Nuovo Sistema Informativo Sanitario

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 |

In Vitro Diagnostic Medical Devices

▸ **Medical Device (IVD)**
▸ **Activities in progress**
▸ **EC certificates**
▸ **Multiple Notifications similar IVDs**
▸ **User Documentation**

In Vitro Diagnostic Devices for Performance Evaluation

▸ **Access to features...**

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Medical Device (IVD)

Research criteria

Search on all IVDs ● **Search in IVD To-do list** ○

System progressive attributed to IVD: 1672771

Manufacturer:

Code assigned by the manufacturer (catalogue identifier): from: to:

Trade name and model:

CND classifications: Search

IVD status:

User role as to the IVD:

Marketing:

Registered on the index:

Search   New search

System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	End Trade Date	Select ☐
1672771/R	BIOLYTICAL LABORATORIES INC.	90-1059	INSTI HIV SELF TEST, PRODUCT NUMBER 90-1059	W0105090302 - HIV 1 / 2 - TEST RAPIDI E "POINT OF CARE"	P		☐

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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 IVD 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 IVD.
- **Copy:** Allows the user to make a copy of the selected IVD, in order to simplify the entry of another IVD reusing the informaton already entered.
- **Edit:** Allows the user to modify the selected IVD to change the data previously entered. The user can modify all IVDs that are in the "In progress" or "Consoldated" status.
- **Delete:** Allows the user to delete the selected IVD from the database.
- **Insert similar IVD:** Allows the user to "quickly" enter the Medical Devices similar to the selected IVD 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 IVDs 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 IVD:** 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 IVDs. The user can modify all IVDs that are in the "Consolidated" status.
- **Documentation:**Allows the user to edit the label "pdf" files, the instructions for use of the selected IVD and to edit the data sheet. The feature can be activated on the Medical Devices in the "Published" status present in the database.
- **Needed IVDs:** Allows to change the list of IVDs needed for the functioning of the selected IVD in the "Published" status
- **Agent:** Allows to change the Agent for the selected IVD 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 IVD off-trade date.
- **Manufacturing putback:** Allows to gain access to the manufacturing putback page for the selected IVD.
- **Detail:** Allows the user to view the data detail of the selected IVD.
- **Version history:** Allows to view the history of the different versions of the IVD 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.

Medical Devices notification

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

Notification validation (change of the manufacturing status)

| Consolidate | Off line validation |

Post publication update

| Documentation | Needed IVDs | Agent | Repertoire registration | Off trade |
| Manufacturing putback |

Consultation and Utilities

| Detail | Version history | Print |