

**GUIDANCES FOR THE ON-LINE REGISTRATION OF CLASS IIA, IIB AND III
MEDICAL DEVICES AND IMPLANTABLE ACTIVE MEDICAL DEVICES BY THE
MANUFACTURERS PUTTING INTO SERVICE THESE DEVICES IN PORTUGAL**

(ACCORDINGLY TO ARTICLE 11º OF DECREE-LAW N.º 145/2009)

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INTRODUCTION

Manufacturer of medical devices, is, according, with Decree-Law 145/2009, of 17 June, 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;

Accordingly with article 11^o Decree-Law n.^o 145/2009, of 17 June **all manufacturers of medical devices (MD), active and non active of classes IIa, IIb and III**, as well as the manufacturers **of implantable active medical devices** shall communicate their identification data as well as the devices data.

Besides the data required through the on-line registration system, devices notification is completed with the delivery of CE Conformity Certificates, labelling and instructions for use, including the calibration instructions and maintenance manual to Medical Devices Department usual contacts.

The on-line registration of medical devices, by its manufacturers, has been improved so that it satisfies the system users.

The new functionalities prepared by INFARMED were:

- **Pendent notifications**, which allows to initiate one or more notifications in a session (each time one accesses the system), register the devices and add others or edit, in different sessions, submitting officially the notification to INFARMED (“Closing” the notification) after data validation by the notifying entity;
- **Groups management**, which allows the notifying entity to select medical devices in groups, independent of the date the medical devices where registered, and ask for registration certificates. Groups are never “closed” allowing the notifying entity to add or eliminate devices, according to its interest;
- **Password changing**, after receiving de user name and the first *password* automatically given by the system, for a better security in electronic notification.

ACCESS TO THE SYSTEM

- **All manufacturers of active and non active, class IIa, IIb and III, medical devices (MD), as well as implantable active medical devices manufacturers**, shall register their data in “Register now” and a password will be delivered by e-mail.

- **If the Manufacturer** is already registered they shall continue to use the attributed user name and password. For security reasons should change the password as soon as he enters the system.

- **After entering the login and password you shall enter in a page with the following functionalities:**
 - Notification management

 - Groups management

 - Password changing

NOTIFICATION MANAGEMENT

- Here you will find a list with the notifications already submitted and can initiate other notifications.
- To initiate a **new notification** a description of the new notification should be assigned. After this step it will automatically be shown in the notification list with an ID number, notification date and notification status – Submit or Submitted
- While the notification is not submitted the manufacturer can edit it, meaning that can:
 - Register new devices;
 - Change the data of already registered devices;
 - Eliminate already registered devices.
- The notification can remain unsubmitted, even after exiting the system and may be edited again in another date.
- While the notification is unsubmitted, the data are not formally notified to INFARMED nor will they be visible to INFARMED's collaborators through the database.
- The notification data, to be submitted to INFARMED, should be validated before so that no incorrect data is registered.
- After submitting a notification to INFARMED you can still review the data but no longer change it *on-line*.

Edit Notification

MD Registration

- In order to register a new medical device (MD), you will have to mark whether it is a non active MD, an active MD or an implantable active MD.

Note:

Do not register a **new Distributor** before verifying if this entity is already available in the Distributors list, when you are about to register a new MD.

- The “Designation” of the MD should be indicated (for example *coronary stent*, *bone cement*, *etc*) as well as its commercial name, by filling in the “*Make*” and “*Model*” information (The NA letters, for non applicable, should be used when there is no “*Model*”).

Note:

Different presentations of the MD, as for example different quantities or sizes, should be communicated as **one Medical Device only**, since they have no difference in the compounds or the end use. For example, condoms with the same compound, but with different sizes, should be notified as one device only.

- Other commercial names in the EU should be registered. The NA letters, for non applicable, should be used if the device has no other commercial names in the EU.
- At least one of the information regarding the MD must be filled in:
 - either the code related to the GMDN* nomenclature (“*Global Medical Devices Nomenclature*”),
 - or the pair “**Short Description**” + “**Intended Use**” regarding the MD (the MD “**Short Description**” should refer to the device characteristics that differentiates it from its similar or that are considered relevant by the Manufacturer).
- The MD “*Classification*” must be marked from the available multiple-choice list (class IIa, class IIb or class III).

Note:

When registering an implantable active medical device it will not be asked to choose a classification.

- The “Notified Body identification code”, responsible for the MD conformity evaluation, must be filled in.
- The date when the MD was placed on the Portuguese market (or was put into service), must be filled in.

Distributors and Authorized Representative registration

- A new Distributor should be registered only when this entity is not present in the Distributors list, available when registering a new MD.
- If the **Manufacturer**, using the on-line registration system, is placed outside European Union, he shall register the data concerning its Authorized Representative.

GROUP MANAGEMENT

- The Group Management functionality was created in order to allow the Manufacturer to gather medical devices according to its needs, when requesting registration certificates for specific medical devices, independently of its notification date.
- Each Group arrangement can be changed according to the manufacturers need.
- The Group arrangement will never be “closed”; it is permitted to the Manufacturer to edit each Group, adding more devices or eliminating others through time. That means that, the created Groups and its content, are not formally submitted like notifications, but are always visible to INFARMED’s collaborators through the database.
- To create a new Group you should choose a name for the Group. After this step it will automatically appear, in the Group list, the new Group identified by its name and the date it was created.
- The Group can always be edited:
 - Search and include devices previously notified;
 - Eliminate devices from Group arrangement.
- The Group can be eliminated.

Note

When requesting a registration certificate for a specific group, this group will be **blocked for edition**, temporarily, until the certificate emission.

Edit Group

- Through the *Search* button the manufacturer shall fulfil the fields with the devices criteria, he wants to include on the group.
- The search is made, for each Manufacturer, between the medical devices already notified and submitted to INFARMED, by this same Manufacturer.
- The search result will take the form of a list with the devices fulfilling the assigned criteria. The manufacturer shall choose amongst these devices, the ones to be included in the group.
- A chosen device can always be deleted afterwards.

PASSWORD CHANGE

- For more security in the electronic submission, after receiving the first user name and password generated by the system, the Manufacturer can change its password.
- To be able to change the password on-line, you will have to know the first password.

ADDITIONAL INFORMATION

The browser for going back in the page, specific of the system, should be used.

Information on GMDN nomenclature can be found on www.gmdn.org. This nomenclature will be used in the European Medical Devices Data Base– EUDAMED.

Requests for Registration Certificates should be instructed according to the information available in the site www.infarmed.pt

Any **modification to the notified data** should be communicated through e-mail, fax or letter identifying the Manufacturer and the information to be altered.

Any additional questions can be made to the following contacts:

Tel.: + 351 217987235

Fax.: +351 217987281

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The Medical Devices Department