Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Article 1

Scope, definitions

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

2 For the purposes of this Directive, the following definitions shall apply:

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

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

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

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

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

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

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

(c) 'accessory' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose.

For the purposes of this definition, invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall not be considered to be accessories to *in vitro* diagnostic medical devices;

(d) 'device for self-testing' means any device intended by the manufacturer to be able to be used by lay persons in a home environment;

(e) 'device for performance evaluation' means any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises;

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

The obligations of this Directive 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 devices with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devicesalready on the market to their intended purpose for an individual patient;

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

(h) '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 for use and/or in promotional materials;

(i) '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 performance evaluation with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(j) 'putting into service' means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose.

3 For the purposes of this Directive, calibration and control materials refer to any substance, material or article intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended use of that device.

4 For the purposes of this Directive, the removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any Member States regulations on this matter.

5 This Directive shall not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity. This does not affect the right of Member State to subject such activities to appropriate protection requirements.

6 This Directive shall not affect national laws which provide for the supply of devices by a medical prescription.

7 This Directive is a specific directive within the meaning of Article 2(2) of Directive 89/336/EEC, which shall cease to apply to devices which have complied with this Directive.

Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose. This involves the obligation of Member States to monitor the security and quality of these devices. This Article applies also to devices made available for performance evaluation.

Article 3

Essential requirements

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

Article 4

Free movement

1 Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 16 if these devices have undergone conformity assessment in accordance with Article 9.

2 Member States shall not create any obstacle to devices intended for performance evaluation being made available for that purpose to the laboratories or other institutions listed in the statement referred to in Annex VIII if they meet the conditions laid down in Article 9(4) and Annex VIII.

3 At trade fairs, exhibitions, demonstrations, scientific or technical gatherings, etc. Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that such devices are not used on specimens taken from the participants and that a visible sign clearly indicates that such devicescannot be marketed or put into service until they have been made to comply.

4 Member States may require the information to be supplied pursuant to Annex I, part B, section 8 to be in their official language(s) when a device reaches the final user.

Provided that safe and correct use of the device is ensured, Member States may authorise the information referred to in the first subparagraph to be in one or more other official Community language(s).

In the application of this provision, Member States shall take into account the principle of proportionality and, in particular:

a whether the information can be supplied by harmonised symbols or recognised codes or other measures;

b the type of user anticipated for the device.

5 Where the devices are subject to other directives concerning other aspects which also provide for the affixing of the CE marking, the latter shall indicate that the devices also fulfil the provisions of the other directives.

However, should one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the devices fulfil the provisions only of those directives applied by the manufacturer. In this case, the particulars of these directives, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the directives and accompanying such devices.

Article 5

Reference to standards

1 Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards transposing the harmonised standards the reference numbers of which have been published in the *Official Journal of the European Communities*; Member States shall publish the reference numbers of such national standards.

2 If a Member State or the Commission considers that the harmonised standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6(2).

3 Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices designed and manufactured in conformity with common technical specifications drawn up for the devices in List A of Annex II and, where necessary, the devices in List B of Annex II. These specifications shall establish appropriate performance evaluation and re-evaluation criteria, batch release criteria, reference methods and reference materials.

The common technical specifications shall be adopted in accordance with the procedure mentioned in Article 7(2) and be published in the *Official Journal of the European Communities*.

Manufacturers shall as a general rule be required to comply with the common technical specifications; if for duly justified reasons manufacturers do not comply with those specifications they must adopt solutions of a level at least equivalent thereto.

Where, in this Directive, reference is made to harmonised standards, this is also meant to refer to the common technical specifications.

[F1 Article 6

Committee on Standards and Technical Regulations

1 The Commission shall be assisted by the Committee set up by Article 5 of Directive 98/34/EC (hereinafter referred to as 'the Committee').

2 Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC(1) shall apply, having regard to the provisions of Article 8 thereof.

3 The Committee shall adopt its rules of procedure.**]**

Textual Amendments

F1 Substituted 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.

[F2 Article 7

1 The Commission shall be assisted by the Committee set up by Article 6(2) of Directive 90/385/EEC.

2 Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC(2) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

Textual Amendments

F2 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 8

Safeguard clause

1 Where a Member State ascertains that the devices referred to in Article 4(1), when correctly installed, maintained and used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State

shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

a failure to meet the essential requirements referred to in Article 3;

b incorrect application of the standards referred to in Article 5, insofar as it is claimed that the standards have been applied;

c shortcomings in the standards themselves.

2 The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

— the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6; where the measure referred to in paragraph 1 is attributed to problems related to the contents or to the application of the common technical specifications, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 7(1) within two months,

— the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorised representative.

3 Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever affixed the marking and shall inform the Commission and the other Member States thereof.

4 The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Article 9

Conformity assessment procedures

1 For all devices other than those covered by Annex II and devices for performance evaluation, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex III and draw up the EC declaration of conformity required before placing the devices on the market.

For all devices for self-testing other than those covered by Annex II and devices for performance evaluation, the manufacturer shall, prior to the drawing up of the aforementioned declaration of conformity, fulfil the supplementary requirements set out in Annex III, point 6. Instead of applying this procedure, the manufacturer may follow the procedure referred to in paragraphs 2 or 3.

2 For all devices referred to in List A in Annex II other than those intended for performance evaluation, the manufacturer shall, in order to affix the CE marking either:

a follow the procedure relating to the EC declaration of conformity set out in Annex IV (full quality assurance), or

b follow the procedure relating to EC type-examination set out in Annex V coupled with the procedure relating to the EC declaration of conformity set out in Annex VII (production quality assurance).

3 For all devices referred to in List B in Annex II other than those intended for performance evaluation, the manufacturer shall for the purposes of affixing the CE marking, follow either:

a the procedure relating to the EC declaration of conformity set out in Annex IV (full quality assurance) or

b the procedure relating to EC type-examination set out in Annex V couplet with:

(i) the procedure relating to EC verification set out in Annex VI, or

(ii) the procedure relating to the EC declaration of conformity set out in Annex VII (production quality assurance).

4 In the case of devices for performance evaluation, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before such devices are made available.

This provision does not affect national regulations relating to the ethical aspects of carrying out performance evaluation studies using tissues or substances of human origin.

5 During the conformity assessment procedure for a device, the manufacturer and, if involved, 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 this Directive at an intermediate state of manufacture.

6 The manufacturer may instruct his authorised representative to initiate the procedures provided for in Annexes III, V, VI and VIII.

7 The manufacturer must keep the declaration of conformity, the technical documentation referred to in Annexes III to VIII, as well as the decisions, reports and certificates, established by notified bodies, and make it available to the national authorities for inspection purposes for a period ending five years after the last product has been manufactured. Where the manufacturer is not established in the Community, the obligation to make the aforementioned documentation available on request applies to his authorised representative.

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

9 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.

10 Decisions taken by the notified bodies in accordance with Annexes III, IV, and V 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 up to five years.

11 The records and correspondence relating to the procedures referred to in paragraphs 1 to 4 shall be in an official language of the Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body.

12 By way of derogation from paragraphs 1 to 4, the competent authorities may authorise, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 4 have not been carried out and the use of which is in the interest of protection of health.

13 The provisions of this Article shall apply accordingly to any natural or legal person who manufacturers devices covered by this Directive and, without placing them on the market, puts them into service and uses them in the context of his professional activity.

Article 10

Registration of manufacturers and devices

1 Any manufacturer who places devices on the market under his own name shall notify the competent authorities of the Member State in which he has his registered place of business:

— of the address of the registered place of business,

— of information relating to the reagents, reagent products and calibration and control materials in terms of common technological characteristics and/or analytes and of any significant change thereto including discontinuation of placing on the market; for other devices, the appropriate indications,

— in the case of devices covered by Annex II and of devices for self-testing, of all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Annex I, part A, section 3, the outcome of performance evaluation pursuant to Annex VIII, certificates and any significant change thereto, including discontinuation of placing on the market.

2 For devices covered by Annex II and for devices for self-testing, Member States may request to be informed of the data allowing identification together with the label and the instructions for use when such devices are placed on the market and/or put into service within their territory.

These measures cannot constitute a precondition for the placing on the market and/or putting into service of devices which are in conformity with this Directive.

3 Where a manufacturer who places devices on the market under his own name does not have a registered place of business in a Member State, he shall designate an authorised representative. The authorised representative shall notify the competent authorities of the Member State in which he has his registered place of business of all particulars as referred to in paragraph 1.

4 The notification referred to in paragraph 1 shall also include any new device. In addition, where, in the context of such notification, a device notified, bearing the CE marking, is a ‘new product’, the manufacturer shall indicate this fact on his notification.

For the purposes of this Article, a device is ‘new’ if:

a there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter;

b the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years.

[[F2]5 Member States shall take all necessary measures to ensure that the notifications referred to in paragraphs 1 and 3 are registered immediately in the databank described in Article 12.

The procedures for implementing this Article and in particular those referring to the notification and the concept of significant change shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).**]**

6 Transitionally, pending the establishment of a European databank accessible to the competent authorities of the Member States and containing the data relating to all devices available on the territory of the Community, the manufacturer shall give such notification to the competent authorities of each Member State concerned by the placing on the market.

Textual Amendments

F2 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 11

Vigilance procedure

1 Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving devices bearing the CE marking is recorded and evaluated centrally:

a any malfunction, failure 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, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health;

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

2 Where a Member State requires medical practitioners, the medical institutions or the organisers of external quality assessment schemes to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorised representative, is also informed of the incident.

3 After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which appropriate measures, including possible withdrawal, have been taken or are contemplated.

4 Where, in the context of notification referred to in Article 10, a device notified, bearing the CE marking, is a 'new' product, the manufacturer shall indicate this fact on his notification. The competent authority so notified may at any time within the following two years and on justified grounds, require the manufacturer to submit a report relating to the experience gained with the device subsequent to its being placed on the market.

[[F2]5 Member States shall on request inform the other Member States of the details referred to in paragraphs 1 to 4. The procedures implementing this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).**]**

Textual Amendments

F2 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of

the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 12

European databank

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

The databank shall contain the following:

a data relating to registration of manufacturers and devices in accordance with Article 10;

b data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedure as laid down in Annexes III to VII;

c data obtained in accordance with the vigilance procedure as defined in Article 11.

2 Data shall be forwarded in a standardised format.

[F2 3 The procedures implementing this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).**]**

Textual Amendments

F2 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

[**F2 Article 13

Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Article 36 of the Treaty, the availability of such products should be prohibited, restricted or made subject to particular requirements, it may take any necessary and justified transitional measures. It shall then inform the Commission and all the other Member States, giving the reasons for its decision. The Commission shall consult the interested parties and the Member States and, where the national measures are justified, adopt necessary Community measures.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4).**]**

Textual Amendments

F2 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 14

Amendments to Annex II, and derogation clause

[[F2]1 Where a Member State considers that:

a the list of devices in Annex II should be amended or extended; or

b the conformity of a device or category of devices should be established, by way of derogation from the provisions of Article 9, by applying one or more given procedures taken from amongst those referred to in Article 9,

it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures.

Where those measures concern matters referred to in point (a), designed to amend non-essential elements of this Directive, they shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

Where those measures concern matters referred to in point (b), they shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).**]**

2 When a measure is to be taken in accordance with paragraph 1, due consideration shall be given to:

a any relevant information available from the vigilance procedures and from external quality assessment schemes as referred to in Article 11;

b the following criteria:

(i) whether total reliance has to be placed on the result obtained with a given device, this result having a direct impact on subsequent medical action, and

(ii) whether action taken on the basis of an incorrect result obtained using a given device could prove to be hazardous to the patient, to a third party or to the public, in particular as a consequence of false positive or false negative results, and

(iii) whether the involvement of a notified body would be conducive to establishing the conformity of the device.

3 The Commission shall inform the Member States of the measures taken and, where appropriate, publish these measures in the *Official Journal of the European Communities*.

Textual Amendments

F2 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 15

Notified bodies

1 Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Article 9 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as 'notified bodies'.

The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the *Official Journal of the European Communities*. It shall ensure that the list is kept up to date.

Member States shall not be obliged to designate a notified body.

2 Member States shall apply the criteria set out in Annex IX 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 Member States shall apply continual surveillance of notified bodies to ensure ongoing compliance with the criteria set out in Annex IX. A Member State that has notified a body shall withdraw or restrict that notification if it finds that the body no longer meets the criteria referred to in Annex IX. It shall immediately inform the other Member States and the Commission of any withdrawal of notification or any restriction placed on it.

4 The notified body and the manufacturer, or his authorised representative established in the Community, shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes III to VII.

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

6 Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof. The Member State 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 Member State to verify compliance with Annex IX requirements.

Article 16

CE marking

1 Devices, other than devices for performance evaluation, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.

2 The CE marking of conformity, as shown in Annex X, must appear in a visible, legible and indelible form on the device, where practicable and appropriate, and on the instructions for use. The CE marking of conformity must also appear on the sales packaging. The CE marking shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes III, IV, VI and VII.

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

Article 17

Wrongly affixed CE marking

1 Without prejudice to Article 8:

a where a Member State establishes that the CE marking has been wrongly affixed, the manufacturer or his authorised representative shall be obliged to end the infringement under conditions imposed by the Member State;

b where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8.

2 The provisions stated in paragraph 1 shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.

Article 18

Decisions in respect of refusal or restriction

1 Any decision taken pursuant to this Directive:

a to refuse or restrict the placing on the market or any making available or putting into service of a device, 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 partyconcerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time limits to which such remedies are subject.

2 In the event of a decision as referred to in paragraph 1, the manufacturer or his authorised representative shall have an opportunity to put forward his point of view in advance,

unless such consultation is not possible because of the urgency of the measure to be taken as justified in particular by public health requirements.

Article 19

Confidentiality

Without prejudice to national law and practice on medical secrecy, Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to information obtained in carrying out their tasks. This does not affect the obligations of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

Article 20

Cooperation between Member States

Member States shall take appropriate measures to ensure that competent authorities charged with the implementation of this Directive cooperate with each other and convey to each other the information necessary to ensure application in compliance with this Directive.

Article 21

Amendment of directives

[[X1]1 In Directive 98/37/EC, the second indent of Article 1(3), 'machinery for medical use, used in direct contact with patients' shall be replaced by the following:**]**

— medical devices,

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2 Directive 93/42/EEC is hereby amended as follows:

a in Article 1(2):

— point (c) shall be replaced by the following:

(c) "*in vitro* diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations,

derived from the human body, solely or principally for the purpose of providing information:

— concerning a physiological or pathological state, or

— concerning a congenital abnormality, or

— to determine the safety and compatibility with potential recipients, or

— to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. "Specimen receptacles" are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

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

— point (i) shall be replaced by the following:

(i) "putting into service"	means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose;

— the following point shall be added:

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

b Article 2 shall be replaced by the following:

Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied andproperly installed, maintained and used in accordance with their intended purpose.

c the following paragraph shall be added to Article 14(1):

For all medical devices of classes IIb and III, Member States may request to be informed of all data allowing for identification of such devices together with the label and the instructions for use when such devices are put into service within their territory.

d the following Articles shall be inserted:

Article 14a

European databank

1 Regulatory data in accordance with this Directive shall be stored in a European database accessible to the competent authorities to enable them to carry out their tasks relating to this Directive on a well-informed basis.

The databank shall contain the following:

a data relating to registration of manufacturers and devices in accordance with Article 14;

b data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures, as laid down in Annexes II to VII;

c data obtained in accordance with the vigilance procedure as defined in Article 10;

2 Data shall be forwarded in a standardised format.

3 The procedures implementing this Article shall be adopted in accordance with the procedure laid down in Article 7(2).

Article 14b

Particular health monitoring measures

Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Article 36 of the Treaty, the availability of such products should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures. It shall then inform the Commission and all the other Member States giving the reasons for its decision. The Commission shall, whenever possible, consult the interested parties and the Member States and, where the national measures are justified, adopt necessary Community measures in accordance with the procedure referred to in Article 7(2).

e the following paragraphs shall be added to Article 16:

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

6 Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof. The Member State 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 Member State to verify compliance with Annex XI requirements.

f the following paragraph shall be added to Article 18:

Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.

g in Article 22(4), the first subparagraph shall be replaced by the following:

4. Member States shall accept:

— devices which conform to the rules in force in their territory on 31 December 1994 being placed on the market during a period of five years following the adoption of this Directive, and

— the aforementioned devices being put into service until 30 June 2001 at the latest.

h Annex II, section 6.2, Annex III, section 7.1, Annex V, section 5.2 and Annex VI, section 5.2 shall be deleted;

i in Annex XI, section 3 the following sentence shall be inserted after the second sentence: 'This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Directive and, in particular, those set out in Annex I.'

Editorial Information

X1 Substituted by Corrigendum to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (Official Journal of the European Communities L 331 of 7 December 1998).

Article 22

Implementation, transitional provisions

1 Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 7 December 1999. They shall immediately inform the Commission thereof.

Member States shall apply these provisions with effect from 7 June 2000.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2 Member States shall communicate to the Commission the texts of the main provisions of domestic law which they adopt in the field governed by this Directive.

3 The Committee referred to in Article 7 may undertake its tasks from the date of entry into force of this Directive. The Member States may take the measures referred to in Article 15 **[**[X2]as from the entry into force of this Directive.**]**

4 Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 9 for conformity assessment take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant test and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices.

5 During a period of five years following the entry into force of this Directive, Member States shall accept the placing on the market of devices which conform to the rules in force in their territory on the date on which this Directive enters into force. For an additional period of two years, the said devices may be put into service.

Editorial Information

X2 Substituted by Corrigendum to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (Official Journal of the European Communities L 331 of 7 December 1998).

Article 23

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 24

This Directive is addressed to the Member States.

(1) **[**[F1]Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).**]**

(2) **[**[F2]OJ L 184, 17.7.1999, p. 23.**]**

Textual Amendments

F1 Substituted 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.

F2 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.