Medical Devices and *In vitro* Diagnostic Medical Devices registration by its Manufacturer/Authorized Representative

Brief instructions on how to use the on-line registration system

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1 Introduction

1.1 Context

Inserted in the plan to reform the IT architecture for information management of products regulated by Infarmed, IP, and together with the implementation of a repository of information on medical devices, was understood to be necessary to provide the process for registration of medical devices by its manufacturer/ authorized representative of a support that allows computerized notification of medical devices and the computerized management of the entire process.

Thus, the new registration system for Medical Device Manufacturers / Authorized representatives, aims to replace the current registration procedures (some of which are being carried out not in electronic format, "on paper").

Under the new system were implemented a set of processes and features that are based on the activities inherent to the process of registration of DM / DIV by their Manufacturers / Authorized representatives addressing the legal requirements set out in European Directives and national legislation[1].

According to the European Directives applicable to medical devices and medical devices for in vitro diagnostic a **manufacturer is 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, regardless of whether these operations are carried out by that person himself or on his behalf by a third party."

When the manufacturer is not **established in the European Community should establish a contract with an entity based in Europe, which will act and will be addressed by the Community authorities and bodies**, on behalf **of the manufacturer, as regards his obligations in accordance with applicable law**. **This entity will be considered the manufacturer's authorized representative. To a medical device manufactured by the same manufacturer can only be associated one authorized representative.**

As part of market surveillance is essential to know the devices and those responsible for placing on the market so, the following requirements for registration / notification of medical devices for manufacturers or their representatives are established:

- **Registration of Class I Medical Device by national manufacturers:** The national manufacturer of class I medical devices or his authorized representative based in Portugal shall notify the INFARMED, IP, as set out in paragraph 1 of Article 11, Decree-Law No. 145/2009 of 17 June.

- **Registration of Custom Made Medical Device by national manufacturers:** The national manufacturer of custom made medical devices or his authorized representative based in Portugal shall notify the INFARMED, IP, as set out in paragraph 1 of Article 11, Decree-Law No. 145/2009 of 17 June.

[1] More information on:
http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS

-Registration of systems or procedure packs by national manufacturers (assemblers):
The national manufacturer of systems and procedure packs or his authorized representative based in Portugal shall notify the INFARMED, IP, as set out in Article 10, Decree-Law No. 145/2009 of 17 June.

- **Registration of class IIa, IIb, III and implantable active medical devices by national and non national manufacturers:**
The manufacturer of class IIa, IIb, III and implantable active medical devices or his authorized representative which put in service medical devices in Portugal shall notify the INFARMED, IP, as set out in paragraph 3 of Article 11, Decree-Law No. 145/2009 of 17 June.

- Registration of *in vitro* diagnostic medical devices by national manufacturers:
The national manufacturer of *in vitro* diagnostic medical devices or his authorized representative based in Portugal shall notify the INFARMED, IP, as set out in paragraph 1 and 2 of Article 10, Decree-Law No. 189/2000 of 12 August.

- Registration of *in vitro* diagnostic medical devices by non national manufacturers:
The non-national manufacturer of *in vitro* diagnostic medical devices or his authorized representative shall notify the INFARMED, IP, of Annex II and self-testing in vitro diagnostic medical devices as set out in paragraph 3 Article 10, Decree-Law No. 189/2000 of 12 August.

For all these registration, data and documentation to be submitted to INFARMED, IP will be required in the system.

1.2 Purpose

The Registration of medical devices and *in vitro* diagnostic medical devices by its Manufacturer/Authorized Representative is one of the processes that have been certified within the Infarmed's Quality Management System and which goal is - the information validation **on the medical devices notification** (MD, IAMD and IVD).

In the new registration system the following sub processes were implemented involving the notifying entities:

- User registration
- Notifying entity registration as Manufacturer;
- Notifying entity registration as Authorized Representative;
- Medical device registration as Manufacturer;
- Medical device registration as Authorized Representative;
- Elements request to notifying entity;
- Medical devices data change notification;
- Registration certificate request;
- Medical device cancelation;
- Process cancelation.

There are other sub-processes only for BackOffice use, by Infarmed's users which interact with the above indicated:

- Medical Device data validation;
- Internal request;
- Elements request to an external entity.

Note that this system approach is based on Business Process Management (BPM), which means that the application is in detail the sub-business processes Infarmed under the registration of medical devices by the manufacturers / Authorised representatives, through sequences of tasks pre-defined and that are completed by users of the application (Manufacturers/Authorized Representatives and Infarmed users).

The application also includes several features, search of information online, as well as an working area intended to manage the interaction with Infarmed (such as elements requests or pending payments following Certificates request) intending to make the process management more efficient for both users.

The purpose of this manual is to describe the processes available to external users, included in this new system, as well as the features available in it.

This manual is intended to Infarmed External users, who have access to the features described in this document available through the Portal Infarmed

http://extranet.infarmed.pt/dmfab

1.3 Abbreviations

MD	Medical Device
I	Class I MD
Is	Class I sterile MD
Imf	Class I with measuring function MD
Is + mf	Class I sterile and with measuring function MD
IIa	Class IIa MD
IIb	Class IIb MD
III	Class III MD

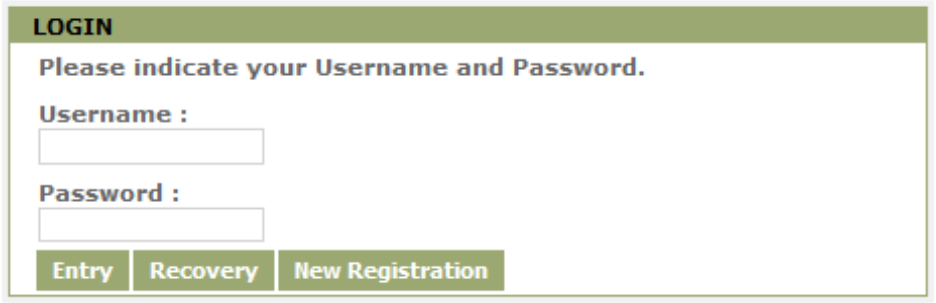
IAMD	Implantable Active Medical Device
IVD	*In Vitro* Diagnostic Medical Device
Others	IVD not listed in Annex II of the 98/79/CE Directive and not meant for self-testing
List A	Annex II, List A of the 98/79/CE IVD
List B	Annex II. List B of the 98/79/CE IVD
Self-testing	Self-testing IVD
CMMD	Custom Made Medical Device
SPP	System and procedure pack
GMDN	Global Medical Device Nomenclature
N/A	Not Applicable

2 User Registration

Autentication

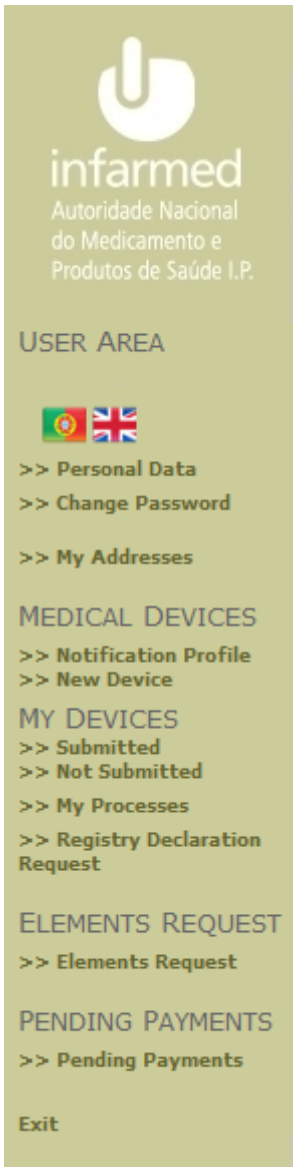
External users Infarmed, ie, Manufacturers / Authorised representatives access to the Medical Device Registration Portal via http://extranet.infarmed.pt/dmfab

address. If already registered you will need to login as a registered user:



When you enter your username and password the application verifies that the data are correct and allow access to your desktop.

When accessing the Medical Device Registration portal the following options emerge:



Through these links, the Manufacturer / authorized representative will have several features available, such as the ability to query your data and change them, change your access password, register the notification profile as a notifying entity, registering new devices, refer to the devices you have as an input for new processes, check processes, requests for devices registration certificates, answer to requests for information related to devices, consult pending payments.

2.1 Features

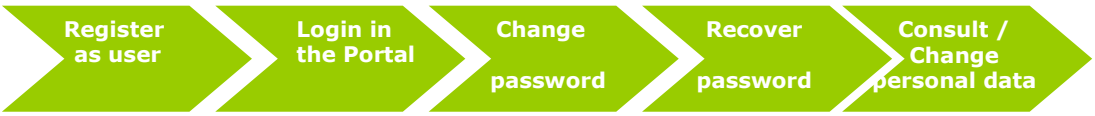


Image 1 – User registration features

2.2 Brief Description

Simplified flow
Action
The user accesses to Infarmed website
User Registration
Login **Infarmed Website**
Select the action **Register**
Fill in registration data
Select the action **Submit**
Access to the e-mail box and check if the user registration was validated . Consult your *password* and *username*
Change Password
Do the login in **Infarmed Website**
Select the link **Change Password**
Fulfil the fields
Select the action **Save**
Recover Password
Login **Infarmed Website**
Select the action **Recover Password**
Consult/Change Personal Data
Login **Infarmed Website**
Select the link **Personal data**
Consult/Change **Personal Data**

Simplified flow
Action
Select the action **Save**

3 Notifying Entity Registration

3.1 Features

Image 2 – Features of the Notifying Entity Process

3.2 Brief Description

Simplified flow
Action
The user accesses to Infarmed website
Select the option **Notification Profile**
Fulfil the fields
Select the action **Submit**

4 Medical Devices registration

4.1 Features

Image 3 – Medical Devices Registration feature

4.2 Brief Description

Simplified flow
Action
The user accesses to Infarmed website
Select the link **New Device**
Screen of New Device registration
Fulfil the fields related to the Medical Device
Select the action **Submit**
Search a Medical Device
Select one of the options **My Devices Submitted or My Devices Not Submitted** weather you want to consult the submitted devices or the ones which were saved and not submitted.
Fulfil the search criteria
Select the action **Search**
Consult the results after search
After selecting the action **Search**, the devices which fulfil the search criteria will appear in a table.
Consult the device selecting the link **Detail**
The information on the device register will be available on the different screens.

5 Notifying Entity elements request

5.1 Features

Image 4 – Notifying entity elements request features

5.2 Brief Description

Simplified flow
Action
The user accesses to Infarmed website
Answer to the Elements Request
Select the link **Elements Request**
Fulfil the fields
Select the action **Submit**.
Consult the details on Elements request
Search for the Process
Consult the details on the process
Select the screen Sent Elements Request
Select the link **Details** on the Elements Request you want to consult.

6 Medical Device Data Change Notification

6.1 Features

Image 5 – Medical Device data change notification features

6.2 Brief Description

Simplified flow
Action
The user accesses to Infarmed website
Search a Medical Device
Select the option **My Devices Submitted or My Devices Not Submitted**
Fulfil the search criteria
Select the action **Search**
Medical Device Data Change Notification
In the screen **My Devices Submitted**, after searching for the device you want to change, select the link **Edit** or **Modification Process**.
In the screen **My Devices Submitted**, after searching for the device, select the link **Edit** or **Modification Process.** The link **Edit** will be available if the device is still not validated. The link **Modification Process** will be available when the device is under validation or already validated.
In the screen **My Devices Not Submitted**, after searching for the device, select the link **Edit** in order to modify any saved data or fulfil new data on the device fields.
In the screen Modification process, the data in the fields will appear on editable status.
Change the device data
Select the action **Submit**
Consult the results obtained in the Search feature
After selecting the action **Search**, the devices which fulfil the search criteria will appear in a table.
Select the medical device, through the link **Detail**
The information on the device register will be available on the different screens.
Search for a Process
Select the option **My Processes**

Simplified flow
Action
Fulfil the search criteria
Select the action **Search**
Consult the results obtained in the search
After selecting the action **Search**, the processes which fulfil the search criteria will appear in a table.

7 Registry Declaration Request

7.1 Features

Image 6 – Registry Declaration Request features

7.2 Brief Description

Simplified flow
Action
The user accesses to Infarmed website
Request a Medical Device Registry Declaration
Select the action **Registry Declaration Request**
Search for the medical devices
Select the medical device(s) you want to see on the declaration
Select the action **Registry Declaration request**
Choose the way you want to receive your registry declaration
Select the action **Submit**
Do the payment
Select the link **Pending Payments**
Consult the details on how you can do the payment
Finalize the payment
Consult an Medical Device Registry Declaration Process
Select the link **My Processes**
Search for an **Registry Declaration Process**
Select the link **Details** on the Registry Declaration process

8 Cancelation of a Medical Device register or a Process

8.1 Features

Image 7 – Medical Device Cancelation feature

Image 8 - Process Cancelation feature

8.2Brief Description

Cancelation of a Medical Device register

Simplified flow
Action
The user accesses to Infarmed website
Search for a Medical Device
Select the option **My Devices**
Fulfil the search criteria
Select the action **Search**
Cancelling a Medical Device
In the screen **My Devices,** after searching for the device you want to cancel, select the link Cancelation Process.
Choose one of the indicated motives which standardize the reasons on wanting to cancel the device.
Choose the action **Submit**

Process Cancelation

Simplified flow
Action
Search for a Process
Select the option **My Processes**
Fulfil the search criteria
Select the action **Search**
Canceling a Process
In the screen **My Processes**, after searching for the process to be canceled, select the link **Cancel**. You can not choose to cancel a Cancelation Process.
In the pop-up fulfil the motive you want to cancel the process
Choose the action **Submit.**
Consult the Cancelation Process
In the screen **My Processes**, after selecting the action **Search**, the processes which fulfil the criteria will appear in a table.
Select the link **Details** on the cancelation process
Consult the screen with the cancelation process information.