractor/ subcontractor and which are related to the works done by them so that it may submit them to the Ministry if necessary.

A certified body should have such personnel and technical means necessary to proceed with technical and administrative procedures required by the assessment and verification procedures. Moreover, it should employ sufficient number of expert personnel with such profound knowledge and experience allowing them to assess the medical viability and performance of a medical device reported by it, taking into consideration the requirements of the Regulation, in particular, the terms and conditions defined in Annex I. Such equipment necessary for verification should be accessible.

4) The relevant personnel of a certified body shall have the following:

- A professional education which covers all assessment and verification procedures to which he as assigned;
- A sufficient knowledge and audit experience about the rules of the audit operation;
- Skills to issue certificates, records and reports evidencing the audits completed by it.

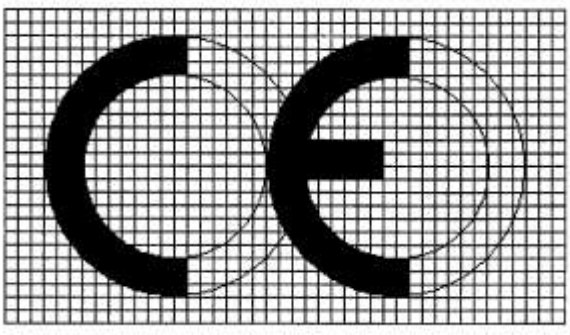
5) A certified body should assure its objectivity. Fees should not be based on the number of audits or their results.

6) A certified body should assume the entire legal liability with respect to all procedures based on the powers granted to it.

7) According to the provisions of the present Regulation, the personnel of the certified body should keep confidential all information that it comes to know in the course of his profession as professional secrets except for the demands by the competent administrative and judicial authorities.

CE CONFORMITY MARK

CE Conformity Mark is made up of the letters “CE”.



- If the mark is enlarged or scaled down, the ratios shown in the drawing above should remain the same.

- Letters in CE mark should have the same style and be in the same vertical dimensions. The vertical dimension may not be less than 5 (five) millimeters. This minimal size shall not be mandatory for small sized medical devices.