Dispositivi Medici

⌣**HelpDesk** ⌣**LogOut** ⌣**Italian English**

| Class I, II a/b, III Medical Devices | In Vitro Diagnostic Medical Devices | Company's Data | Off Line Signature |

Class I, II a /b, III Medical Devices

▶ **Medical Device (DM)**
▶ **Systems or Assembled Kits (c.2 Art.12)**
▶ **Activity in progress**
▶ **EC certificates**
▶ **Deposit**
▶ **Data Transmission**
▶ **Entered DMs data download**
▶ **Documentation**
▶ **Multiple Notifications similar DMs**

Home > **Class I, II a /b, III Medical Devices** > Medical Device (DM)   **?**

Medical Device (DM)

Research criteria

Search on all DMs ⦿ **Search in DM To-do list** ○

⚠ **WARNING:** system detected the presence of 'In progress' DMs in the database, which refer to first notifications / manufacturing putback. Select 'Search in DM To-do list' option to find the DMs in order to complete the notification process (Validation by signing). User is required to delete data entered by mistake into the system which only refer to first notifications. It's not possible to delete 'In progress' DMs which come from 'manufacturing putback'

System progressive attributed to Device:	
Manufacturer:	REDDRESS
Code assigned by the manufacturer (catalogue identifier): from: to:	
Trade name and model:	
CND classifications:	⌃⌄ Search
DM status:	⌄
User role as to the DM:	⌄
Marketing:	⌄
Registered on the index:	⌄

Search   New search

System progressive attributed to Device	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	End Trade Date	Select ☐
2042171/R	REDDRESS LTD.	RD2002	ACTIGRAFT	B0599 - DISPOSITIVI PER LA PREPARAZIONE DI EMOCOMPONENTI AD USO TOPICO - ALTRI	V		☐

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Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

If the System progressive attributed to the DM is followed by the symbol (*), this means that in the database there are links with other notifications.

If more pages match the search results, by checking 'Select All', only the records in the current page will be selected, leaving out those in the following pages. To select the records in the remaining pages, use the 'previous / next' links and activate the corresponding check ('Select All') for each page.

Select: Click on one of the squares beside the component(s) in the list depending on operations.

Activable operations:

- **Insert:** Allows the user to enter a new DM.

- **Copy:** Allows the user to make a copy of the selected DM, in order to simplify the entry of another DM reusing the informaton already entered.
- **Edit:** Allows the user to modify the selected DM to change the data previously entered. The user can modify all DMs that are in the "In progress" or "Consoldated" status.
- **Delete:** Allows the user to delete the selected DM from the database.
- **Enter similar DMs:** Allows the user to "quickly" enter the Medical Devices similar to the selected DM having the same features with the following exceptions: Code assigned by the manufacturer, trade name, size and label. The functionality differs from that of the "Copy" since the so entered DMs form a "group" of medical devices having a core of information in common, and on which it is possible to act simultaneously activating the same processes ("Consolidation" and "Validation") or using the same functions (data "Editing" and "Off-trade").
- **Update similar DMs:** Allows the user to access the editing page of the sole specific data of a Medical Device entered through the quick entry festure (Code assigned by the manufacturer, trade name, size and label).
- **New notification:** If the Manufacturer's data have varied significantly, it allows the user to make simplified notifications for a published medical device, ensuring the link to the previous notification.
- **Consolidate:** Allows the user to consolidate the data of one or more Medical Devices that are in the "In progress" status.
- **Off line validation:** Allows to digitally sign-off all selected DMs. The user can modify all DMs that are in the "Consolidated" status.
- **Commercial data:** Allows the user to access the commercial data entry page of a Medical Device.
- **Documentation:** Allows the user to edit the label "pdf" files, the instructions for use of the selected DM and to edit the data sheet. The feature can be activated on the Medical Devices in the "Published" status present in the database.
- **Needed DMs:** Allows to change the list of DMs needed for the functioning of the selected DM in the "Published" status
- **Agent:** Allows to change the Agent for the selected DM in the "Published" status
- **Repertoire registration:** Allows the user to enroll the Medical Device in the selected Repertoire.
- **Off-trade:** Allows the user to state the selected DM off-trade date.
- **Manufacturing putback:** Allows to gain access to the manufacturing putback page for the selected DM.
- **Detail:** Allows the user to view the data detail of the selected DM.
- **Version history:** Allows to view the history of the different versions of the DM put back to manufacturing at least once.
- **Print:** Allows the user to print (in pdf format) a return receipt as evidence of the notification made. Said receipt will report all data signed in the validation stage.
- **Download xml:** Allows the user to download data about the selected medical devices, in the xml format, on the compressed file. The user may only download 10 Medical devices at a time.

Medical Devices notification

| Insert | | Copy | | Edit | | Delete | | Insert Similar DM | | Update Similar DM | | New notification |

Notification validation (change of the manufacturing status)

| Consolidate | | Off line validation |

Post publication update

| Trade Data | | Documentation | | Needed DMs | | Agent | | Repertoire registration | | Off trade |
| Manufacturing putback |

Consultation and Utilities

| Detail | | Version history | | Print | | Download XML |