

**Declaration of natural or legal persons engaged in the manufacture, marketing, distribution, import or export of in vitro diagnostic medical devices**

**Explanatory note**

**1/ Reference texts**

- Article L.5221-3 of the public health code

- Articles R. 5221-34 to R. 5221-37 of the public health code

- Order of February 25, 2005 relating to the declaration provided for in Article L. 5221-3 of the Public Health Code (declaration form appended to this order)

**2/ Who is concerned by the declaration?**

All natural or legal persons having one of the following activities in the field of in vitro diagnostic medical devices (IVDDs), as a main or accessory activity :

- Manufacturers or their authorized representative

- Distributors

- Importers

- Exporters

- Persons engaged in the manufacture of IVDDs

Individuals and legal entities with several activities only make, of course, a declaration, the form having been designed for this purpose.

**3/ What do these terms cover?**

They are defined in articles R.5221-4, R.5211-5 and R.5211-4 in the public health code :

**Manufacturer** means the natural or legal person responsible for the design, manufacture, packaging and labelling of a medical device with a view to placing it on the market in his own name, whether these operations are carried out by that person or on his behalf by another person;

**Authorized Representative** means any natural or legal person who, after having been expressly designated by the manufacturer, acts in the place of the manufacturer with regard to his obligations;

**Distributor** means any natural or legal person engaged in the storage of DMDIV and their distribution or export, excluding sale to the public ;

**Importer** means any natural or legal person engaged in the import and storage of IVDMDs, import being defined as the import of an IVDMD from a State that is not a member of the European Union or not a party to the European Economic Area Agreement with a view to placing it on the market;

**Exporter** means any natural or legal person engaged in the export of IVDDs to States that are not members of the European Union or that are not parties to the European Economic Area Agreement;

**Those engaged in manufacturing** are either manufacturers, subcontractors, or persons who manufacture IVDVDs for their own use, such as medical biology analytical laboratories ;

This declaration only concerns natural or legal persons established in France.

**4/ How are the IVDMDDs, objects of the declarant's activity, identified ?**

- In any case, the declarant must identify the products subject to his activity in item 2 of the form according to the following list:

DMDIV of list A (decree of November 09, 2004) DMDIV of list B (decree of November 09, 2004) Self-tests outside lists A and B

Other IVDDs Software Accessories

- In addition, manufacturers or their authorized representatives must provide in section 4 the information provided for in Directive 98/79/EC, the nature of which has been agreed by consensus between the competent authorities of the Member States of the European Union.

**5/ What is meant by establishment?**

An establishment is defined as the place where the activities covered by the public health code in the field of IVDDs take place.

**6/ To whom should the declaration be addressed?**

The declaration must be sent by registered mail with acknowledgement of receipt to : National Agency for the Safety of Medicines and Health Products (ANSM)

Quality, Flows and Repositories Department / Flows Management Unit

DM Communications - Code 800

143/147 Boulevard Anatole France

93285 Saint-Denis Cedex

**7/ When to declare?**

- Initial declaration: at the time of placing on the market in France or in another State of the European Economic Area

- Any change in the information contained in the initial declaration must be the subject of a new declaration, within a maximum period of one month after the occurrence of the change. The amending declaration will, of course, only cover the modified elements.

**8/ Some special cases**

**8.1 After an initial declaration, I put new products on the market, what do I have to do?**

This is an **amending** declaration as referred to in the second subparagraph of point 7, and is limited to part 4 of the form.

**8.2 Should European manufacturers outside of France continue to declare the marketing of their in vitro diagnostic medical devices in France when their products are distributed by a French distributor?**

No, this is no longer useful since the entry into force of the EUDAMED database. However, the French distributor will have to declare to the ANSM by the form of the decree of February 25, 2005, his activity as a distributor without filling in part 4.

**8.3 I am both a manufacturer of my own products and a distributor of another manufacturer's products. What do I have to do?**

A single declaration is sufficient. You identify your products in section 2 :

- in the manufacturer column for the products that you put on the market,

- in the distributor column for the products you distribute.

**A**

**8.4 What happens to Forms A, B, C?**

The Declaration Form for natural or legal persons engaged in the manufacture, marketing, distribution, import or export of in vitro diagnostic medical devices replaces them.

**8.5 I am a health care facility and I manufacture IVDVDDs for my own use. Do I have to declare?**

Yes, as part of the manufacturing activity. Simply fill in sections 1 and 2 of the form, as well as the

3, if the manufacturing activity is carried out in several establishments. If the IVDVDs manufactured by the health care establishment are supplied to other health care establishments or to city medical biology analysis laboratories, the establishment becomes a manufacturer in the sense of article R.5211-.

4**.** It must therefore CE mark the IVDDs manufactured and declare itself as the manufacturer.

**9/ Who can I contact at ANSM for further questions? For any question relating to the declaration of IVDDs**

**Contact :**

Quality, Flows and Repositories Department / Flows Management Unit

Fax : (+33) 01.55.87.42.62

Email: [communications.dm@ansm.sante.fr](mailto:dm@ansm.sante.fr)

**For any questions regarding IVDD facility reporting procedures Contact :**

Quality, Flows and Repositories Department / Flows Management Unit

Fax : (+33) 01.55.87.42.62

Email: [communications.dm@ansm.sante.fr](mailto:dm@ansm.sante.fr)

**For questions relating to the persons in charge of reactovigilance**

**Contact :**

Surveillance Department

E-mail: [reactovigilance@ansm.sante.fr](mailto:reactovigilance@ansm.sante.fr)

**For regulatory issues related to the status or class of these devices**

**Contact :**

Department of Medical Diagnostic Devices and Technical Platforms

Tel : (+33) 01.55.87.37.18

Fax : (+33) 01.55.87.37.62

Email : [dmdpt@ansm.sante.fr](mailto:dmdpt@ansm.sante.fr)