CONFORMITY ASSESSMENT OF MEDICAL DEVICES (CE & KFDA)

April 2011

CONFORMITY ASSESSMENT PROCEDURE (CAP)

Before placing a product on the market, the manufacturer must subject the product to a conformity assessment procedure provided in the applicable directive, with the view of affixing the CE marking.

The procedure depends on the risk of the product.

CAP means a method defined by a directive by which the manufacturer demonstrates conformity of the product properties with essential requirements, usually in the presence of a **Notified Body**.

In general, the manufacturer is free to choose conformity assessment procedures (known as modules)

NOTIFIED BODIES (NB)

Third party conformity assessment is carried out by **notified bodies**, which have been designated by the Member States among bodies that fulfill the requirements laid down in the directive and that are established on their territory

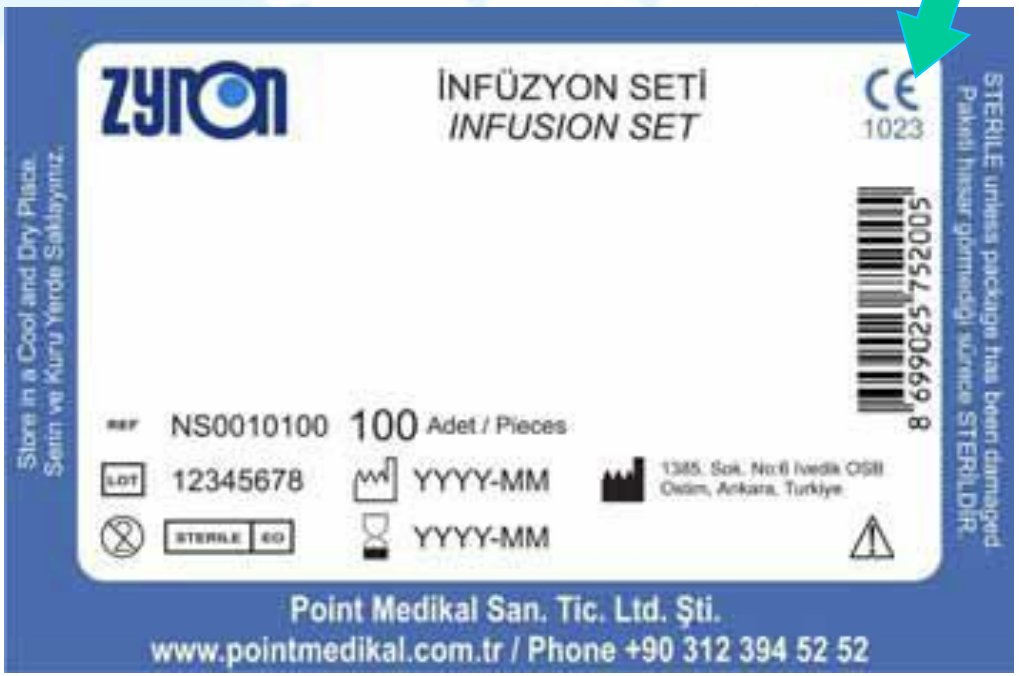
CE Marking

Products in compliance with all provisions of the applicable directives providing for the CE marking must bear this marking.

The CE marking is an indication that the **products comply with the essential requirements** and that the products have been subject to the requested conformity assessment procedure.

MDD, Art. 17 - CE marking

- On the device or its sterile pack
- On instructions for use
- On the sales packaging



DEFINITION of MEDICAL DEVICE

any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation of an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception

... and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

DEFINITION

MANUFACTURER - any natural or legal person responsible for the design, manufacture, packaging and labeling of a medical device and placing it on the market under his own name

INTENDED PURPOSE - the use for which the device is designed; it shall be indicated by the manufacturer on the labeling, in the instructions and/or in promotional materials

PLACING ON THE EU MARKET - the first time making available (against payment or free of charge) on the EU market, regardless of whether it is new or fully refurbished

PUTTING INTO SERVICE - the first time making ready for intended use on the EU market

DEFINITION

Products imported from third countries

Manufacturers located **outside the EC** can export CE marked products to the EC (conformity assessment: self-declaration, or Notified Body).

These manufacturers must designate an authorised representative located in a Member State to act on their behalf

DEFINITION

MANUFACTURER'S REGISTRATION - any manufacturer who, under his own name, places medical devices on the market shall:

- officially register a place of business at least in one EU Member State (MS)
- inform the Competent Authority of the MS on the place of business address
- inform the Competent Authority about class and description of the MD

alternatively, these obligations can fulfill the responsible person appointed by manufacturer

RESPONSIBLE PERSON - where a manufacturer does not have any registered place of business in a Member State, he may not sale medical devices in the EU.

To facilitate the placing of MD´s on EU market, the manufacturer shall designate the person(s) responsible for marketing them who is (are) established in the Community and who assumes the responsibility for registration at Competent Authority.

Role of the Member States (MS)

In this system MS don't deliver pre-market approvals.

MS are not allowed to restrict the placing on the market and putting in service of **CE marked products**, unless such measures can be justified on the basis of evidence of the non-compliance of the product.

MS must protect the CE mark by exerting a market surveillance. The vigilance system is a part of the market surveillance system.

MS are also responsible for the designation and the monitoring of the NBs that are located on their territory.

DEFINITION

MDD 93/42/EEC does not apply to:

- in vitro diagnostic devices
- active implantable devices covered by Directive 90/385/EEC
- medicinal products covered by Directive 2001/83/EC
- cosmetic products covered by Directive 76/768/EEC
- human blood, human blood products, human plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells
- transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin
- transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue

Essential Requirements

- ✓ **General Requirements**
- ✓ **Design & Construction Requirements**
- ✓ **Chemical, Physical and Biological Properties**
- ✓ **Infection and Microbial Contamination**
- ✓ **Construction and Environmental Properties**
- ✓ **Information Supplied by the Manufacturer on the Label and in the Instructions for Use**

The devices shall meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned

Compliance with the essential requirements is the basic pre-requisite of conformity assessment

MDD, Art. 4

Free movement

Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking

Devices intended for special purposes

- ✓ devices intended for clinical investigation
- ✓ custom-made devices

These devices shall not bear the CE marking

Member States may require labeling and instructions for use in their national language

Harmonized Technical Standards

Member States shall presume compliance with the essential requirements in respect of devices which are in conformity to the harmonized standards the references of which have been published in the Official Journal of the European Communities

A survey of harmonized standards for medical devices is extensive and an up-dated version can be found also on web pages

http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/index_en.html

Classification Criteria

Devices are divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX of MDD.

By special rule “breast implants” classification is governed as Class III devices within Directive 2003/12/EC determined

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

Medical devices incorporating as an integral part a derivative of human blood fall within Class III

Reclassification of hip, knee, and shoulder joint replacements

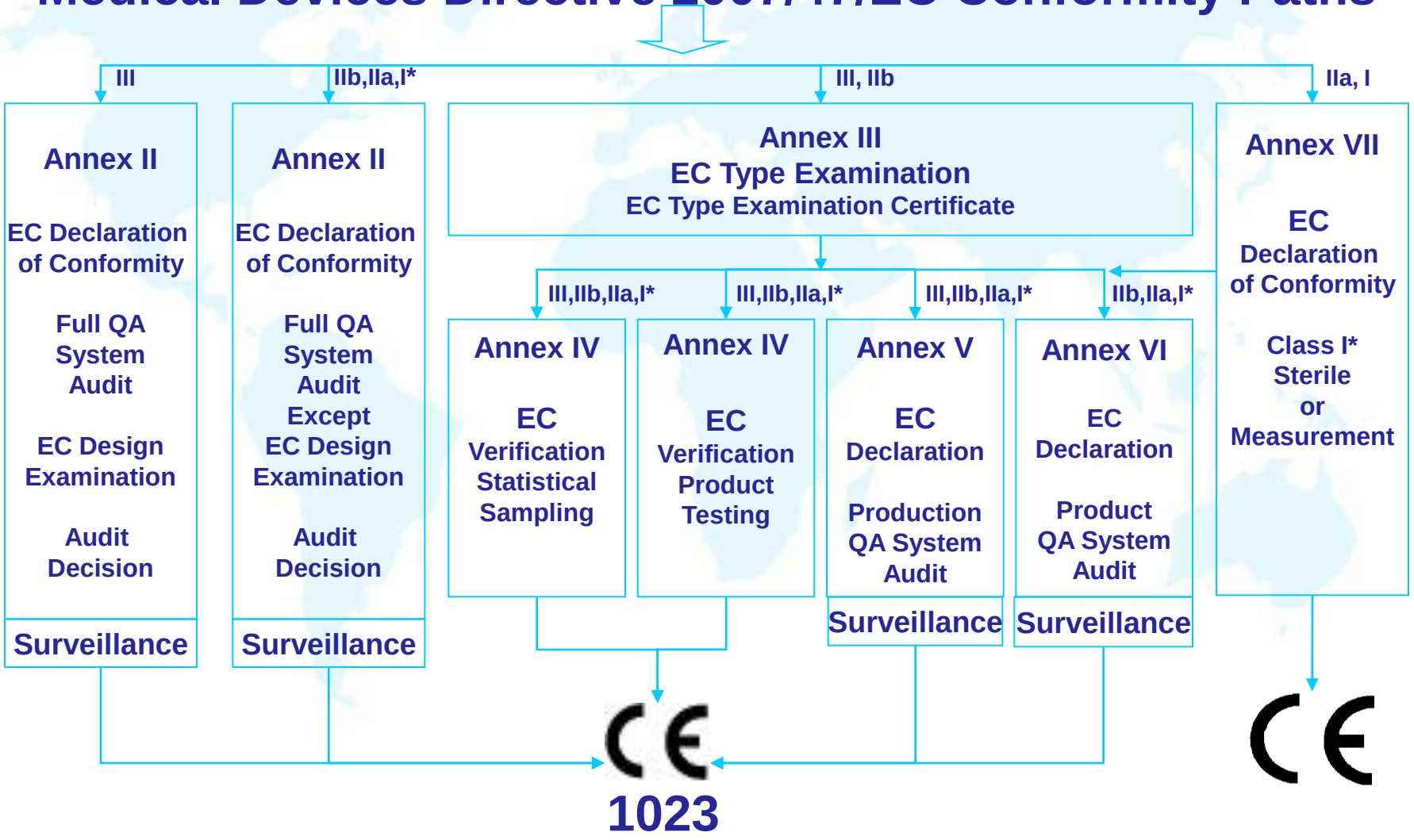
Directive **2005/50/EC** defines that the implantable component parts of total hip, knee and shoulder replacement system to be classified, by derogation to the rules contained in Annex IX of MDD, as **Class III** medical devices.

Member States must apply the provisions of the Directive by the 1st September 2007 with a transition period lasting until 1st September 2009 for devices currently approved under Annex II, and until 1st September 2010, for devices currently approved under Annex V or VI in conjunction with Annex III

CONFORMITY ASSESSMENT PROCEDURE

ITC ASIA

Medical Devices Directive 2007/47/EC Conformity Paths



Selection of Conformity Assessment Procedure

The choice of a conformity assessment procedure depends on inclusion of MD into separate Classes:

Annexes II, III, IV, V, VI and VII - alone or in combination according classes (various possible routes)

Annex VII - mainly for Class I devices

Annex VIII - custom made devices or devices intended for clinical investigation

It is apparent that even in case of MD of the same Class there are more alternatives for selection of a conformity assessment procedure

Selection of Conformity Assessment Procedure

Class I (with measuring function) MDs

Manufacturer´s possibility to choose:

- technical documentation according to Sec. 3 of Annex VII and verification of the conformity with metrological requirements on each piece or on a statistically selected sample according to Annex IV
- Annex VII technical documentation according to Sec. 3 and assessment of production quality system according to Annex V related to metrological requirements
- Annex VII technical documentation according to Sec. 3 and quality assessment of MD according to Annex VI related to metrological requirements

Selection of Conformity Assessment Procedure

Class I sterile MDs

Manufacturer proceeds as follows:

- technical documentation according to Sec. 3 Annex VII and assessment of production quality system according to Annex V related to sterile conditions

Selection of Conformity Assessment Procedure

Class IIa medical devices

Manufacturer´s possibility to choose:

- technical documentation according to Sec. 3 of Annex VII and verification of the conformity with the technical documentation on each piece or on a statistically selected sample according to Sec. 8 of Annex IV
- technical documentation according to Sec. 3 of Annex VII and assessment of production quality system according to Sec. 6 of Annex V (by an audit at the manufacturer's sites)

Selection of Conformity Assessment Procedure

Class IIa medical devices (*contd.*)

Manufacturer´s possibility to choose:

- technical documentation according to Sec. 3 of Annex VII and assessment of medical device quality according to Sec. 6 of Annex VI (by an audit at the manufacturer's sites)

- technical documentation according to Sec. 3 of Annex VII and assessment of full quality system by an audit at the manufacturer's sites according to Annex II (except design examination according to Sec. 4)

Selection of Conformity Assessment Procedure

Class IIb medical devices

Manufacturer´s possibility to choose:

- technical documentation according to Section 3 of Annex III, examination of type and verification of conformity of each piece manufactured; the verification is done according to Section 5 or on a statistically (randomly) selected sample according to Section 6 of Annex IV
- technical documentation according to Section 3 of Annex III, examination of type and assessment of production quality system according to Annex V (by an audit of the manufacturer's sites)

Selection of Conformity Assessment Procedure

Class IIb medical devices *(continued)*

Manufacturer´s possibility to choose:

- technical documentation according to Section 3 of Annex III, examination of type and assessment of medical device quality according to Section 6 of Annex VI (by an audit at the manufacturer's sites)
- technical documentation according to Section 3.2 of Annex II and assessment of full quality system by an audit at the manufacturer's sites according to Annex II (except design examination according to Section 4)

Selection of Conformity Assessment Procedure

Class III medical devices

Manufacturer´s possibility to choose:

- technical documentation according to Section 3.2 of **Annex II**, description of the design according to Section 4.2 and assessment of full quality system according to **Annex II** (by an audit at the manufacturer's sites)
- technical documentation according to Section 3 of **Annex III**, examination of type and verification of conformity of each piece produced; the verification is done according to Section 5 or on a statistically (randomly) selected sample according to Section 6 of **Annex IV**

Selection of Conformity Assessment Procedure

Class III medical devices *(continued)*

Manufacturer´s possibility to choose:

- technical documentation according to Section 3 of **Annex III** and Section 3.2 of **Annex V**, examination of type and assessment of production quality system (by an audit of the manufacturer's sites)

Note: Annual surveillance audit is carried out by using Annexes II, V and/or VI within conformity assessment procedure

Conformity Assessment for MD systems and MD Sets

A special procedure described in Section 12 of the MDD

The person (natural or legal) assembling MDs bearing CE marking and intending to place them on the market as a system or a set will elaborate a declaration in which he/she states that:

- ✓ he/she has verified mutual compatibility of the assembled MDs according to instructions of their manufacturers
- ✓ he/she has packed the system or set and added to it a corresponding information for users including instruction by manufacturers of separate medical devices
- ✓ activity of this person in assembling the set of MD corresponds to internal inspection methods

Conformity Assessment for MDs Containing Animal Tissues

Tissues derived from some kinds of cattle, sheep or goats, and further from deer, elks, minks and cats as specified within Directive **2003/32/EC**

- procedure according to one of the possibilities given for Class III MDs
- additional requirement is elaboration of specifications established in Risk analysis and risk control (Annex to Directive 2003/32/EC) contains:

✓ the information supplied by the manufacturer,
✓ reasons given for use of the tissues or derivatives of animal origin,
✓ results of elimination or deactivation studies or searches of technical literature,
✓ inspection of suppliers, original materials and final products conducted by the manufacturer
✓ the necessity to verify the origin of the initial materials, including deliveries from manufacturer's suppliers

Conformity Assessment of MDs Incorporating a Medicinal Substance with Anciliary Action

- incorporate substances as an **integral part**, which, if used separately, may be considered to be a medicinal product
- CA procedure for Class III device determined
- Notified Body shall consult the safety, quality and usefulness of the substance one of the competent bodies established by the Member States in accordance with Directive 2001/83/EC before taking a decision (*the MDD - Annex 1, section 7.4*)

The consultation process is described in detail within MEDDEV 2. 1/3 rev 2, July 2001, *Demarcation between: Directive 90/385/EEC on AIMDs, Directive 93/42/EEC on MDs, and Directive 65/65/EEC relating to Medicinal Products and related Directives*

Conformity Assessment of MDs Containing a Substance from Human Blood or Plasma

- incorporating, as an integral part a substance, which, if used separately, can be considered as a component of a medicinal product or a medicinal product originating from human blood or human plasma (pursuant to Directive 2001/83/EC)
- CA procedure for Class III device determined
- NB shall ask the European Agency for the Evaluation of Medicinal Products (EMEA) for a scientific viewpoint concerning quality and safety of the derivative and verify usefulness of this derivative as a part of the medical device in connection with its intended purpose of use (Section 7.4 of Annex I the MDD in wording Directive 2000/70/EC and Directive 2001/104/EC)
- if scientific viewpoint is unfavorable NB may not issue the certificate
- NB will inform EMEA of its final decision

Conformity Assessment of MDs Containing a Substance from Human Blood or Plasma

The sample of each batch of bulk or final product of this derivative shall be examined in the appropriate laboratory appointed for this purpose by the member state of the European Communities (in compliance with amendments to Annexes II, III, IV and V determined in Directive 2000/70/EC)

The manufacturer will inform the Notified Body about the release of this batch of the MD and send to it an official certificate on release of the batch of the derivative from human blood used in the MD issued by the appropriate laboratory

Revision of the directive 93/42/EEC (MDD)

Each directive is revised every five years

During the revision of MDD it was estimated that the system was good in general but that there was a need for improvements or clarification on various aspects

Directive 2007/47/EEC amending Directive 93/42/EEC can be found on the European Commission website.
http://ec.europa.eu/enterprise/medical_devices/index_en.htm

We detail here the main changes

Definition of MD:

- Software on its own appears now clearly in the definition
- Diagnostic and/or medical purpose in the definition

More details are provided regarding clinical evaluations

Need for authorised representative clearly expressed for all manufacturers not having a registered place of business in a member state

Custom-made devices:

- post market vigilance system as other devices
- delivery of declarations of conformity to the patient

Extension of European Database to data related to clinical investigations

- **Information on refused clinical investigations communicated to other member states**

Measures to increase transparency:

- **information public about e.g. CE certificates**
- **possibility to make other information public by comitology**

Better coordination and communication of market surveillance activities

Amendments of the other directives to bring these in-line

Korean Regulatory System

The Ministry of Health and Welfare (MHW) is the primary healthcare agency regulating the medical devices.
Under Korea's Medical Devices Act, the Korea Food and Drug Administration (KFDA), an agency under MHW, independently regulates all medical devices.
The Medical Devices Act, passed by Korea's National Assembly in 2003, is now fully in force with the requirement that all medical devices sold in Korea meet Good Manufacturing Practices (KGMP).
Imported medical devices require an original Certificate to Foreign Government (CFG) by the appropriate regulatory body in the product's country of manufacture before they can be sold in Korea.
KFDA requires foreign manufacturers to have local partners or a physical presence (business registration, along with office and warehouse space) in Korea rather than interact with regulators directly. All foreign suppliers must apply for either a manufacturing or importer business license in order to market medical devices.

Definition of Korea Medical Device Law for Registration

- Manufacturer: Based on real Manufacturing site
- Responsible manufacturer: legal manufacturer
- License holder or representative: local importer
- Amendment/changes: change of existing license in case of changes, which doesn't influence on the safety and performance of products.

manufacturer" means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

In Vitro Diagnostic (IVD) instruments and some reagents in it are classified as Class I products; however, most IVD reagents are categorized as pharmaceutical products. Separate regulatory approval procedures exist for IVD instruments and manual reagents.

Classification Criteria

Devices are divided into Classes I, IIa, IIb and III by CE. Classification shall be carried out in accordance with Annex IX of MDD.

KFDA Classification	Risk classification	Approval or Certification
Class 4	High risk	Product approval by KFDA Clinical data
Class 3	Medium risk	Product approval by KFDA
Class 2	Low risk	Product approval by KFDA
		Technical document review by Review Agency
Class 1	Extremely low risk	Product notification to KFDA

Thank you.

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