
SÚKL

APPLICATION FOR MEDICAL DEVICE NOTIFICATION ACCORDING TO SECTION 33 PAR. 2 OF THE ACT ON MEDICAL DEVICES

Medical Devices Branch

The distributor or importer of a medical device shall be obliged according to Section 33 of the Act on Medical Devices (Act on MD) to submit an application for notification of the medical device to the Institute no later than within 15 days of the date of its placement on the market or supply to the market in the Czech Republic. The application is submitted via the Registry of Medical Devices (RZPRO).

Notification of medical device according to Section 33 paragraph 2 of the Act on MD

Where the medical device has been already notified, any other distributor or importer of the concerned medical device **shall be obliged to notify the Institute of the fact that this medical device is also distributed or imported thereby.** Such notification shall be filed by the distributor or importer electronically, via the Registry of Medical Devices.

In case, the already notified MD is placed on the market by other distributor / importer in different variants, or should the distributor / importer prefer to be able to modify the Medical device detail within RZPRO, the application for Medical device notification may be submitted, see Manual – Application for MD notification.

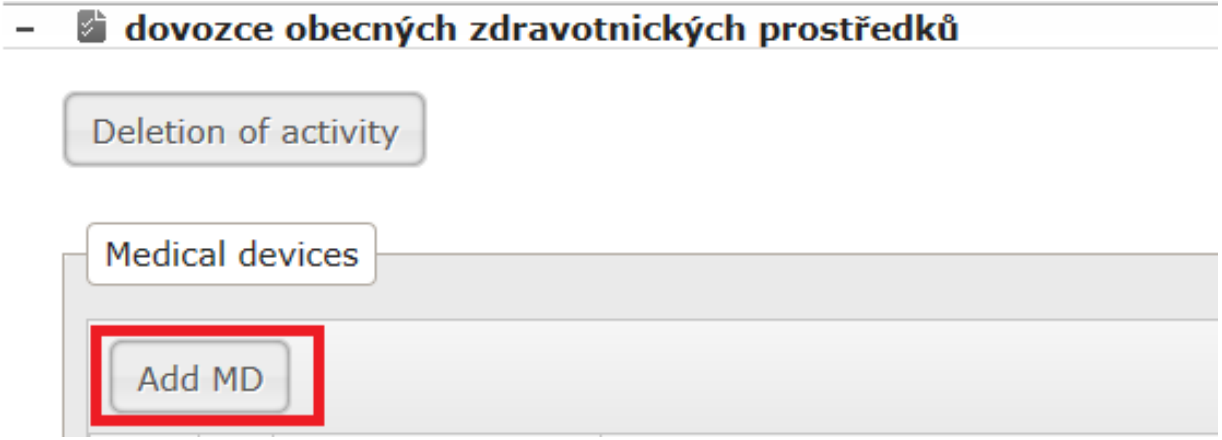
Medical device notification according to Section 33 paragraph 2 of the Act on MD in RZPRO

The distributor / importer shall notify the Institute **that this medical device is also distributed or imported** via the Data change notification of the registered person in RZPRO.

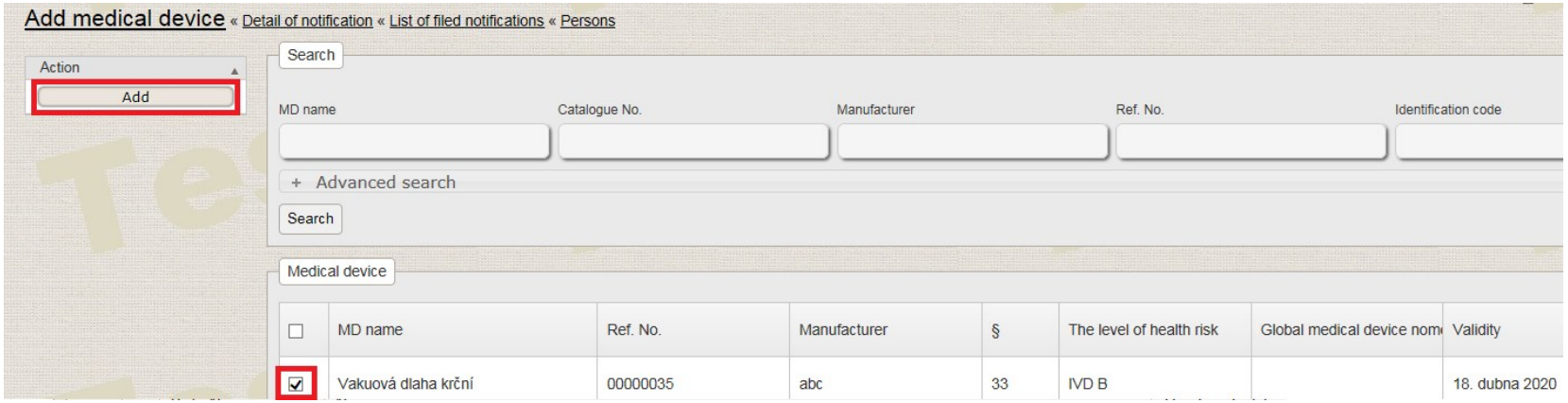
In case, you have registered the operation of distributor / importer, go to the module Person in RZPRO.

Click Data change notification

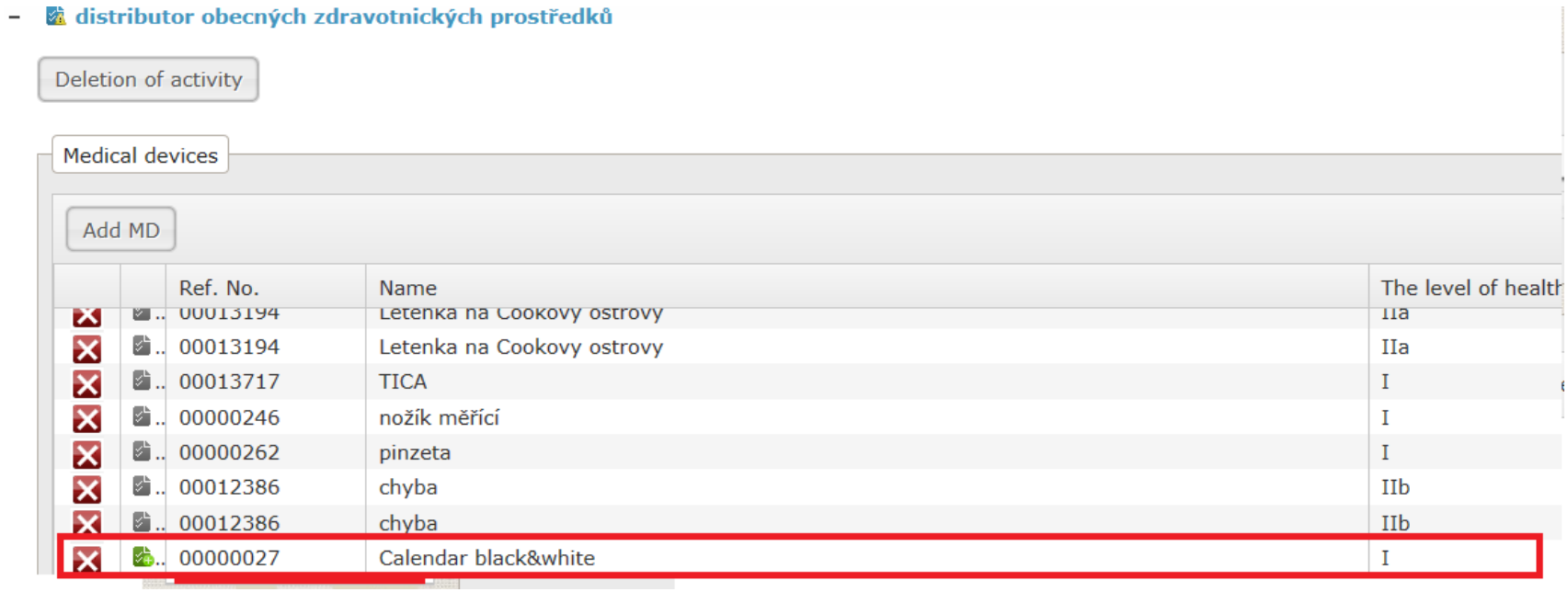
Once the data change form is generated, go to the operation under which the Medical device is intended to be notified and click Add MD.



Select MDs to be notified and confirm by clicking Add.



Verify the status of the added MD before filing the notification. To verify the status, click the MD that is marked green.

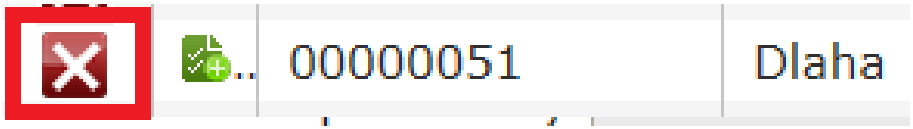


The status of MD is displayed

Remove MD with the below stated status from the notification:

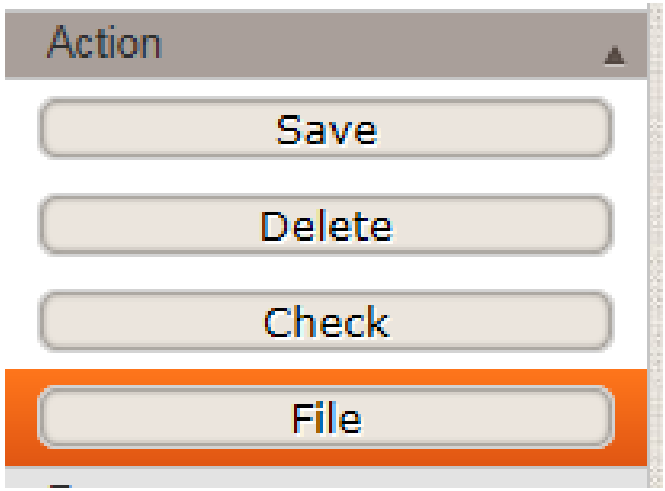
- MD not supplied / offered on market
- Marked for deletion
- Expired or deleted

Remove the MD from the list in the notification by clicking the red cross.

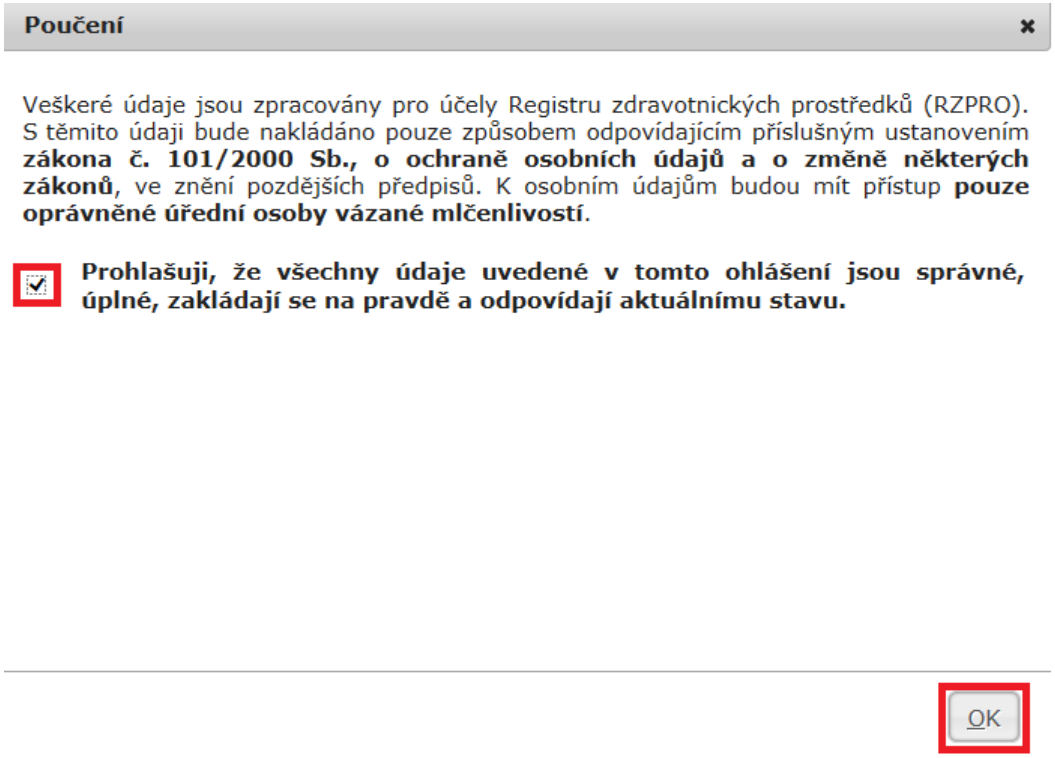


Should the MD you intend to place on market be expired or deleted, the application for the concerned MD notification according to Section 33 par. 1 of the Act on MD shall be submitted, see Manual – Application for MD notification.

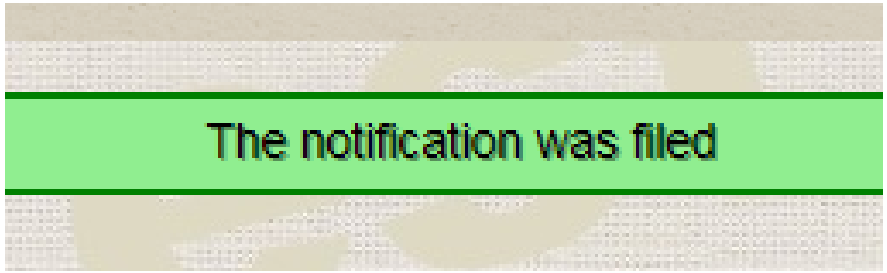
Once the notification is prepared, click File.



A notice confirming the correctness of the notification is displayed (*available only in Czech*). Confirm and click OK.



The notification has been filed

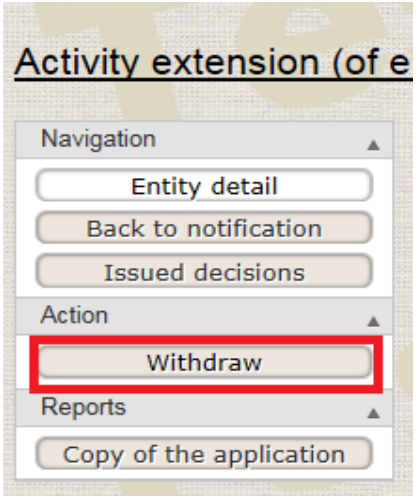


The status of the notification is to be found under Filed notifications

Notification withdrawal

The notification may be withdrawn at any time from the the moment of filing until the Certificate of compliance is issued.

Attention – this step is irreversible!



Status in RZPRO

- **EDITING** – (reference number issued) you may edit (modify) the notification
- **SUBMITTED** – the notificationhas been filed or appended to the Institute
- **PROCESSED** – the notification is being assessed by the assessor
- **ACCEPTED** – the notification meets the legal requirements and the Institute has issued the decision
- **CALL FOR COMPLETION** – you have been delivered call for completion, it is necessary to append the notification within the predefined timeline set forth by the resolution, which is part of the call for completion
- **STOPPED** – you have not appended the notification within the predefined timeline, the Institute cannot confirm the application, you will be informed thereof by a letter sent via post or data box.
- **THE APPLICATION WAS WITHDRAWN** – you have taken your notification back. The decision cannot be issued. You shall be informed on this fact by a resolution sent via the data box or post. After the resoulution has been issued, the application status changes to „cancellation administration“.
- **CANCELLATION ADMINISTRATION – see THE APPLICATION WAS WITHDRAWN.**

You may find only status Editing in the list of **EDITED APPLICATION**:

- **EDITING** – (no reference number issued) the application has not been filed, you may edit it.

In case of doubt contact the State Institute for Drug Control:

email: SZP_RZPRO_dotazy@sukl.cz or
tel. + 420 272 185 262 on Wednesdays between 9:00 a.m. and 12:00 a.m.