Member States' Expectations

B.

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 Approach[[1]](#footnote-1)).

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:

1. Declaration of conformity,
2. Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
3. Notified Body certificates (where relevant),
4. Post market surveillance process and data, vigilance reports and complaints, processes and data,
5. Technical documentation relevant to market surveillance investigation being undertaken by the Member State,
6. Relevant clinical data / notification,
7. Details of any distributors / suppliers putting the CE marked devices on the market,
8. 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) | InVitro 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 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(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 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(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 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) | Article 9(6) | Article 9(3) |
| The manufacturer may instruct his | The manufacturer may instruct his | Where appropriate, the procedures |
| authorized representative to initiate | authorised representative to initiate | provided for in Annexes 3, 4 and 6 |
| the procedures provided for in | the procedures provided for in | may be discharged by the |
| Annexes III, IV, VII and VIII. | Annexes III, V, Vi and VIII. | manufacturer's authorized representative established in the |
| See also  Annex III section 2 | See also  Annex III section 1 | 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 |
| Annex IV section 1 | Annex V section 2 |
| Annex VII section 1 | Annex VI section 1 |
| Annex VIII section 1 | Annex VIII section 1 |

CONFORMITY ASSESSMENT DOCUMENTATION

MDD

IVD

AIMD

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 III section 7

1. 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.
2. 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

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

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

1. 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:

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.

1. 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 staring 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 (performance evaluation IVDD) | | |
| 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   1. 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   1. 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. |

1. [http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/index en.htm](http://ec.europa.eu/DocsRoom/documents/4942/attachments/1/translations/en/renditions/native) [↑](#footnote-ref-1)