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# Proposed Document

**Title: Egyptian Regulation for Medical Devices**

**Reference**

European Medical Device Regulation 93/42/EEC and its amendment 2007/47/EC  
Global Harmonization Task Force Final Documents

**The document is intended to provide binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.**

**Endorsed by:** The Egyptian Supreme Consultative Committee to develop rules regulating devices and medical supplies – Ministry of Health

**The proposed effective date for these regulations is -----**

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## Scope:

1. This Regulation shall apply to medical devices and their accessories. For the purposes of this Regulation, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

2. Products which combine a medicinal substance with a medical device are regulated in one of the following ways:

- **Drug-delivery products presented as an integral combination with a medicinal product are regulated as medicinal products**

e.g. pre-filled syringes

- **Drug-delivery products presented separately from the medicinal product are regulated as medical devices**

e.g. drug delivery pump

- **Medical devices incorporating, as an integral part, an ancillary medicinal substance**

e.g. catheters coated with heparin or an antibiotic agent

These products are subject to devices control but the ancillary medicinal substance must be verified by analogy with data requirements in medicines legislation, and The Technical Pharmaceutical Committee must be consulted.

3. **Medical devices incorporating, as an integral part, an ancillary human blood derivative' ,**

These products are subject to devices control but the ancillary human blood derivative must be verified by analogy with data requirements in medicines legislation, and The Technical Pharmaceutical Committee must be consulted.

4. This Regulation shall not apply to:

(a) In Vitro Diagnostic Devices (IVD);

(b) Active Implantable Devices (AIMD);

(c) Medicinal products

In deciding whether a product is a medical device or a medicinal product, particular account shall be taken of the principal mode of action of the product;

(d) Cosmetic products

(e) Human blood, blood products, 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, with the exception of devices referred to in paragraph 3;

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\* A substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human Blood or human plasma and which is liable to act upon the human body with action ancillary to that of the device



(f) Transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 3;

(g) 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.

**5.** This Regulation does not apply to personal protective equipment. In deciding whether a product falls under this Regulation, particular account shall be taken of the principle intended purpose of the product:

- **If the product is intended to be used in a medical context with the aim to provide protection of health and safety for the patient, regardless of whether the product aims simultaneously to protect also the user.**

**Examples for medical devices**

- Surgical gloves, examination gloves
- face masks
- Corrective glasses (including those intended at the same time for sun protection)
- Surgeons gowns and hats

- **\*Where a product is mainly intended to protect the person using it, irrespectively whether in a medical environment or not, it falls under Regulation of personal protective equipment.**

**Examples for personal protective equipment**

- Protective gloves (for example, for use in a medical laboratory)
- Clothing for protection against ionizing radiation
- Sun glasses
- Eye protection devices for professional use (for example, for welders, regardless of whether or not they contain corrective glasses adapted to the need of the user)
- gum shields for boxers.

The labeling of the product is crucial for its classification under this or the other Regulations



## Article 1

# Definitions

For the purposes of this Regulation, the following definitions shall apply:

### **Medical Device\***

‘Medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for 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 of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception,

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

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\* Ref. European MDD 2007/47/EC, Article 1



### **Medical Device-Key Points\*:**

- Principle mode of action must be physical(as opposed to pharmaceutical)
- Must be for use on Humans(Not animals)
- Must have a medical purpose
- Can be a Software if fulfilling the above

-**“Pharmacological”**, means an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.

**“Immunological”**, means an action in or on the body by stimulation and/or mobilization of cells and/or products involved in a specific immune reaction.

**“Metabolic”**, means an action which involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function.

### **In Vitro for the Examination\*\***

**(The regulation of IVD will be defined in a separate Guideline)**

Means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- Concerning a physiological or pathological state,
- Concerning a congenital abnormality,
- To determine the safety and compatibility with potential recipients,
- To monitor therapeutic measures.

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\* Ref. MEDDEV 2. 1/3 rev 2

\*\* Ref. European MDD 2007/47/EC, Article 1



**Specimen Receptacles** are considered to be in vitro diagnostic -medical devices.

‘Specimen Receptacles’ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

- **Products for General Laboratory Use** are **not** in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

**Medical Devices:** used Directly on the patient\*

**In Vitro Diagnostic:** are used in vitro to perform diagnosis based on a sample taken from the patient (Don't usually touch the patient)

## Accessories\*\*

Means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a parent' medical device to enable that medical device to achieve its intended purpose by the manufacturer of the device, should be subject to the same procedures as applicable to the medical device itself.

For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification than the 'parent' device.

### Examples for accessories depending on defined circumstances of device related use:\*\*\*

- Sterilizers for use in a medical environment,
- Pouches for packaging re-sterilized medical devices,
- Specific battery chargers for battery driven electro medical devices,
- Contact lens care products, disinfectants specifically intended for invasive medical devices
- Special water treatment device for use in conjunction with dialyzing machines,
- Gas cylinders/pressure release devices for use in conjunction with anesthesia machines.

## Components to Medical Devices\*\*\*\*

Means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device

Components to medical devices are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device.

\* Ref. MEDDEV 2. 14/1

\*\* MDD 2007/47/EC

\*\*\* Ref. MEDDEV 2. 1/1)

\*\*\*\*FD&C Act (820.3(e))



## 'Custom-made device'

- Means any device specifically made in accordance with a duly qualified medical practitioner's written prescription or any other person authorized by virtue of his professional qualifications, which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient
- Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not considered to be custom-made devices

## 'Device intended for clinical investigation'

- Means any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Section 2.1 of Annex X of European MDD 93/42/EEC and its amendment 2007/47/EC in an adequate human clinical environment.
- For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner\*

## 'Manufacturer'

Means the natural or legal person with responsibility for the design, manufacture, packaging and labeling of a device before it is placed on the market under his own name

In case the operations above are carried out by a third party on behalf of the manufacturer, the following conditions are applied:

### **- For Local Manufacturing:**

#### **(i) Intending export only**

A local manufacturer can manufacture a medical device for a foreign company without entailing medical device registration on condition that:

- The Manufacturer shall submit a declaration stating that the medical device is manufactured for the purpose of exportation only and not for sale in the Egyptian market.
- The Manufacturer shall submit a legalized copy of the contract between the two parties to the MOH.

#### **(ii) Intending local sales**

- Shall follow normal registration procedures.
- \*Country of origin of both the Actual Manufacturer & Legal Manufacturer should be stated on all labels of the medical device and its packages in accordance to the provisions of Egyptian law.

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\* To be consulted with the Legal Department



**- For Imported Medical Devices:**

Country of origin of both the Actual Manufacturer & Legal Manufacturer should be stated on all labels of the medical device and its packages in accordance to the provisions of Egyptian law .

**'Intended purpose'**

Means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

**'Placing on the market'**

means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

**'Putting into service'**

Means the stage at which a device is ready for use on the Community market for the first time for its intended purpose.

**'Authorized representative' \***

Means any natural or legal person established in Egypt who, explicitly designated by the foreign manufacturer, acts and may be addressed by authorities and bodies in Egypt instead of the manufacturer with regard to the latter's obligations under this Regulation;

**"Market", "Community market"**

Wherever mentioned, and is not specified within the context of this regulation, shall solely mean the Egyptian market.

**Clinical data**

Means the safety and/or performance information that is generated from the use of a device.  
Clinical data are sourced from:

- Clinical investigation(s) of the device concerned;
- Clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated;
- Published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;

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\* To be consulted with the Legal Department



**'Device subcategory**

' means a set of devices having common areas of intended use Or common technology;

**'Generic device group'**

means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics; '

**'Single use device'**

Means a device intended to be used once only for a single patient

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Article 2

**Placing on the market and putting into service**

- MOH shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Regulations when duly supplied and properly installed, maintained and used in accordance with their intended purpose
  - All medical devices whether intended to be placed on the market or put into service must be registered before they can be marketed.
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Article 3

**Essential Principles and Evidence of Conformity Requirements**

- The devices must meet the essential requirements set out in Annex I of European medical directive MDD 93/42/EEC and its amendment 2007/47/ EC which apply to them, taking account of the intended purpose of the devices concerned.

Where a relevant Hazards exists, devices which are also machinery (within the meaning of Article 2 (a) of European Directive 2006/42/EEC of the European Parliament) shall also meet the essential health and safety requirements set out in Annex I of that Directive to the extent to which those essential requirements are more specific than the essential requirements set out in Annex I of European medical directive MDD 93/42/EEC and its amendment 2007/47/ EC.

The manufacturer shall keep objective evidence to establish that the medical device meets those requirements and have available for review by MOH.

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## Article 4

### Reference to standards

1. MOH shall presume compliance with the essential Principles and Evidence of Conformity requirements referred to in Article 3 in respect of devices which are in conformity with the relevant Egyptian national standards\* adopted pursuant to the harmonized standards
2. For the purposes of this Regulation, reference to harmonized standards also includes the monographs of the European Pharmacopoeia notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products,
3. If MOH considers that the harmonized standards do not entirely meet the Essential Principles and Evidence of Conformity Requirements referred to in Article 3, the measures to be taken by The MOH with regard to these standards and the publication shall be adopted by the procedure defined in Article 5.

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## Article 5

### Committee on Standards and Technical Regulations.

1. The MOH shall be assisted up by a Standing Committee consisting of representatives appointed by the MOH who may call on the assistance of experts or advisers; its chairman shall be a representative of the MOH. The Committee shall draw up its own rules of procedure.
2. The representative of the MOH shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member shall have the right to ask to have its position recorded in the minutes.

The MOH shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account

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\*Standards issued by Egyptian Organization for Standardization and Quality (EOS)



## Article 6

### **Classification.**

1. Medical device is to be classified into 4 classes 1(I), 2 (IIa), 3 (IIb) and 4 (III) depending upon the risk it imposes during its use

Classification shall be carried out in accordance with rules set out at Principles of medical device classification Annex IX of European medical directive MDD 93/42/EEC and its amendment 2007/47

If a medical device can be classified into more than one class, the class representing the higher risk applies.

2. In the event of a dispute between the manufacturer and the MOH, resulting from the application of the classification rules, the matter shall be referred for decision to the committee on standards and technical regulation referred to in Article 5.

3. Where MOH considers that the classification rules set out in Annex IX of European medical directive MDD 93/42/EEC and its amendment 2007/47 require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 18, it may submit a duly substantiated request to the committee on standards and technical regulation referred to in Article 5 and ask it to take the necessary measures for adaptation of classification rules. The measures designed to amend non-essential elements of this Regulation relating to adaptation of classification rules shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 5 .

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## Article 7

### **Decisions with regard to classification, and derogation clause**

1. MOH concerned department shall submit a duly substantiated request to the committee on standards and technical regulation referred to in Article 5 and ask it to take the necessary measures in the following situations:

(a) That MOH considers that the application of the classification rules set out in Annex IX of European medical directive MDD 93/42/EEC and its amendment 2007/47/EC requires a decision with regard to the classification of a given device or category of devices;

(b) That MOH considers that a given device or family of devices should, by way of derogation from the provisions of Annex IX of European medical directive MDD 93/42/EEC and its amendment 2007/47 be classified in another class;



(c) That MOH considers that the conformity of a device or family of devices should, by way of derogation from Article 9, be established by applying solely one of the given procedures chosen from among those referred to in Article 9

(d) That MOH considers that a decision is required as to whether a particular product or product group falls within one of the definitions in Article 1

The measures referred to in the first subparagraph of this paragraph shall, as appropriate, be adopted in accordance with the procedure referred to in Article 5

2. The committee on standards and technical regulation referred to in Article 5 shall inform MOH of the measures taken.

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## Article 8

### Clinical investigation

1. In the case of devices intended for clinical investigations, the manufacturer or the authorized representative, established in Egypt, shall follow the procedure referred to in Annex VIII and notify MOH by means of the statement mentioned in **Section 2.2 of Annex VIII of European medical directive MDD 93/42/EEC and its amendment 2007/47/ EC.**

2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after MOH notification, unless MOH have notified the manufacturer within that period of a decision to the contrary based on considerations of public health or public policy. MOH may however, authorize manufacturers to commence the relevant clinical investigations before the expiry of the period of 60 days, insofar as the relevant ethics committee has issued a favorable opinion on the programme of investigation in question, including its review of the clinical investigation plan.

3. In the case of devices other than those referred to in paragraph 2, MOH may authorize manufacturers to commence clinical investigations immediately after the date of notification, provided that the ethics committee concerned has issued a favorable opinion on the programme of investigation in question including its review of the clinical investigation plan.

4. The clinical investigations must be conducted in accordance with the provisions of Annex X of European medical directive MDD 93/42/EEC and its amendment 2007/47/ EC.

5. MOH shall, if necessary, take the appropriate steps to ensure public health and public policy.

6. The manufacturer or his authorized representative shall notify MOH of the end of the clinical investigation, with a justification in case of early termination. The manufacturer or his authorized representative shall keep the report referred to in



Section 2.3.7 of Annex X of European medical directive MDD 93/42/EEC and its amendment 2007/47/ EC at the disposal of MOH

7. The provisions of paragraphs 1 and 2 do not apply where the clinical investigations are conducted using devices which are authorized in accordance with Article 9 unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The relevant provisions of Annex X remain applicable.

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## Article 9

### **Conformity assessment procedures**

The following conformity assessment elements are required for each medical device regardless its classification:

1. A quality management system,
2. A system for post-market surveillance,
3. Summary technical documentation,
4. A declaration of conformity and
5. Licensing of the manufacturer and Registration its medical devices by the MOH.

The extent of application and relevant standards of the above requirements is detailed in the corresponding Annexes (E) of this Regulation. The decision about satisfaction of the Conformity Assessment Elements shall be left discretionary to MOH through Committees referred to in Article 5.

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## Article 10

### **Third Party Review**

1. The MOH may notify Third parties for carrying out the tasks pertaining to the procedures referred to in Article 9 hereinafter referred to as 'Third Party'. The Responsibilities of MOH & Third Party will be defined in the corresponding Annex that will be attached to this Regulation.

The MOH shall publish a list of the recognized 'Third Parties' and the tasks for which they have been notified, on the MOH Website. It shall ensure that the list is kept up to date.

2. MOH shall apply the criteria set out in Annex (F) of to this Regulation for the designation of Third Parties. Third parties that meet the criteria laid down in the national standards which transpose the relevant harmonized standards shall be presumed to meet the relevant criteria.

When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in the corresponding Annex that will be attached to this



Regulation for the designation of Third Parties by the MOH shall be adopted in accordance with the regulatory procedure referred to in Article 5.

3. The MOH shall withdraw its recognition of a third party if it finds that such Third party no longer meets the criteria referred to in paragraph 2. It shall immediately be published on the MOH Website

4. The Third Party' and the manufacturer, or his authorized representative shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in article 9.

5. The Third Party' shall inform MOH about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other Third Party within the scope of this Directive regulation about certificates suspended, withdrawn or refused and, on request, about certificates issued. The Third Party shall also make available, on request, all additional relevant information.

6. Where a Third Party finds that pertinent requirements of this regulation have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the MOH may become necessary, the Third party shall inform MOH thereof.

7. The Third Party shall, on request, supply all relevant information and documents, required to enable the MOH to verify compliance with Annex (F).

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## Article 11

### **Particular procedure for systems and procedure packs and procedure for sterilization**

1. By way of derogation from Article 9 this Article shall apply to control and inspection Systems and procedure packs.

2. Any natural or legal person who puts devices bearing the Registration Number together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack a new registration process is not required. However the manufacturer shall draw up a declaration by which he states that:

- A. He has verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and
- B. He has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- C. The whole activity is subjected to appropriate methods of internal control and inspection.



This declaration will be verified by Committee referred to in Article 5 and a new Registration Number will be applied to the system or procedure pack.

Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a Registration Number or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant procedure pursuant to Article 9.

3. Any natural or legal person who sterilizes, for the purpose of placing on the market, systems or procedure packs referred to in paragraph 2 or other medical device that bear a Registration Number, designed by their manufacturers to be sterilized before use shall, at his choice, follow one of the procedures referred to in Article 9. The application of one of the procedures referred to in Article 9 and the intervention of the Third party review are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged. The person shall draw up a declaration stating that sterilization has been carried out in accordance with the manufacturer's instructions.

4. The products referred to in paragraphs 2 and 3 themselves shall be accompanied by the information referred to in point 13 of Annex I which includes, where appropriate, the information supplied by the manufacturers of the devices which have been put together. The declarations referred to in paragraphs 2 and 3 shall be kept at the disposal of the MOH for a period of five years.

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#### Article 11a

### **Reprocessing of medical devices**

All medical devices intended for single use are prohibited from being reprocessed

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#### Article 12

### **The Registration Number.**

1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear their Registration Number when they are placed on the market.

2. The Registration Number, according to annex (H) of this Regulation, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the Registration Number must also appear on the



sales packaging.

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

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### Article 13

#### **Free movement, devices intended for Special purposes**

1. MOH shall not create any obstacle to the placing on the market or the putting into service within Egypt for devices bearing the Registration Number provided for in Article 12 which indicates that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 9.

2. MOH shall not create any obstacle to:

- devices intended for clinical investigation being made available to medical practitioners or authorized persons for that purpose if they meet the conditions laid down in Article 8, and in Annex VIII, of European medical directive 93/42/EEC and its amendment 2007/47/EC
- Custom-made devices being placed on the market and put into Service if they meet the conditions laid down in Article 9 in combination with Annex VIII of European medical directive 93/42/EEC and its amendment 2007/47/EC; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex VIII. which shall be available to the particular patient identified by name, an acronym or a numerical code.

These devices shall not bear the Registration Number.

3. Devices intended for trade fairs, exhibitions, demonstrations shall be exempted of prior registration within MOH. However, they should receive prior approvals by MOH for each medical device, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply with the regulation.



## Article 14

### **Registration of persons responsible for placing devices on the market**

1. Any manufacturer who, under his own name, places devices on the market in accordance with the procedures referred to in Article 9 and any other natural or legal person engaged in the activities referred to in Article 11 shall inform the MOH in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned.
2. Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Egypt, he shall designate a single authorized representative. The authorized representative shall inform the MOH of the details referred to in paragraph 1.

## Article 15

### **Safeguard clause**

- 1- Where MOH ascertains that the devices referred to in Article 13 (1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The MOH shall indicate the reasons for its decision and, in particular, whether non-compliance with this Regulation is due to:
  - (a) Failure to meet the essential Principles and Evidence of Conformity requirements referred to in Article 3
  - (b) Incorrect application of the standards referred to in Article 4 in so far as it is claimed that the standards have been applied;
  - (c) Shortcomings in the standards themselves
2. MOH through the committee referred to in Article 5 shall enter into consultation with the Parties concerned as soon as possible. Where, after such consultation, MOH finds that:
  - (a) The measures are justified:
    - (i) Will take the decision intends to maintain it and shall initiate the advisor procedure referred to in Article 5;
    - (ii) When necessary in the interests of public health, appropriate measures designed to amend nonessential elements of this regulation relating to withdrawal from the market of devices referred to in paragraph 1 or to prohibition or restriction of their placement on the market or being put into service or to introduction of particular requirements in order for such products to be put on the market shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 5.
  - (b) The measures are unjustified; it shall immediately take the measures and the manufacturer or his authorized representative.
3. Where a non-complying device bears registration number, MOH shall take appropriate action against the manufacturer or his authorized representative.



## Article 16

### **Wrongly affixed Registration Number**

(a) Where MOH establishes that the Registration Number has been affixed unduly or is missing in violation of the Regulation, the manufacturer or his authorized representative shall be obliged to end the infringement under conditions imposed by the MOH;

(b) Where non-compliance continues, the MOH must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 15.

Those provisions shall also apply where the Registration Number has been affixed in accordance with the annex (E) and (G) of this Regulation, but inappropriately, on products that are not covered by this Regulation.

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## Article 17

### **Decision in respect of refusal or restriction**

1. Any decision taken pursuant to this Regulation:

(a) To refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations;

Or

(b) To withdraw devices from the market, shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in Egypt in question and of the time limits to which such remedies are subject.

2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.

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## Article 18

### **Information on incidents occurring following placing of devices on the market**

1. MOH shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Regulation, regarding the incidents mentioned below involving a Class I, IIa, IIb or III device is recorded and evaluated centrally:



- (a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
- (b) Any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

2. Where MOH requires medical practitioners or the medical institutions to inform the MOH of any incidents referred to in paragraph 1, it shall take the necessary steps, to ensure that the manufacturer of the device concerned, or his authorized representative, is also informed of the incident.

3. After carrying out an assessment, if possible together with the manufacturer or his authorized representative, MOH shall, take measures to minimize the recurrence of the incidents referred to in paragraph 1, including information on the underlying incidents.

4. Any appropriate measures to adopt procedures to implement this Article shall be adopted in accordance with the regulatory procedure referred to in Article 5.

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## Article 19

### **Confidentiality**

1. Without prejudice to the existing national provisions and practices on medical confidentiality, all the Parties involved in the application of this Regulation are bound to observe confidentiality with regard to all information obtained in carrying out their tasks.

This does not affect the obligation of MOH and Third party with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

2. The following information shall not be treated as confidential:

(a) Information on the registration of persons responsible for placing devices on the market in accordance with Article 14;

(b) Information to users sent out by the manufacturer, authorized representative or distributor in relation to a measure according to Article 18;

(c) Information contained in certificates issued, modified, supplemented, Suspended or withdrawn.

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Article 20

## Language requirement

Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer such as label and instruction for use must be made available to the user and the patient at least in Arabic language, regardless of whether it is for professional or other use.

Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colors must be described in the documentation supplied with the device

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### References:

ANNEX (A)	Quality system requirements	
ANNEX (B)	Summary of technical information	
ANNEX (C)	Post market and notification requirements	
ANNEX (D)	Declaration of conformity	
ANNEX (E)	Conformity assessment procedure	
ANNEX (F)	Third party review	
ANNEX (G)	Establishment & device Registration	
ANNEX (H)	The registration number	
ANNEX (I)	Medical Devices for Clinical Investigation	Annex X of European MDD 93/42/EEC and its amendment 2007/47/EC. Annex VIII of European medical directive MDD 93/42/EEC and its amendment 2007/47/ EC.
ANNEX (J)	Classification	Annex IX of European medical directive MDD 93/42/EEC and its amendment 2007/47/EC
ANNEX (K)	Essential Principles and Evidence of Conformity Requirement	Annex I of European medical directive MDD 93/42/EEC and its amendment 2007/47/ EC