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MEDICAL DEVICES: Guidance document

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GUIDELINE FOR AUTHORISED REPRESENTATIVES

The present guidelines are part of a set of guidelines relating to questions of application of EC-Directives on MEDICAL DEVICES. They are legally not binding. The guidelines have been carefully drafted through a process of intensive consultation of the various interested parties (competent authorities, Commission services, industries, other interested parties) during which intermediate drafts were circulated and comments were taken up in the document. Therefore, this document reflects positions taken by representatives of interested parties in the MEDICAL DEVICES sector.

Foreword

This guidance document is informative and advisory and has no legal authority. Individual national enforcement authorities are bound by their own legislation and can only apply this guidance within their confines.

Only the text of the Directives is authentic in law. The text of the Directives is applicable where there are differences between the provisions of the Directives and the contents of this guide. The interpretation of Community law is ultimately the responsibility and the privilege of the European court of Justice (ECJ). Any legal analysis set out in this guide does not in any way preclude a different interpretation by the ECJ in a particular case, and does not in any way commit the European Commission.

Introduction

Concern has been expressed for a number of years about the lack of clarity on the role of an authorised representative in the three Medical Devices Directives. There has been particular confusion because manufacturers have delegated certain responsibilities to their authorised representatives. There has also been confusion about what information authorised representatives could/should be able to provide.

Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products¹ and Regulation 765/2008/EC of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products² lay down common principles across sector legislation and will eventually be considered at the next revision of the Medical Devices Directives.

The purpose of this guideline is (a) to set out what the Directives currently say on the role and the responsibilities of authorised representatives and (b) to set out the Member States' expectations as to the role of the authorised representatives in terms of market surveillance.

References made to the Medical Device Directives include the Council Directive 93/42/EEC concerning medical devices³ (MDD), the Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices⁴ (AIMDD), and the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices⁵ (IVDD). If appropriate, selective reference to either of these Directives will be made.

¹ Official Journal L218/82 of 13.8.2008, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF>

² Official Journal L218/30 of 13.8.2008, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF>

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF>

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:EN:PDF>

⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:EN:PDF>

When reference is made to the EU, this is meant to include the EEA, Switzerland and Turkey.

A. Summary of current provisions of the medical device Directives

The definition of a manufacturer in the Medical Devices Directives is:

'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 manufacturer is responsible for his obligations under the Medical Device Directives, not the authorised representative.

Where a manufacturer who places a device on the market under his own name does not have a registered place of business in EU, he shall designate an authorised representative (AIMDD Art 10a(2); MDD Art 14(2); IVDD Art 10.3). Recital 14 of Directive 2007/47/EC clarifies: *'to introduce the obligation for such manufacturers to designate an authorised representative for a device. This designation should be effective at least for all devices of the same model.'* It is not the intention that this provision restricts a manufacturer to a single authorised representative for the whole range of his products. The manufacturer may have more than one authorised representative as long as each device (type/model) is linked to only one authorised representative.

For MD and IVD, the label or outer packaging or instructions for use shall contain the name and the address of the authorised representative where the manufacturer does not have a registered place of business in the Community (MDD Annex I Section 13.3(a); IVDD Annex I Section 8.4 (a)). For AIMD this information shall be affixed on the sales packaging (AIMDD Annex 1 Section 14.2).

The purpose of this compulsory designation is, as expressed in Recital 16 (MDD), Recital 14 (Directive 2007/47/EC), and Recital 29 (IVDD), that the authorities must be able to contact a person responsible for placing the device on the market and established in the Community, particularly in cases of emergency.

The definition of an authorised representative in the Medical Devices Directives, is:

"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;"

The definition of an authorised representative in Regulation 765/2008/EC is as follows:

"authorised representative" shall mean any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Community legislation;

The authorised representative has certain obligations as defined by the relevant Directives, such as:

- informing the competent authorities of his registered place of business (MDD: class I, procedure packs and custom made devices; AIMDD: custom made devices; IVDD), and of the devices and certificates (IVDD);
- keeping certain information at the disposal of the national authorities, such as declarations of conformity and technical documentation (AIMDD Annex II 6.1; MDD Annex II 6.1, Annex III Section 7.3, Annex IV Section 7, Annex V Section 5.1, Annex VI Section 5.1, Annex VII Section 2; IVDD Arts 9(7) and 10(3)).

The manufacturers may instruct his authorised representative to initiate certain procedures provided for in the conformity assessment annexes (IVDD Art 9(6), MDD Art 11(9), AIMD Art 9(3)).

A.1. Role of the authorised representative

A.1.1. General

As the directives do not include a detailed description of the role and obligations of an authorised representative it will be of vital importance to both the manufacturer and the authorised representative to set up a contract specifying the task and authority the manufacturer will delegate to the authorised representatives, also where the authorised representative is a daughter company of the manufacturer established outside the EU.

The appointment of an authorised representative does not change the responsibilities of the manufacturer. The authorised representative must be duly selected and supervised by the manufacturer.

However, in some Member States the authorised representative will have responsibilities directly under national law. For instance he might have the responsibility to ensure that the appropriate conformity assessment procedure has been carried out, that the device is properly CE marked and that information is provided in a specified national language. Another example may be that the authorised representative must have a vigilance system in place which is compatible with that of the manufacturer. An authorised representative must therefore be fully informed about the legal obligations included in the national legislation of the Member State in which he has his residence / where devices are placed on the market. Those “national” obligations should be reflected in the above mentioned contract with the manufacturer.

Given the Authorised Representative's limited role with regard to the placing on the market of a medical device, he cannot be held responsible for actions by the manufacturer over which it has no control, unless national legislation specifies otherwise.

A.1.2. Designation of an authorised representative

A manufacturer who places a medical device on the market must designate “a single authorised representative in the European Union” if he does not have a registered place of business in EU (AIMDD Art 10a(2), MDD Art 14(2)). The same request is made by IVDD Art 10(3), though without the inclusion of the specification “single”.

As clarified in Recital 14 of Directive 2007/47/EC, an authorised representative must be the single authorized representative within EU for at least all devices of the same type. A manufacturer may have different authorized representatives for different devices (types).

The requirement to have an authorised representative is applicable to all medical devices placed on the Community market, where the manufacturer is based outside of the EU.

The requirement to have an authorised representative is also applicable to devices intended for clinical investigation (MDD, AIMDD) or performance evaluation (IVDD) within the Community market, where the manufacturer is based outside of the EU.

A.1.3. Registration

In addition to the requirements described hereunder, there may be specific national notification requirements, which are incumbent to the manufacturer, but which can be delegated to the authorised representative.

MDD and AIMDD

Registration of the authorised representatives, manufacturers and devices

An authorised representatives designated for a device covered by the obligation to notify the Competent Authorities (MDD class I, procedure packs and custom made devices and AIMDD custom made devices) is obliged to register with the competent authority of the member state in which he is located and to inform the Competent Authorities of the address of the registered place of business of the manufacturer and the description of the devices concerned (AIMDD Art 10a, MDD Art 14).

Registration of Clinical Investigations

The manufacturer or the authorised representative must notify of the intention to carry out a clinical investigation to the Competent Authorities of the Member States in which the investigations are to be conducted. They shall also notify when it ends and shall make available the written report of the clinical investigation (AIMDD Art 10, MDD Art 15). The manufacturer may delegate these tasks entirely or in part to the authorised representative (MDD Annex VIII Section 2.2; AIMDD Annex VI Section 2.2).

IVDD

Registration of the authorised representatives, manufacturers, devices and certificates

An authorised representative designated for a device covered by the IVDD is required to register with the competent authority of the Member State in which he is located and to inform the Competent Authorities of the address of the registered place of business of the manufacturer, and to provide information related to the devices, and to the certificates (Art 10).

Registration of performance evaluations

A manufacturer who does not have a registered place of business in a Member State of the EU, and who wants to undertake a performance evaluation of a diagnostic

device, within these territories, must appoint an authorised representative. The authorised representative will communicate the information on the manufacturer and on the device to the Competent Authorities of the Member State in which he has his registered place of business. The declaration required for devices for performance evaluation (IVDD Annex VIII) is drawn up by the manufacturer or the authorised representative

A.1.4. Conformity Assessment

The Directive enables a manufacturer to delegate the performance of certain requirements of the Directive to his designated authorized representative. This should be specifically taken on board in the contract between the manufacturer and the authorized representative.

MDD

Art 11(8): The manufacturer may instruct his authorized representative to initiate the procedures provided for in Annexes III, IV, VII and VIII.

- Lodge a conformity assessment application for EC type-examination (Annex III),
- Establish the declaration of conformity to the type described in the EC type-examination certificate (EC Verification: Annex IV),
- Establish the Annex VII EC declaration of conformity, including Annex VII Section 5 in case of products placed on the market in sterile condition and Class I devices with a measuring function,
- Establish the statement for custom-made devices (Annex VIII Section 2.1).

AIMDD

Art 9.3.: Where appropriate, the procedures provided for in Annexes 3, 4 and 6 may be discharged by the manufacturer's authorized representative established in the Community.

- Lodge a conformity assessment application for EC type-examination (Annex III),
- Establish the declaration of conformity to the type described in the EC type-examination certificate (EC Verification: Annex IV),
- Establish the statement for custom-made devices (Annex VI Section 2.1).

IVDD

Art 9.6.: The manufacturer may instruct his authorised representative to initiate the procedures provided for in Annexes III, V, VI and VIII.

- Establish the Annex III EC declaration of conformity,
- Lodge a conformity assessment application for EC type-examination (Annex V),
- Establish the declaration of conformity to the type described in the EC type-examination certificate (EC Verification: Annex VI).

A.1.5. An authorised representative will be addressed by authorities and other bodies in the Community instead of the manufacturer with regard to the latter's obligations under this directive

a) Information requested from the manufacturer

The authorised representative is obliged to keep certain information at the disposal of the national authorities, such as declarations of conformity and technical documentation (AIMDD Annex 2 Section 6.1; MDD Annex II Section 6.1, Annex III Section 7.3, Annex IV Section 7, Annex V Section 5.1, Annex VI Section 5.1, Annex VII Section 2; IVDD Arts 9(7) and 10(3)).

An authorised representative must be able to provide all documentation and information that a market surveillance authority may require for the purpose of market surveillance (Art 19 of Regulation 765/2008/EC).

Any request for information by an authority would be made under the national legislation that transposes the Directives or under Regulation 765/2008/EC. Any question as to the legitimacy or not of such a request or 'Order' is therefore a matter for national courts to decide.

The information may be stored with the authorised representatives who shall be authorized to distribute the information directly to the authority. In this case the contract should include an obligation from the manufacturer to keep the information updated at all times.

If the manufacturer chooses not to store information with the authorised representatives, he shall provide the authorised representatives with all documentation and information that a market surveillance authority may require for the purpose of market surveillance upon the reception of the request forwarded by the authorised representatives to the manufacturer. The authorised representatives should have access to all documentation and information.

In this case the contract must secure that the manufacturer will provide the requested information to the authorised representatives in a timely manner, and should include an obligation from the manufacturer to keep the authorised representatives informed of any changes at all times.

The authorised representatives shall rescind his contract with the manufacturer if the latter does not provide him with the access to the necessary information.

The requested information may include

- i) Declaration of conformity,
- ii) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
- iii) Notified Body certification (where relevant),
- iv) Post market surveillance process and data, vigilance reports and complaints, processes and data,
- v) Technical documentation relevant to market surveillance investigation being undertaken by the Member State,
- vi) Relevant clinical data / notification,
- vii) Details of any distributors / suppliers putting the CE marked devices on the market,
- viii) Incident reports and corrective actions taken.

A manufacturer must keep his authorised representative informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs c) to e) hereunder shall be covered. This should be included in the contract between the two parties.

b) Information requested from the authorised representative

An authorised representative must keep the manufacturer informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs c) to e) hereunder shall be covered. This should be included in the contract between the two parties.

c) Safeguard Clause

“Where a Member State ascertains that a medical devices, 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.”
If the relevant Competent Authority contacts the authorised representative, he should immediately communicate such measures to the manufacturer and advise the manufacturer as to the implications of this decision.

When the Commission finds that national measures taken under the Safeguard Clause “are unjustified, it shall immediately so inform the Member State which took the measures and the manufacturer or his authorised representative”.

If the relevant Competent Authority contacts the authorised representative, he should immediately communicate such information to the manufacturer and advise the manufacturer as to the implications of this decision.

d) Vigilance

The Guideline on a Medical Device Vigilance System (MEDDEV 2.12-1 rev 6)¹ describes the requirements of the Medical Device Vigilance System as it applies to or involves manufacturers, including their authorised representatives.

In the event of an incident with a medical device, the Competent Authority must carry out “an assessment if possible together with the manufacturer or his authorised representative”.

After carrying out an assessment, Member States shall immediately inform the Commission and the other Member States of the incidents for which appropriate measures, have been taken or are contemplated.

If the relevant Competent Authority contacts the authorised representative, he should immediately communicate such information to the manufacturer and advise the manufacturer as to the implications of this decision.

The manufacturer should ensure that the involved authorised representative is kept informed of incident reports and Field Safety Corrective Actions.

e) Serious adverse events during clinical investigation, i.e. in the pre-market phase

According to Annex 7 to Directive AIMDD and according to Annex X to Directive MDD “all serious adverse events must be fully recorded and immediately notified to

¹ http://ec.europa.eu/health/medical-devices/files/meddev/2_12_1-rev_6-12-2009_en.pdf

all Competent Authorities of the Member States in which the clinical investigation is being performed”; see MEDDEV 2.7/3 (Dec 2010) Clinical investigations: Serious Adverse Event reporting under Directives AIMDD and MDD¹.

Reportable events have to be reported by the sponsor of the clinical investigation, which could be the manufacturer (MFR), the authorized representative (AR) or another person or entity.

f) Enforcement

“Where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of the Directives, the manufacturer or his authorised representatives shall be obliged to end the infringement under conditions imposed by the Member States” (AIMDD Art 13; MDD Art 18; IVDD Art 17).

The authorised representatives shall inform the manufacturer of such an infringement and the action required to end it.

g) Decisions in respect of refusal or restriction

“Any decision taken pursuant to this Directive (a) to refuse or restrict the placing on the market 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 manufacturer or his authorised representatives” (common content of: MDD Art 19(1), AIMDD 14, IVDD Art 18(1)).

The measures envisaged by the CA relating to the actions of the authorised representatives should be proportionate and reasonable.

“..., the manufacturer or his authorised representatives 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” (MDD Art 19(2), AIMDD 14, IVDD Art 18(2)).

¹ http://ec.europa.eu/health/medical-devices/files/meddev/2_7_3_en.pdf

B. Member States' Expectations

Manufacturers shall delegate tasks explicitly to the authorised representatives, and this preferably in a written contract. They shall define the authorised representative's tasks and the limits of his powers (Guide to the implementation of directives based on the New Approach and the Global Approach¹).

To ensure that the roles of the authorised representative and the manufacturer are clear, it is recommended, therefore that the responsibilities be specified in a written contract between the manufacturer and his authorised representative.

The contract between the manufacturer and the authorised representative shall stipulate that the authorised representative is obliged to inform the manufacturer of decisions of a Member State in respect of refusal or restriction of the placing on the market or any making available or putting into service of a device pursuant to this Directive.

The contract between the manufacturer and the authorised representative shall stipulate that the authorised representative is obliged to inform the manufacturer of incidents brought to his knowledge.

The contract between the manufacturer and the authorised representative shall stipulate that the manufacturer is obliged to inform the authorised representative of all matters that may be connected to the devices placed on the EU market.

The Notified Bodies should verify that a manufacturer who does not have a place of business in the EU, has designated an authorised representative and that the appropriate contract demonstrating delegation of appropriate responsibilities is available.

Hereunder are listed the expectations of Member States Competent Authorities. These should be ideally covered in a contract between the manufacturer and the authorised representative.

- The authorised representative should be able to assess whether the manufacturer has the ability to fulfil his regulatory obligations. In order to carry out the assessment the authorised representative should have access to the technical documentation.
- The authorised representatives should be in a position to verify that the required information / documentation exists with their manufacturer and that the necessary processes (e.g. for post market surveillance) are established.
- The authorised representative must possess appropriate knowledge, expertise and resources to assess and verify the above.
- A Member State must be able to assume, when it addresses an authorised representative, that it will receive all the information that it requests (see A.1.5.)
- A Member State can expect an authorised representative to provide on request the following information:
 - i) Declaration of conformity,

¹ http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/index_en.htm

- ii) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
- iii) Notified Body certificates (where relevant),
- iv) Post market surveillance process and data, vigilance reports and complaints, processes and data,
- v) Technical documentation relevant to market surveillance investigation being undertaken by the Member State,
- vi) Relevant clinical data / notification,
- vii) Details of any distributors / suppliers putting the CE marked devices on the market,
- viii) Incident reports and reports on corrective actions taken.

- In the event of a disagreement, where the authorised representative considers that the manufacturer is not complying with the requirements of the Directives, it has a duty to communicate this to the manufacturer. If the disagreement continues, the matter should be submitted to the authorised representative's Competent Authority for decision. The authorised representative may opt to rescind the contract.
- In the event of a clear non-compliance by the manufacturer that could engage the responsibility of the authorised representative and which the manufacturer refuses to correct, the authorised representative has the right to rescind his contract with the manufacturer. The authorised representative has even the obligation to rescind the contract if the non-fulfilment of the manufacturer's obligations causes him to infringe national law. It should then notify his Competent Authority and the manufacturer's Notified Body of this.

ANNEX I

The table lists the articles and the sections of the Annexes of the three Medical Devices Directives which contain requirements relating to authorised representatives.

MDD	IVD	AIMD
Medical Devices Directive 93/42/EEC (as amended by Directive 2007/47/EC)	<i>In Vitro</i> Diagnostic Medical Devices Directive 98/79/EC	Active Implantable Medical Devices Directive 90/385/EEC (as amended by Directive 2007/47/EC)
DESIGNATION		
Article 14(2) 1st sentence Where a manufacturer who places a device on the 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.	Article 10(3) 1st sentence 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.	Article 10a(2) 1st sentence Where a manufacturer who places a device on the 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.
REGISTRATION		
Article 14(2) 2nd sentence For devices referred to in the first subparagraph of paragraph 1, the authorised representative shall inform the competent authority of the Member State in which he has his registered place of business of the details referred to in paragraph 1.	Article 10(3) 2nd sentence 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.	Article 10a(2) 2nd sentence For devices referred to in the first subparagraph of paragraph 1 the authorised representative shall inform the competent authority of the Member State in which he has his registered place of business of all details as referred to in paragraph 1.
Article 14(1) Any manufacturer who, under his own name, places devices on the market in accordance with the procedures referred to in Article 11 (5) and (6) and any other natural or legal person engaged in the activities referred to in Article 12 shall inform 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 and the description of the devices concerned. For all medical devices of classes IIa, 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.	Article 10(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 selftesting, 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.	Article 10a(1) 1st subparagraph Any manufacturer who, under his own name, places devices on the market in accordance with the procedure referred to in Article 9(2) shall inform 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 and the description of the devices concerned.

MDD	IVD	AIMD
CONFORMITY ASSESSMENT PROCEDURE		
Article 11(8) The manufacturer may instruct his authorized representative to initiate the procedures provided for in Annexes III, IV, VII and VIII. See also Annex III section 2 Annex IV section 1 Annex VII section 1 Annex VIII section 1	Article 9(6) The manufacturer may instruct his authorised representative to initiate the procedures provided for in Annexes III, V, VI and VIII. See also Annex III section 1 Annex V section 2 Annex VI section 1 Annex VIII section 1	Article 9(3) Where appropriate, the procedures provided for in Annexes 3, 4 and 6 may be discharged by the manufacturer's authorized representative established in the Community. See also Annex 2 section 2 Annex 3 section 2 Annex 4, sections 1 and 2 Annex 5 section 2 Annex 6 section 1

MDD	IVD	AIMD
CONFORMITY ASSESSMENT DOCUMENTATION		
Annex III section 7 7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The Annexes to the certificates must be made available to other notified bodies on reasoned application, after the manufacturer has been informed. 7.3. The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured. In the case of implantable devices, the period shall be at least 15 years after the last product has been manufactured. Annex IV section 7 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: — the declaration of conformity, — the documentation referred to in Section 2, — the certificates referred to in Sections 5.2 and 6.4, — where appropriate, the type-examination certificate referred to in Annex III. Annex V section 5.1 5.1. The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: — the declaration of conformity, — the documentation referred to in the fourth indent of Section 3.1, — the changes referred to in Section 3.4, — the documentation referred to in the seventh indent of Section 3.1, — the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4, — where appropriate, the type-examination certificate referred to in Annex III. Annex VI section 5.1 Administrative provisions	Article 9(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.	Annex 2 section 6.1 For at least 15 years from the last date of manufacture of the product, the manufacturer or his authorised representative shall keep available for the national authorities: — the declaration of conformity, — the documentation referred to in the second indent of Section 3.1, and in particular the documentation, data and records referred to in the second paragraph of Section 3.2, — the amendments referred to in Section 3.4, — the documentation referred to in Section 4.2, — the decisions and reports of the notified body referred to in Sections 3.4, 4.3, 5.3 and 5.4. Annex 3 section 7.3 The manufacturer or his authorized 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. Annex 4 section 6.5 The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request. Annex 6 section 3 The manufacturer shall undertake to keep available for the competent national authorities: 3.1. For custom-made devices, documentation, indicating manufacturing site(s) 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 this Directive 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. 3.2. For devices intended for clinical investigations, the documentation shall also contain: — a general description of the product and its intended use, — design drawings, manufacturing

MDD	IVD	AIMD
5.1. The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: — the declaration of conformity, — the documentation referred to in the seventh indent of Section 3.1, — the changes referred to in Section 3.4, — the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4, — where appropriate, the certificate of conformity referred to in Annex III. Annex VII section 2 The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices the period shall be at least 15 years after the last product has been manufactured. Annex VIII section 4 The information contained in the declarations concerned by this Annex shall be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years.		methods, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc., — the descriptions and explanations necessary for the understanding of the said drawings and diagrams and of the operation of the product, — the results of the risk analysis and a list of the standards laid down in Article 5, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements of the Directive where the standards in Article 5 have not been applied, — if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Annex 1, 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, — the results of the design calculations, checks and technical tests carried out, etc. 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 3.1 and in the first paragraph of this section. The manufacturer may authorize the evaluation, by audit where necessary, of the effectiveness of these measures.
LABELLING		
Annex I Section 13.3(a) (The label must bear the following particulars:) (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;	Annex I section 8.4 (a) (The label must bear the following particulars which may take the form of symbols as appropriate:) (a) the name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative of the manufacturer;	Annex I section 14.2 (Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:) On the sales packaging: — 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 the Community, — a description of the device, — the purpose of the device, — the relevant characteristics for its use, — if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',

MDD	IVD	AIMD
		— if the device is custom-made, the words: 'custom-made device', — a declaration that the implantable device is in a sterile condition, — the month and year of manufacture, — an indication of the time limit for implanting a device safely, — the conditions for transporting and storing the device , — in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.
CLINICAL INVESTIGATIONS (<i>performance evaluation IVDD</i>)		
Article 15(1) In the case of devices intended for clinical investigations, the manufacturer or the authorised representative, established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the Member States in which the investigations are to be conducted by means of the statement mentioned in Section 2.2 of Annex VIII.	Annex VIII section 1 For devices for performance evaluation the manufacturer or his authorised representative shall draw up the statement containing the information stipulated in section 2 and ensure that the relevant provisions of this Directive are met.	Article 10(1) In the case of devices intended for clinical investigations, the manufacturer or authorized representative established in the Community shall, at least 60 days before the commencement of the investigations, submit the statement referred to in Annex 6 to the competent authorities of the Member State in which the investigations are to be conducted.
ENFORCEMENT		
Article 18 (a) (Without prejudice to Article 8:) (a) where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of the Directive, the manufacturer or his authorised representative shall be obliged to end the infringement under conditions imposed by the Member State;	Article 17(1) (a) (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;	Article 13(a) (Without prejudice to Article 7:) (a) where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of this Directive, the manufacturer or his authorised representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State;
DECISIONS IN RESPECT OF REFUSAL OR RESTRICTION		

MDD	IVD	AIMD
Article 19(2) In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.	Article 18(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 14 Any decision taken pursuant to this Directive (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 a decision 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 laws in force in the Member State in question and of the time limits to which such remedies are subject. In the event of a decision as referred to in the previous paragraph the manufacturer, or his authorized representative, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measures to be taken.



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