Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 18,308, 12 ta' Settembru, 2008
Taqsima B

L.N. 211 of 2008

PRODUCT SAFETY ACT (CAP. 427)

Active Implantable Medical Devices Regulations, 2008

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, the Minister of Finance, Economy and Investment, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation and commencement.

1. (1) The title of these regulations is the Active Implantable Medical Devices Regulations, 2008.

(2) These regulations transpose the following Directives:

a) Council Directive 90/385/EEC[1] of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices; and

b) Directive 2007/47/EC[2] of the European Parliament and of the Council of 5 September 2007 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.

(3) These regulations shall enter into force on the 21st March, 2010.

(4) The following transitional measures shall remain applicable:

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[1] OJ L.189, 20-07-1990, p.17. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty (OJ No. L. 284, 31-10-2003, p.1).

[2] OJ L.247, 21-09-2007, p.21.

(a) CE marking shall not be obligatory prior to the 1st October 2001 in respect of stocks of active implantable medical devices already placed on the market prior to 1st April 2001 and active implantable medical devices ordered before 1st April 2001 and imported into Malta up to 30th September 2001; and

(b) The provisions of these regulations shall not apply to contracts made before 1st April 2001, covering the supply of active implantable medical devices to the Government of Malta over the period up to and including 31st December 2002, as well as those contracts which had terminated before 1st April 2001 or which, before 1st April 2001, were determined or dissolved by agreement or by a judgement which had become a *res judicata*, or by operation of the law; in respect of such contracts the law applicable at the time, including the time of their termination, determination or dissolution, shall in so far as necessary, continue to apply.

Scope.

2. (1) These regulations shall apply to active implantable medical devices.

(2) (a) For the purposes of these regulations, the Regulatory Affairs Directorate will act as the Maltese national competent authority in terms of the Committee referred to in Article 6 of Directive 93/42/EEC and with respect to the exchange of information, necessary to enable these regulations to be applied uniformly, with other Member States and the Commission.

(b) For the purposes of these regulations, the Regulatory Affairs Directorate will act as Malta's national competent authority with respect to exchange of experience organised by the Commission in order to coordinate the uniform application of these regulations.

Definitions.

3. For the purposes of these regulations, the following definitions shall apply:

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

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

"authorised representative" means any natural or legal person established in the Community or Malta who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community or Malta instead of the manufacturer with regard to the latter's obligations under these regulations;

"CE marking" means marking as set out in Schedule IV of these regulations;

"clinical data" means the safety and, or performance information that is generated from the use of a device. Clinical data are sourced from:

(a) any clinical investigation of the device concerned; or

(b) any clinical investigation or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or

(c) 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;

"the Community" means the European Community;

"custom-made device" means any device specifically made in accordance with a duly qualified medical practitioner's written prescription 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 be 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 clinical investigations as referred to in Section 2(a) of Schedule VII to these regulations in an adequate human clinical environment. For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorised to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

"harmonised standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with the Notification Procedure Regulations, 2003;

L.N. 373 of 2003.

"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 material;

"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, regardless of whether these operations are carried out by that person himself or on his behalf by a third party:

(a) the obligations of these regulations to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and, or labels one or more ready-made products and, or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name;

(b) paragraph (a) hereof does not apply to the person who, while not a manufacturer within the meaning of this definition, assembles or adapts devices already on the market to their intended purpose for an individual patient;

"Market Surveillance Directorate" means the Market Surveillance Directorate of the Malta Standards Authority as described in the Establishment of Directorates of the Malta Standards Authority Order, 2008;

L.N. 39 of 2008.

"medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, 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:

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(c) investigation, replacement or modification of the anatomy or of a physiological process,

(d) control of conception,

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

"national standard transposing the harmonised standard" means a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be identical to the Harmonised Standard originally issued by CEN/CENELEC/ETSI;

"notified body" means a body notified to the Commission and to the Member States of the Community, assessed according to the criteria laid down in Schedule VIII to these regulations and appointed to carry out the procedures referred to in regulations 11(1) to (7) of these regulations. The names of such bodies are published in the OJ;

"OJ" means the Official Journal of the European Union;

"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 or Maltese market, regardless of whether it is new or fully refurbished;

"putting into service" means making available to the medical profession for implantation.

"Regulatory Affairs Directorate" means the Regulatory Affairs Directorate of the Malta Standards Authority as described in the Establishment of Directorates of the Malta Standards Authority Order, 2008. L.N. 39 of 2008.

4. (1) Where an active implantable medical device is intended to administer a substance defined as a medicinal product within the meaning of article 2 of the Medicines Act, that device shall be governed by these regulations, without prejudice to the provisions of the Medicines Act with regard to the medicinal product. Applicability. Cap. 458.

(2) (a) Where an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of article 2 of the Medicines Act and which is liable to act upon the human body with action that is ancillary to that of the device, that device shall be evaluated and authorised in accordance with these regulations.

(b) Where a device incorporates, as an integral part, 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 within the meaning of article 2 of the Medicines Act and which is liable to act upon the human body with action that is ancillary to that of the device, hereinafter referred to as a "human blood derivative", that device shall be assessed and authorised in accordance with these regulations.

(3) These regulations constitute a specific Directive within the meaning of regulation 4(5) of the Electromagnetic Compatibility Regulations, 2007.

L.N. 28 of 2007.

(4) These regulations shall not apply to:

(a) medicinal products covered by the Medicines Act. In deciding whether a product falls under that Act or these regulations, particular account shall be taken of the principal mode of action of the product;

(b) 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 sub-regulation 4(2)(b) above;

(c) transplants or tissues or cells of human origin or to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 4(2)(b) above;

(d) transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

CE Marking and Conformity.

5. (1) The active implantable medical devices referred to in the definitions of "active implantable medical device", "custom-made device" and""device intended for clinical investigation", hereinafter referred to as "devices", shall satisfy the essential requirements set out

in Schedule I to these regulations which apply to them, account being taken of the intended purpose of the devices concerned.

(2) All necessary steps shall be taken to ensure that the devices may be placed on the market and, or put into service only if they comply with the requirements laid down in these regulations when duly supplied, properly implanted and, or properly installed, maintained and used in accordance with their intended purposes.

(3) Where a relevant hazard exists, devices which also satisfy the definition of machinery in the Machinery Regulations, 2002 shall also meet the essential health and safety requirements set out in Schedule I to those regulations to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Schedule 1 to these regulations. L.N. 369 of 2002.

(4) Devices, other than those which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in regulation 5(1) of these regulations must bear the CE marking of conformity.

(5) (a) The CE marking of conformity, as shown in Schedule IX to these regulations, must appear in a visible, legible and indelible form on the sterile pack and, where appropriate, on the sales packaging, if any, and on the instruction leaflet.

(b) The CE marking must be followed by the identification number of the notified body responsible for implementation of the procedures set out in Schedules II, IV and V to these regulations.

(6) It is prohibited to affix markings which are likely to deceive third parties as to the meaning and form of the CE marking. Any other marking may be affixed to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.

(7) Compliance with the essential requirements referred to in regulation 5(1) above shall be presumed in respect of devices which are in conformity with the relevant national standards adopted pursuant to harmonised standards the reference of which have been published in the OJ.

(8) For the purposes of these regulations, reference to harmonised standards also includes the monographs of the European Pharmacopoeia notably on the interaction between medicinal products

and materials used in devices containing such medicinal products, the references of which have been published in the OJ.

(9) (a) Where the devices are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the devices are also presumed to conform to the provisions of the other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the OJ, must be given in the documents, notices or instructions required by the Directives and accompanying such devices; these documents, notices or instructions shall be accessible without it being necessary to destroy the packaging which keeps the device sterile.

(10) Obstacles shall not be created to the placing on the market or the putting into service within the Maltese territory of devices complying with the provisions of these regulations and bearing the CE marking provided for in regulations 5(4) to (6) of these regulations, which indicates that they have been the subject of an assessment of their conformity in accordance with regulations 6(1) to (9) of these regulations.

(11) Obstacles shall not be created to:

(a) devices intended for clinical investigations being made available to duly qualified medical practitioners or authorised persons for that purpose if they satisfy the conditions laid down in regulations 7(1) to (4) and in Schedule VI to these regulations.

(b) custom-made devices being placed on the market and put into service if they satisfy the conditions laid down in Schedule VI to these regulations and are accompanied by the statement, which shall be available to the particular identified patient, referred to in that Schedule.

Such devices shall not bear the CE marking.

(12) At trade fairs, exhibitions, demonstrations, etc., no obstacles shall be created to the showing of devices which do not conform to these regulations, provided that a visible sign clearly indicates that such devices do not conform and cannot be marketed or put into

service until they have been made to comply by the manufacturer or his authorised representative.

(13) When a device is put into service, the information described in Sections 14, 15, 16 and 17 of Schedule I to these regulations is required to be in, at least, Maltese and, or English.

Conformity Assessment Procedures.

6. (1) In the case of devices other than those which are custom-made or intended for clinical investigations, the manufacturer must, in order to affix the CE marking, at his own choice:

(a) follow the procedure relating to the EC declaration of conformity set out in Schedule II to these regulations; or

(b) follow the procedure relating to the EC type-examination set out in Schedule III to these regulations, coupled with:

(i) the procedure relating to EC verification set out in Schedule IV to these regulations, or

(ii) the procedure relating to the EC declaration of conformity to type set out in Schedule V to these regulations.

(2) In the case of custom-made devices, the manufacturer must draw up the declaration provided for in Schedule VI to these regulations before placing each device on the market.

(3) Where appropriate, the procedures provided for in Schedule III, IV and VI to these regulations may be discharged by the manufacturer's authorised representative.

(4) The records and correspondence relating to the procedures referred to in regulations 6(1), (2) and (3) above shall be in, at least, Maltese and, or English, and, or in a language acceptable to the notified body defined in regulations 11(1) to (7) of these regulations.

(5) During the conformity assessment procedure for a device, the manufacturer and, or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with these regulations at an intermediate stage of manufacture.

(6) Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorised representative, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

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

(8) Decisions taken by the notified bodies in accordance with Schedules II, III and V to these regulations shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of a maximum length of five years.

(9) By derogation from regulations 6(1) and (2) hereof, the Director of Regulatory Affairs, after consultation with the Superintendent of Public Health, may authorise, on duly justified request, the placing on the market and putting into service, within the Maltese territory, of individual devices for which the procedures referred to in regulations 6(1) and (2) of these regulations have not been carried out and the use of which is in the interest of protection of health.

(10) The Regulatory Affairs Directorate shall submit a duly substantiated request to the Commission and ask it to take the necessary measures in the following situations:

(a) the Maltese authorities consider that the conformity of a device or family of devices should be established, by way of derogation from the provisions of regulations 6(1) to (9) above, by applying solely one of the given procedures chosen from among those referred to in regulations 6(1) to (9) of these regulations;

(b) the Maltese authorities consider that a decision is required as to whether a particular product or product group falls within the definition of "active implantable medical device", "custom-made device", "device intended for clinical investigation" or "medical device".

Clinical investigations.

7. (1) In the case of devices intended for clinical investigations, the manufacturer or the authorised representative shall, at least 60 days before the commencement of the investigations, submit the statement referred to in Schedule VI to these regulations to the Regulatory Affairs Directorate and the competent authorities in other Member States in which the investigations are to be conducted.

(2) (a) The manufacturer may commence the relevant clinical investigations at the end of a period of 60 days after notification, unless the Regulatory Affairs Directorate or the Ethics Committee established by the Clinical Trials Regulations, 2004, have notified him,

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within that period, of a decision to the contrary, based on considerations of public health or public policy.

(b) However, the Regulatory Affairs Directorate may authorise manufacturers to start the clinical investigations in question before the expiry of the 60-day period, provided that the Ethics Committee mentioned above has issued a favourable opinion with respect to the investigation programme in question, including its review of the clinical investigation plan.

(3) If necessary, any appropriate steps to ensure public health and public policy shall be taken according to the Public Health Act. Cap. 465.

(4) Where a clinical investigation is refused or halted by the Maltese authorities, the Regulatory Affairs Directorate shall communicate such decision and the grounds thereof to all Member States and the Commission. Where the Regulatory Affairs Directorate have called for a significant modification or temporary interruption of a clinical investigation, the Regulatory Affairs Directorate shall inform the Member States concerned about such actions and the grounds for the actions taken.

(5) The manufacturer or his authorised representative shall notify the Regulatory Affairs Directorate and the competent authorities of the other Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in Section 2(c)(vii) of Schedule VII to these regulations at the disposal of the Market Surveillance Directorate, the Regulatory Affairs Directorate and the competent authorities of the other Member States concerned.

(6) Clinical investigations shall be conducted in accordance with the provisions of Schedule VII to these regulations.

Withdrawal and prohibition from market.

8. (1) Where it is found that the devices referred to in the definitions of "active implantable medical device" and "custom-made device", correctly put into service and used in accordance with their intended purpose, may compromise the health and, or safety of patients, users or, where applicable, other persons, all appropriate measures shall be taken by the Market Surveillance Directorate to withdraw such devices from the market or prohibit or restrict their being placed on the market or their being put into service.

The Regulatory Affairs Directorate shall immediately inform the Commission of any such measure, indicating the reasons for such decision and, in particular, whether non-compliance with these regulations is due to:

(a) failure to meet the essential requirements referred to in regulation 5(1), where the device does not meet in full or in part the standards referred to in regulation 5(7);

(b) incorrect application of those standards;

(c) shortcomings in the standards themselves.

(2) Where a device which does not comply bears the CE marking, the Market Surveillance Directorate shall take appropriate action against whomsoever has affixed the mark. The Regulatory Affairs Directorate shall inform the Commission and other Member States of such actions.

(3) The Market Surveillance Directorate and the Regulatory Affairs Directorate shall take the necessary steps to ensure that information brought to their knowledge regarding the incidents mentioned below involving a device is recorded and evaluated in a centralised manner:

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

(b) any technical or medical reason in relation to the characteristics or performances of a device for the reasons referred to in paragraph (a) above, leading to systematic recall of devices of the same type by the manufacturer.

(4) The necessary steps shall be taken to ensure that the manufacturer of the device concerned, or his authorised representative, is also informed of the incident referred to in sub-regulation (3) above.

(5) (a) An assessment of the incidents mentioned in sub-regulation (3) above will be carried out by the Regulatory Affairs Directorate, if possible together with the manufacturer or his authorised representative.

(b) The Regulatory Affairs Directorate shall, without prejudice to sub-regulations (1) and (2) hereof, immediately inform the Commission and the other Member States of the incidents referred to in sub-regulation (3) hereof and of the measures that have been taken or are contemplated to minimise the recurrence of such incidents, including information on the underlying incidents.

(6) (a) Where the Market Surveillance Directorate considers, in relation to a given product or group of products, that, in order to ensure the protection of health and safety and, or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, any necessary and justified transitional measures may be taken.

(b) The Regulatory Affairs Directorate shall then inform the Commission and all other Member States of these transitional measures, giving the reasons for such decisions.

(7) Any decision taken pursuant to these regulations:

(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 Maltese law and of the time limits to which such remedies are subject.

(8) In the event of a decision as referred to in sub-regulation (7) hereof, the manufacturer or his authorised 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.

(9) Without prejudice to sub-regulations (1) and (2) hereof:

(a) where it is established that the CE marking has been affixed unduly or is missing in violation of these regulations, the manufacturer or his authorised representative shall be obliged to

end the infringement under conditions imposed by the Market Surveillance Directorate.

(b) where non-compliance continues, all appropriate measures shall be taken by the Director of Market Surveillance 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 as laid down in sub-regulations (1) and (2) hereof.

(10) The provisions of sub-regulation (9) hereof shall also apply where the CE marking has been affixed in accordance with the procedures in these regulations, but inappropriately, on products that are not covered by these regulations.

Registration of persons responsible for placing devices on the market.

9. (1) Any manufacturer who has his registered place of business in Malta and, under his own name, places devices on the market in accordance with the procedure referred to in regulation 6(2) above shall inform the Regulatory Affairs Directorate of the address of the registered place of business and the description of the devices concerned.

(2) All data allowing for the devices to be identified, together with the label and instructions for use, may be requested when such devices are put into service in Malta.

(3) (a) Where a manufacturer who places a device on the Maltese or Community market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative in the European Union.

(b) When the authorised representative referred to in sub-regulation (3)(a) has a registered place of business in Malta, he shall inform the Regulatory Affairs Directorate of the details referred to in sub-regulation (1) hereof.

(4) The Regulatory Affairs Directorate shall, on request, inform the other Member States and the Commission of the details referred to in sub-regulation (2) hereof given the manufacturer or authorised representative.

European databank.

10. (1) Regulatory data in accordance with these regulations shall be stored in a European databank accessible to the competent authorities to enable them to carry out their tasks relating to these regulations on a well-informed basis.

(2) The databank shall contain the following:

(a) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures as laid down in Schedules II to V to these regulations;

(b) data obtained in accordance with the vigilance procedure as defined in regulations 8(3) to (5) of these regulations;

(c) data relating to clinical investigations referred to in regulations 7(1) to (7) of these regulations.

(3) Data shall be forwarded in a standardised format by the Regulatory Affairs Directorate.

Notified bodies.

11. (1) The Regulatory Affairs Directorate shall notify the Commission and other Member States of the bodies which it has designated for carrying out the tasks pertaining to the procedures referred to in regulations 6(1) to (9) of these regulations together with the specific tasks for which the bodies have been designated.

(2) The Regulatory Affairs Directorate shall apply the criteria set out in Schedule VIII to these regulations for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonised standards shall be presumed to meet the relevant criteria.

(3) The Regulatory Affairs Directorate shall withdraw the notification if it finds that the body no longer meets the criteria referred to in sub-regulation (2) hereof. It shall immediately inform the other Member States and the Commission thereof.

(4) The notified body and the manufacturer, or his authorised representative, shall lay down, by common accord, the time limits for completion of the evaluation and verification operations referred to in Schedules II to V to these regulations.

(5) The notified body shall inform the Regulatory Affairs Directorate about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of these regulations about certificates suspended, withdrawn or refused and, on request, about certificates issued. Provided that, the notified body shall also make available, on request, all additional relevant information.

(6) (a) Where a notified body finds that pertinent requirements of these regulations 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.

(b) 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 competent authority may become necessary, the notified body shall inform the Regulatory Affairs Directorate thereof. The Regulatory Affairs Directorate shall inform the other Member States and the Commission.

(7) The notified body shall, on request, supply all relevant information and documents including budgetary documents, required to enable the Regulatory Affairs Directorate to verify compliance with the criteria laid down in Schedule VIII to these regulations.

Confidentiality.

12. (1) Without prejudice to the existing national provisions and practices on medical confidentiality, the Market Surveillance Directorate shall ensure that all the parties involved in the application of these regulations are bound to observe confidentiality with regard to all information obtained in carrying out their tasks.

Provided that the provisions of sub-regulation (1) hereof do not affect the obligation of the above authority 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 regulations 9(1) to (4) of these regulations;

(b) information to users sent out by the manufacture, authorised representative or distributor in relation to a measure in accordance with regulations 8(3) to (5) of these regulations;

(c) information contained in certificates issued, modified, supplemented, suspended or withdrawn.

13. The penalties applicable for the infringement of any of the provisions above shall be those provided for in Part IV of the Product Safety Act. Penalties. Cap. 427.

14. The Active Implantable Medical Devices Regulations, 2001 are hereby being revoked. Revokes L.N. 66 of 2001.

Schedule I
ESSENTIAL REQUIREMENTS

I GENERAL REQUIREMENTS

(1) The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.

(2) The devices must achieve the performances intended by the manufacturer, namely that they are designed and manufactured in such a way that they are suitable for one or more functions referred to in the definition of a “medical device” as specified by him.

(3) The characteristics and performances referred to in Sections 1 and 2 above must not be adversely affected to such a degree that the clinical condition and safety of the patients or, as appropriate, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.

(4) The devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacturer (temperature, humidity, etc.).

(5) Any side effects or undesirable conditions must constitute acceptable risks when weighed against the performances intended.

(6) Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Schedule VII to these regulations.

II REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

(7) The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles taking account of the generally acknowledged state of the art.

(8) Implantable devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted.

(9) Devices must be designed and manufactured in such a way as to remove or minimise as far as possible:

(a) the risk of physical injury in connection with their physical, including dimensional, features,

(b) risks connected with the use of energy sources with particular reference, where

electricity is used, to insulation, leakage currents and overheating of the devices,

(c) risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,

(d) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,

(e) risks connected with ionising radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in the Nuclear Safety and Radiation Protection Regulations, 2003 and the Ionising Radiation Medical Exposure Control Regulations, 2004,

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(f) risks which may arise where maintenance and calibration are impossible, including:

(i) excessive increase of leakage currents,

(ii) ageing of the materials used,

(iii) excess heat generated by the device,

(iv) decreased accuracy of any measuring or control mechanism.

(10) The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Sections 1 to 6 above, with particular attention being paid to:

(a) the choice of materials used, particularly as regards toxicity aspects,

(b) mutual compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the device,

(c) compatibility of the devices with the substances they are intended to administer,

(d) the quality of the connections, particularly in respect of safety,

(e) the reliability of the source of energy,

(f) if appropriate, that they are leak proof,

(g) proper functioning of the programming and control system, including software. For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

(11) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 2 of the

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Medicines Act, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

(a) For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004[3] on the quality and safety of the substance including the clinical benefit and risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

(b) Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance, including the clinical benefit and risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

(c) Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit and risk profile of the addition of the substance in the device.

(d) When the relevant competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit and risk profile of the addition of the substance to the device, it shall provide the notified body with advice, whether this information has an impact on the established benefit and risk profile of the addition of the substance to the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

(12) The devices and, if appropriate, their component parts must be identified to allow any

[3] Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L.136, 30-04-2004, p.1). Regulation as last amended by Regulation (EC) No. 1901/2006.

necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.

(13) Devices must bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.

(14) When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

(15) Every device must bear, legibly and indelibly, the following particular, where appropriate in the form of generally recognised symbols:

(a) On the sterile pack:

(i) the method of sterilisation,

(ii) an indication permitting this packaging to be recognised as such,

(iii) the name and address of the manufacturer,

(iv) a description of the device,

(v) if the device is intended for clinical investigations, the words: “exclusively for clinical investigations”,

(vi) if the device is custom-made, the words “custom-made device”,

(vii) a declaration that the implantable device is in a sterile condition,

(viii) the month and year of manufacture,

(ix) an indication of the time limit for implanting a device safely,

(b) On the sales packaging:

(i) the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in Malta or in the Community,

(ii) a description of the device,

(iii) the purpose of the device,

(iv) the relevant characteristics for its use,

(v) if the device is intended for clinical investigations, the words: “exclusively for clinical investigations”,

(vi) if the device is custom-made, the words: “custom-made device”,

(vii) a declaration that the implantable device is in a sterile condition,

(viii) the month and year of manufacture,

(ix) an indication of the time limit for implanting a device safely,

(x) the conditions for transporting and staring the device,

(xi) in the case of device within the meaning of regulation 4(2)(a) of these regulations, an indication that the device contains a human blood derivative.

(16) When placed on the market each device must be accompanied by instructions for use giving the following particulars:

(a) the year of authorisation to affix the CE mark,

(b) the details referred to in Sections 15(a) and 15(b) above, with the exception of those referred to in the eighth and ninth indents,

(c) the performances referred to in Section 2 of this Schedule and any undesirable side effects,

(d) information allowing the physician to select a suitable device and the corresponding software and accessories,

(e) information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures,

(f) information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided,

(g) information regarding the risks of reciprocal interference[4] in connection with the presence of the device during specific investigations or treatment,

(h) the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of re-sterilisation,

(i) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements,

[4] “Risks of reciprocal interference” means adverse effects on the device caused by instruments present at the time of investigations or treatment, and vice versa.

(j) date of issue or the latest revision of the instructions for use.

(17) The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken. These details should cover in particular:

(a) information allowing the lifetime of the energy source to be established,

(b) precautions to be taken should changes occur in the device's performance,

(c) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, etc.,

(d) adequate information regarding the medicinal products which the device in question is designed to administer.

(18) Confirmation that the device satisfies the requirements in respect of characteristics and performances, as referred to in Sections 1 to 6 above, in normal conditions of use, and the evaluation of the side effects or undesirable effects must be based on clinical data established in accordance with Schedule VII to these regulations.

Schedule II
EC DECLARATION OF CONFORMITY
(Complete quality assurance system)

(1) The manufacturer shall apply the quality system approved for the design, manufacture and final inspection of the products concerned as specified in Sections 3 and 4 and shall be subject to EC surveillance as specified in Section 5 of this Schedule.

(2) The declaration of conformity is the procedure by means of which the manufacturer who satisfies the obligations of Section 1 above ensures and declares that the products concerned meet the provisions of these regulations which apply to them.

The manufacturer or his authorised representative shall affix the CE marking in accordance with regulations 5(4) to (6) of these regulations and shall draw up a written declaration of conformity.

This declaration shall cover one or more clearly identified devices by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.

The CE marking shall be accompanied by the identification number of the notified body responsible.

(3) **Quality system**

(a) The manufacturer shall make an application for evaluation of his quality system to a notified body.

The application shall include:

(i) all the appropriate items of information for the category of products manufacture of which is envisaged,

(ii) the quality-system documentation,

(iii) an undertaking to fulfil the obligations arising from the quality system as approved,

(iv) an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,

(v) an undertaking by the manufacturer to institute and keep updated a post-market surveillance system including the provision referred to in Schedule VII to these regulations. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

(1) any deterioration in the characteristics or performances, and any

inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;

(2) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

(b) The application of the quality system must ensure that the products confirm to the provision of these regulations which apply to them at every stage, from design to final controls.

All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (iii) below.

It shall include in particular an adequate description of:

(i) the manufacturer's quality objectives;

(ii) the organisation of the business and in particular:

(1) the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of design and manufacture of the products is concerned,

(2) the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design and of the products, including control of products which do not conform,

(3) where the design, manufacture and, or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

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

(1) the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply to the products when the standards referred to in regulation 5(7) of these regulations are not applied in full,

(2) the techniques of control and verification of the design, the

processes and systematic actions which will be used when the products are being designed,

(3) a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in Section 11 of Schedule 1 to these regulations and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

(4) the pre-clinical evaluation,

(5) the clinical evaluation referred to Schedule VII to these regulations.

(iv) the techniques of control and of quality assurance at the manufacturing stage and in particular:

(1) the processes and procedures which will be used, particularly as regards sterilisation, purchasing and the relevant documents,

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

(v) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

(c) Without prejudice to regulation 8(9) of these regulations, the notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in section 3(b) hereof. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonised standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and, or subcontractors to inspect the manufacturing processes.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

(d) The manufacturer shall inform the notified body which has approved the quality system of any plan to alter the quality system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in section 3(b) hereof; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

(4) **Examination of the design of the product**

(a) In addition to the obligations incumbent on him under section 3, the manufacturer shall make an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in section 3(a) hereof.

(b) The application shall describe the design, manufacture, and performances of the product in question, and it must include the documents needed to assess whether the product conforms to the requirements of these regulations, and in particular sections 3(b)(iii) and (iv) hereof.

It shall include *inter alia*:

(i) the design specifications, including the standards which have been applied,

(ii) the necessary proof of their appropriations, in particular where the standards referred to in regulation 5(7) of these regulations have not been applied in full. This proof must include the results of the appropriate tests carried out by the manufacturer or carried out under his responsibility,

(iii) a statement as to whether or not the device incorporates, as an integral part, a substance as referred to in section 11 of Schedule I to these regulations, whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted,

(iv) the clinical evaluation referred to in Schedule VII to these regulations,

(v) the draft instruction leaflet.

(c) The notified body shall examine the application and, where the product complies with the relevant provisions of these regulations, shall issue the applicant with an EC design examination certificate. The notified body may require the application to be supplemented by further tests or proof so that compliance with the requirements of the regulations may be evaluated. The certificate shall contain the conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the product.

In the case of devices referred to in section 11(a) of Schedule I to these regulations, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA shall be drawn up within 210 days after receipt of a valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its

decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in section 11(b) of Schedule I to these regulations, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of a valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

(d) The applicant shall inform the notified body which issued the EC design examination certificate of any modification made to the approved design. Modifications made to the approved design must obtain supplementary approval from the notified body which issued the EC design examination certificate where such modifications may affect conformity with the essential requirements of these regulations or the conditions prescribed for the use of the product. This supplementary approval shall be given in the form of an addendum to the EC design examination certificate.

(5) **Surveillance**

(a) The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality system.

(b) The manufacturer shall authorise the notified body to carry out all necessary inspections and shall supply it with all appropriate information, in particular:

(i) the quality-system documentation,

(ii) the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, preclinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow up, if applicable, etc.,

(iii) the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardisations, calibrations and the qualifications of the staff concerned, etc.

(c) The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

(d) In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

(6) **Administrative provisions**

(a) For at least fifteen years from the last date of manufacture of the product, the manufacturer or his authorised representative shall keep available for the

Regulatory Affairs Directorate and the Market Surveillance Directorate:

(i) the declaration of conformity,

(ii) the documentation referred to in section 3(a)(ii), and in particular the documentation, data and records referred to in the second paragraph of section 3(b) hereof,

(iii) the amendments referred to in section 3(d) hereof,

(iv) the documentation referred to in section 4(b) hereof,

(v) the decisions and reports of the notified body referred to in sections 3(d), 4(c), 5(c) and 5(d) of this Schedule.

(b) On request, the notified body shall make available to the other notified bodies and Regulatory Affairs Directorate and the Market Surveillance Directorate all relevant information on approvals of quality systems issued, refused or withdrawn.

(7) **Application to devices referred to in regulation 4(2)(b) of these regulations:**

Upon completing the manufacture of each batch of devices referred to in regulation 4(2)(b) of these regulations, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with article 104A, sub-article (4) of the Medicines Act.

Schedule III
EC TYPE-EXAMINATION

(1) EC type-examination is the procedure whereby a notified body observes and certifies that a representative sample of the production envisaged satisfies the relevant provisions of these regulations.

(2) The application for EC type-examination shall be made by the manufacturer, or by his authorised representative, to a notified body.

The application shall include:

(a) the name and address of the manufacturer and the name and address of the authorised representative if the application is made by the latter,

(b) a written declaration specifying that an application has not been made to any other notified body,

(c) the documentation described in section 3 of this Schedule needed to allow an evaluation to be made of the conformity of a representative sample of the production in question, hereinafter referred to as "type", with the requirements of these regulations.

The applicant shall make a "type" available to the notified body. The notified body may request other samples as necessary.

(3) The documentation must make it possible to understand the design, the manufacture and the performances of the product. The documentation shall contain the following items in particular:

(a) a general description of the type, including any variants planned, and its intended use,

(b) design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of parts, sub-assemblies, circuits, etc.,

(c) the descriptions and explanations necessary for the understanding of the above-mentioned drawings and diagrams and of the operation of the product,

(d) a list of standards referred to in regulation 5(7) of these regulations, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards referred to in regulation 5(7) of these regulations have not been applied,

(e) the results of design calculations, risk analysis, investigations and technical tests carried out, etc.,

(f) a declaration stating whether or not the device incorporates, as an integral part, a substance or a human blood derivative as referred to in section 11 of Schedule I

to these regulations and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

(g) the pre-clinical evaluation,

(h) the clinical evaluation referred to in Schedule VII to these regulations,

(i) the draft instruction leaflet.

(4) The notified body shall:

(a) examine and evaluate the documentation, verify that the type has been manufactured in accordance with that documentation; it shall also record the items which have been designed in accordance with the applicable provisions of the standards referred to in regulation 5(7) of these regulations, as well as the items for which the design is not based on the relevant provisions of the said standards;

(b) carry out or have carried out the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of these regulations where the standards referred to in regulation 5(7) of these regulations have not been applied;

(c) carry out or have carried out the appropriate inspections and the tests necessary to verify whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;

(d) agree with the applicant on the place where the necessary inspections and tests will be carried out.

(5) Where the type meets the provisions of these regulations, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved.

The significant parts of the documentation shall be attached to the certificate and a copy shall be kept by the notified body.

In the case of devices referred to in the second paragraph of section 11 of Schedule I to these regulations, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA shall be drawn up within 210 days after receipt of a valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in the third paragraph, section 11 of Schedule I to these regulations, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of a valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

(6) The applicant shall inform the notified body which issued the EC type-examination certificate of any modification made to the approved product.

Modifications to the approved product must receive further approval from the notified body which issued the EC type-examination certificate where such modifications may affect conformity with the essential requirements or with the conditions of use specified for the product. This new approval shall be issued, where appropriate, in the form of a supplement to the initial EC type-examination certificate.

(7) **Administrative provisions**

(a) On request, each notified body shall make available to the other notified bodies and the competent authority, all relevant information on EC type-examination certificates and addenda issued, refused or withdrawn.

(b) Other notified bodies may obtain a copy of the EC type-examination certificates and, or the addenda to them. The annexes to the certificates shall be made available to the other notified bodies when a reasoned application is made and after the manufacturer has been informed.

(c) The manufacturer or his authorised representative shall keep with the technical documentation a copy of the EC type-examination certificates and the supplements to them for a period of at least 15 years from the manufacture of the last product.

Schedule IV
EC VERIFICATION

(1) EC verification is the procedure whereby the manufacturer or his authorised representative ensures and declares that the products subject to the provisions of section 3 below are in conformity with the type as described in the EC type-examination certification and satisfy the requirements of these regulations that apply to them.

(2) The manufacturer or his authorised representative shall take all measures necessary in order that the manufacturing process ensures conformity of the products to the type as described in the EC type-examination certification and to the requirements of these regulations that apply to them. The manufacturer or his authorised representative shall affix the CE marking to each product and draw up a written declaration of conformity.

(3) The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing processes, in particular as regards sterilisation, together with all the routine, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type as described in the EC type-examination certificate as well as with the relevant requirements of these regulations.

(4) The manufacturer shall undertake to institute and keep updated a post-marketing surveillance system including the provisions referred to in Schedule VII to these regulations. This undertaking shall include the obligation on the part of the manufacturer to notify the Regulatory Affairs Directorate of the following events immediately on learning of them:

(a) any change in the characteristics or performances and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or deterioration in his state of health;

(b) any technical or medical reason resulting in the withdrawal of a device from the market by a manufacturer.

(5) The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of these regulations by examination and testing of products on a statistical basis, as specified in section 6 of this Schedule. The manufacturer must authorise the notified body to evaluate the efficiency of the measures taken pursuant to section 3 above, by audit where appropriate.

(6) **Statistical verification**

(a) Manufacturers shall present the products manufactured in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

(b) A random sample shall be taken from each batch. Products in a sample shall be

individually examined and appropriate tests, as set out in any standard referred to in regulation 5(7) of these regulations, or equivalent tests shall be carried out to verify their conformity to the type as described in the EC type-examination certificate and thereby determine whether a batch is to be accepted or rejected.

(c) Statistical control of products will be based on attributes and, or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in regulation 5(7) of these regulations, taking account of the specific nature of the product categories in question.

(d) Where batches are accepted, the notified body shall affix, or cause to be affixed, its identification number to each product and draw up a written certificate of conformity relating to the tests carried out. All products in the batch may be placed on the market except for those products from the sample which were found not to be in conformity.

Where a batch is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the notified body may suspend the statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.

(e) The manufacturer or his authorised representative shall ensure that he is able to supply the notified body’s certificates of conformity on request.

(7) **Application to the devices referred to in regulation 4(2)(b) of these regulations**

Upon completing the manufacture of each batch of devices referred to in regulation 4(2)(b) of these regulations, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with article 104A, sub-article (4) of the Medicines Act.

Schedule V
EC DECLARATION OF CONFORMITY TO TYPE
(Assurance of production quality)

(1) The manufacturer shall apply the quality system approved for the manufacture and shall conduct the final inspection of the products concerned as specified in section 3 of this Schedule; he shall be subject to the surveillance referred to in section 4 hereof.

(2) This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of section 1 hereof guarantees and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of the regulations which apply to them.

(a) The manufacturer or his authorised representative shall affix the CE marking in accordance with regulations 5(4) to (6) of these regulations and draw up a written declaration of conformity. This declaration shall cover one or more devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer. The CE marking shall be accompanied by the identification number of the notified body responsible.

(3) **Quality system**

(a) The manufacturer shall make an application for evaluation of his quality system to a notified body.

The application shall include:

(i) all appropriate information concerning the products which it is intended to manufacture,

(ii) the quality-system documentation,

(iii) an undertaking to fulfil the obligations arising from the quality system as approved,

(iv) an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,

(v) where appropriate, the technical documentation relating to the approved type and a copy of the EC type-examination certificate,

(vi) an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system including the provisions referred to in Schedule VII to these regulations. The undertaking shall include an obligation for the manufacturer to notify the Regulatory Affairs Directorate of the following incidents immediately on learning of them:

(1) any deterioration in the characteristics or performances, and any

inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;

(2) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

(b) Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

(i) the manufacturer's quality objectives;

(ii) the organisation of the business and in particular:

(1) the organisational structures, the responsibilities of the managerial staff and their organisational authority where manufacture of the products is concerned,

(2) the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the products, including control of products which do not conform,

(3) where the manufacture and, or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party.

(iii) the techniques of control and of quality assurance at the manufacturing stage and in particular:

(1) the processes and procedures which will be used, particularly as regards sterilisation, purchasing and the relevant documents,

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

(iv) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

(c) Without prejudice to regulation 8(9) of these regulations, the notified body shall effect an audit of the quality system to determine whether it meets the requirements referred to in section 3(b) hereof. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonised standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

(d) The manufacturer shall inform the notified body which has approved the quality system of any plan to alter that system.

The notified body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in section 3(b) hereof; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

(4) **Surveillance**

(a) The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality system.

(b) The manufacturer shall authorise the notified body to carry out all necessary inspections and shall supply it with all appropriate information, in particular:

(i) the quality-system documentation,

(ii) the technical documentation,

(iii) the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardisations, calibrations and the qualifications of the staff concerned, etc.

(c) The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

(d) In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

(5) The notified body shall communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

(6) **Application to the devices referred to in regulation 4(2)(b) of these regulations**

Upon completing the manufacture of each batch of devices referred to in regulation 4(2)(b) of these regulations, the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with article 104A, sub-article (4) of the Medicines Act.

Schedule VI
STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES

(1) The manufacturer or his authorised representative shall draw up for custom-made devices or for devices intended for clinical investigations the statement comprising the elements stipulated in section 2 of this Schedule.

(2) The statement must contain the following information:

(a) for custom-made devices:

(i) the name and address of the manufacturer,

(ii) the information necessary for the identification of the product in question,

(iii) the name of the duly qualified medical practitioner who drew up the prescription and, if applicable, the name of the clinic concerned,

(iv) the specific characteristics of the product revealed by the prescription,

(v) a statement affirming that the device complies with the essential requirements given in Schedule I to these regulations and, where applicable, indicating which essential requirements have not been wholly met, together with the grounds.

(b) for devices intended for the clinical investigations covered in Schedule VII to these regulations:

(i) data allowing the devices in question to be identified,

(ii) the clinical investigation plan,

(iii) the investigator’s brochure,

(iv) the confirmation of insurance of subjects,

(v) the documents used to obtain informed consent,

(vi) a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in section 11 of Schedule I to these regulations,

(vii) a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in the Medical Devices Regulations, 2008,

(viii) the opinion of the Ethics Committee concerned and details of the aspects covered by its opinion,

(ix) the name of the duly qualified medical practitioner or other authorised person and of the institution responsible for the investigations,

(x) the place, date of commencement and duration scheduled for the investigations,

(xi) a statement affirming that the device in question complies with the essential requirements apart from the aspects constituting the object of the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

(3) The manufacturer must also undertake to keep available for the Regulatory Affairs Directorate and the Market Surveillance Directorate:

(a) for custom-made devices, documentation, indicating manufacturing sites and enabling the design, manufacture and performances of the product, including the expected performances, to be understood, so as to allow conformity with the requirements of these regulations to be assessed.

The manufacturer shall take all necessary measures to see that the manufacturing process ensures that the products manufactured conform to the documentation referred to in the first paragraph.

(b) for devices intended for clinical investigations, the documentation shall also contain:

(i) a general description of the product and its intended use,

(ii) design drawings, manufacturing methods, in particular as regards sterilisation, and diagrams of parts, sub-assemblies, circuits, etc.,

(iii) the descriptions and explanations necessary for the understanding of the said drawings and diagrams and the operation of the product,

(iv) the results of the risk analysis and a list of the standards referred to in regulation 5(7) of these regulations, applied in full or in part, and descriptions of the solutions adopted to satisfy the essential requirements of these regulations where the standards referred to in regulation 5(7) of these regulations have not been applied,

(v) if the device incorporates, as an integral part, a substance or human blood derivative referred to in section 11 of Schedule I to these regulations, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

(vi) the results of the design calculations, checks and technical tests carried out, etc.

The manufacturer shall take all the measures necessary to see that the manufacturing process ensures that the products manufactured conform to the documentation referred to in section 3(a) above and in the first paragraph of this section.

The manufacturer may authorise the evaluation, by audit where necessary, of the effectiveness of these measures.

(4) The information included in the declarations covered by this Schedule shall be kept for a period of at least 15 years from the data of manufacture of the last product.

(5) For custom-made devices, the manufacturer must undertake to review and document experience gained in the post-production phase, including the provisions referred to in Schedule VII to these regulations, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the Regulatory Affairs Directorate of the following incidents immediately on learning of them and the relevant corrective actions:

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

(b) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in paragraph (a) above leading to systematic recall of devices of the same type by the manufacturer.

Schedule VII
CLINICAL EVALUATION

(1) **General provisions**

(a) As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in sections 1 and 2 of Schedule I to these regulations under the normal conditions of use of the device and the evaluation of the side-effects and of the acceptability of the benefit and risk ratio referred to in section 5 of Schedule I to these regulations, must be based on clinical data. The evaluation of this data, hereafter referred to as clinical evaluation, where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

(i) either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device where:

(1) there is demonstration of equivalence of the device to the device to which the data relates and,

(2) the data adequately demonstrate compliance with the relevant essential requirements;

(ii) or a critical evaluation of the results of all the clinical investigations made,

(iii) or a critical evaluation of the combined clinical data provided in sections 1(a)(i) and (ii) heeof.

(b) Clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

(c) The clinical evaluation and its outcome shall be documented. This documentation shall be included and, or fully referenced in the technical documentation of the device.

(d) The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

(e) Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device-body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance

evaluation, bench testing and preclinical evaluation alone has to be duly substantiated.

(f) All data must remain confidential unless it is deemed essential that they be divulged.

(2) **Clinical investigations**

(a) Purpose

The purpose of a clinical investigation is to:

(i) verify that, under normal conditions of use, the performance of the device comply with those indicated to in section 2 of Schedule I to these regulations,

(ii) determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

(b) Ethical consideration

Clinical investigations shall be made in accordance with the Declaration of Helsinki approved by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and amended by the 29th World Medical Assembly in Tokyo, Japan, in 1975 and the 35th World Medical Assembly in Venice, Italy, in 1983. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Declaration of Helsinki. This includes every step in the clinical investigation from first consideration of need and justification of the study to publication of results.

(c) Methods

(i) Clinical investigations shall be performed according to an appropriate state of the art plan of investigation defined in such a way as to confirm or refute the manufacturer's claims for the device; the investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

(ii) The procedures utilised to perform the investigations shall be appropriate to the device under examination.

(iii) Clinical investigations shall be performed in circumstances equivalent to those which would be found in normal conditions of use of the device.

(iv) All the appropriate features, including those involving the safety and performances of the device, and its effect on patients, shall be examined.

(v) All serious adverse events must be fully recorded and immediately notified to the Market Surveillance Directorate, the Regulatory Affairs

Directorate and all competent authorities of the Member States in which the clinical investigation is being performed.

(vi) The investigations shall be performed under the responsibility of a duly qualified medical practitioner or authorised person, in an appropriate environment.

The medical practitioner or authorised person shall have access to the technical data regarding the device.

(vii) The written report, signed by the responsible medical practitioner or authorised person, shall comprise a critical evaluation of all the data collected during the clinical investigation.

Schedule VIII
MINIMUM CRITERIA TO BE MET WHEN DESIGNATING INSPECTION BODIES TO BE NOTIFIED

LN 136 of 2003

(1) Notified bodies shall be subject to the Method for Designating Conformity Assessment Bodies Regulations, 2003, and they shall also fulfil the criteria set out below.

(2) The body, its director and the staff responsible for carrying out the evaluation and verification operations shall not be the designer, manufacturer, supplier or installer of devices which they control, nor the authorised representative of any of those parties. They may not become directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

(3) The body and its staff must carry out the evaluation and verification operations with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

(4) The body must be able to carry out all the tasks in one of Schedules II to V to these regulations assigned to such a body and for which it has been notified, whether those tasks are carried out by the body itself or under its responsibility. In particular, it must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with evaluation and verification; it must also have access to the equipment necessary for the verifications required.

(5) The staff responsible for control operations must have:

(a) sound vocational training covering all the evaluation and verification operations for which the body has been designated,

(b) satisfactory knowledge of the requirements of the controls they carry out and adequate experience of such operations,

(c) the ability required to draw up the certificates, records and reports to demonstrate that the controls have been carried out.

(6) The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of controls carried out, nor on the results of such controls.

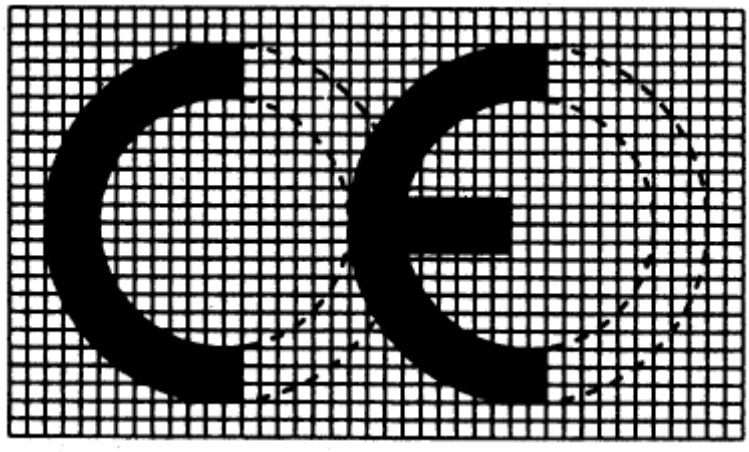
(7) The body must take out liability insurance unless liability is assumed by the State in accordance with Maltese law, or the Regulatory Affairs Directorate itself are directly responsible for controls.

(8) The staff of the body is bound to observe professional secrecy with regard to all

information gained in carrying out their tasks (except vis-à-vis the Regulatory Affairs Directorate or other competent administrative authorities of the State in which their activities are carried out) under these regulations or any provision of national law giving effect to it.

Schedule IX
CE CONFORMITY MARKING

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



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

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

- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5mm.

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

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