Agence nationale de sécurité du médicament et des produits de santé

Placing into service communication for IIa, IIb, III class medical devices and AIMDD Explanatory note

1-Placing into service communication for medical devices in conformity with the French law articles L.5211-4 and R.5211-66

Article L.5211-4 of the code of public health provides for all data allowing the identification of medical devices must be communicated to ANSM when they are put into service within French territory.
The above mentioned article L.5211-4, as well as decrees n°2002-1221 of 30 September 2002 and decree n° 2010-270 of 15 March 2010, represents mea sures of transposition of article 14 of European directive 93/42/EEC.
Decrees specify the categories of medical devices which are to be the subject of the communication and the contents of this communication. It also specifies the persons who are bound by this obligation of communication.

2-Medical devices concerned

Four categories of medical devices are concerned by this obligatory communication:

1. IIa class medical devices,
2. IIb class medical devices,
3. III class medical devices,
4. Active implantable medical devices (AIMDD) as defined in the European directive 90/385/EEC.

3-Datas to be communicated

The data to be communicated to ANSM are:

- Trade name of the medical device,
- Name and address of the person making the communication,
- A specimen of labelling and instruction for use of the medical device in French language (for IIa class medical device, if there is no instruction for use available, specify it)

Provide only one single specimen of each listed element above.

4-Persons bound by this obligatory communication

The persons bound by this obligatory communication are those who first undertake the putting into service onto the French territory to the final user. Three categories of persons are thus concerned, namely:

- The manufacturer as defined as “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,
- The authorised representative as defined as “any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts instead of the manufacturer with regard to the latter’s obligations”.
- The distributor as defined in subparagraph 5 of article R. 5211-4 of the code of the public health.

Only one communication per device is necessary.

To avoid multiple communications for the same device, it is recommended that the distributors check the communication has not been made beforehand by the manufacturer and/or the authorised representative. It is recommended that the manufacturer and/or the authorised representative inform the distributors concerned when they make a communication

5-How to fill in the form?

Medical devices having the same trade name, the same EC declaration of conformity and the same instructions for use are subject to only one communication.

Notch only one class per form.

It is possible to specify the Global Medical Device Nomenclature code (GMDN code). This non obligatory information is useful for processing by ANSM.

6-Communication of data concerning medical devices manufactured utilising tissues or derivates originating from animal

The words “tissues or derivates originating from animal” cover tissues originating from animal and derivates rendered non-viable. A derivative is a material obtained from an animal tissue by a manufacturing process.

The words “manufactured utilising” cover:
-Tissues originating from animal incorporated directly into the medical device (e.g.: pericard, valve…),
-The derivatives incorporated to the medical device (e.g.: collagen…),
-The material originating from animals used in the manufacturing process of the medical device (e.g.: trypsin used in cell culture, foetal bovine serum…) but which do not appears in final product.

- For all medical devices manufactured utilising tissues or derivates originating from animal:
  -Specify the origin,
- For medical devices manufactured utilising tissues or derivates originating from bovine, ovine, and caprine species, as well as deer, elk, mink and cats, European directive 2003/32/CE of 23 April 2003 has been transposed into French law by Decree n°2005-1180:
  -Furnish a copy of the EC certificate established under European directive 2003/32/CE.

It is important to not consider as tissues or derivates originating from animal substances as milk, silk, beeswax, hair and lanolin, in conformity with the guidance MEDDEV 2.4/1 rule 17.

7-When shall the communication be made?
The communication shall be made at the time of the putting into service of the device onto the French territory.
"Putting into service" is defined in subparagraph i of article 1 of the European directive 93/42/ECC.
This definition is as follows: One understands by "putting into service" the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose ".

8-How to submit these data to ANSM?
By sending the filled in form, a sample of the labels and of the instructions for use by e-mail at : communications.dm@ansm.sante.fr or by letter at:
ANSM
DEDIM/DSM/UGI
143-147, Boulevard Anatole France
93285 Saint Denis Cedex

An acknowledgement of receipt will be sent by ANSM after processing the data into our information system.

This information is then regularly published in a list and are available on our website.

9-New communication
A new communication should be done in case there is a change of the intended use or the using of the device, or in case of new version of the software associate to the device. It is recommended to inform ANSM of a change of manufacturer, distributor or authorized representative.

10-Device which putting into service is prior to decree application
Devices of class IIb, III and the AIMDD put into service onto the French territory before October 4th, 2002 are not concerned by this communication.
Devices of class IIa put into service onto the French territory before the March 21st, 2010 are not concerned by this communication.

11-Stop of the placing on the market
It is recommended to inform ANSM of the stop of the placing on the market of devices communicated previously.

12-Communication/EC declaration of conformity
A device shall be EC marked before being put into service onto the French territory to the final user in conformity with article L.5211-3 of the code of public health. Application of decrees above does not interact with EC mark procedure, prior to the communication.

13-Bonding into an hospital
When the first bond into an hospital is the first putting into service onto the French territory to the final users, the device should be communicated.

14-Do I have to produce new documents because of the communication?
The person in charge of the communication should have all data to be communicated.

15 - This communication is it subject to fees?
No, there is no fee to pay for that communication.

16-Do you need to have a distributor on the French territory?
No, an EC marked device can freely be put on the market in France and in Europe. It can be introduced onto the French market without distributor, prior only if exists an authorized representative in case where the device is not manufactured in the Community or a country part of the EFTA.

17-Contacts
Questions concerning Communication of devices of class IIb, III and the AIMDD
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Questions concerning Communication of devices of class IIa
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18-Penalties in the event of non communication
If the communication is not submitted at the time the device is put into service, article R.5461-1of the code of public health lays down penalties incurred by the contravener.