EUROPEAN COMMISSION DG HEALTH & CONSUMERS

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Unit B2 - Health technology and Cosmetics

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 products[[1]](#footnote-1) 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 products[[2]](#footnote-2) 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 devices[[3]](#footnote-3) (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 devices[[4]](#footnote-4) (AIMDD), and the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[[5]](#footnote-5) (IVDD). If appropriate, selective reference to either of these Directives will be made.

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

1. 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 Section7, 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

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

1. 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.

1. 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.

1. 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.

1. Serious adverse events during clinical investigation, i.e. in the premarket 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 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.

1. 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.

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

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF) [↑](#footnote-ref-1)
2. Official Journal L218/30 of 13.8.2008, [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=QJ:L:2008:218:0030:0047:en:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF) [↑](#footnote-ref-2)
3. [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CQNSLEG:1993L0042:20071011:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF) [↑](#footnote-ref-3)
4. [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CQNSLEG:1990L0385:20071011:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:EN:PDF) [↑](#footnote-ref-4)
5. [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CQNSLEG:1998L0079:20090807:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:EN:PDF) [↑](#footnote-ref-5)