
SÚKL

# ACTIVITY / ENTITY EXTENSION ACCORDING TO SECTION 30 OF THE ACT ON MEDICAL DEVICES

Medical Devices Branch

25.3.2020

Registration of a person shall be effective for the period of five years of the date of issue of the certificate of compliance with the notification duty.

Registration of a person may be repeatedly extended, always for the period of five years. A person who intends to continue to carry out the notified operation, shall notify the Institute of such fact no sooner then six months before the expiry of its validity, no later, however, then two months before its expiry. Section 28 of the Act on Medical Devices (Act on MD) shall apply accordingly to the particulars of notification.

The period of extension of registration shall follow-up on the last day of the originally established validity of registration.

# Notice:

- Prior to filing the notification for Activity extension, it is necessary to verify that all registered data in the detail of the person is up to date and valid.
- In case, some data is not up to date, it shall be updated via the Data change notification according to Section 29 par. 3 of the Act on MD.
- It is not possible to edit any data within the Activity extension notification. By filing the Activity extension notification you confirm, that all registered data is valid and up to date. Should the Institute find when inspecting the notification, that some of the data is not up to date or true, the certificate of compliance with notification duty will not be issued and the activity will not be extended.
- It is not possible to submit more than one notification for Activity extension at a time. Should you apply for extension of some of the registered activities, you will have to wait until that is granted, to be able to apply for other activity extension.
- In case, the Activity extension notification is not filed within the date of activity expiry, the registered activites will be terminated.

# What data need to be up to date before filing the notification for Activity extension:

- **Manufacturer of custom made medical devices** – registered generic groups of medical devices have to be valid. The validity may be verified with the GMDN Agency https://www.gmdnagency.org/

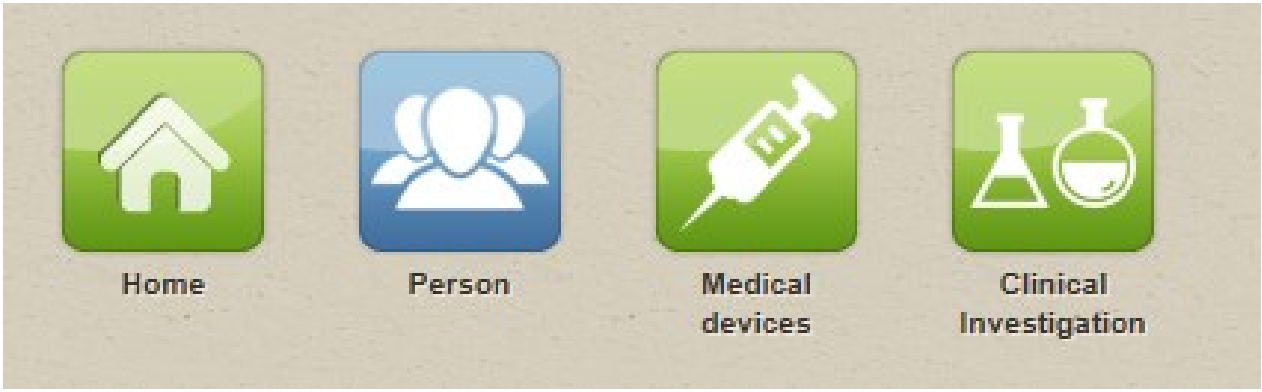
- **Authorised representative** – data about the authorised representative including name and address of its registered office.

# What data need to be up to date before filing the notification for Activity extension:

- **Distributor / Importer** – list of medical devices notified according to Section 33 par. 2 of the Act on MD

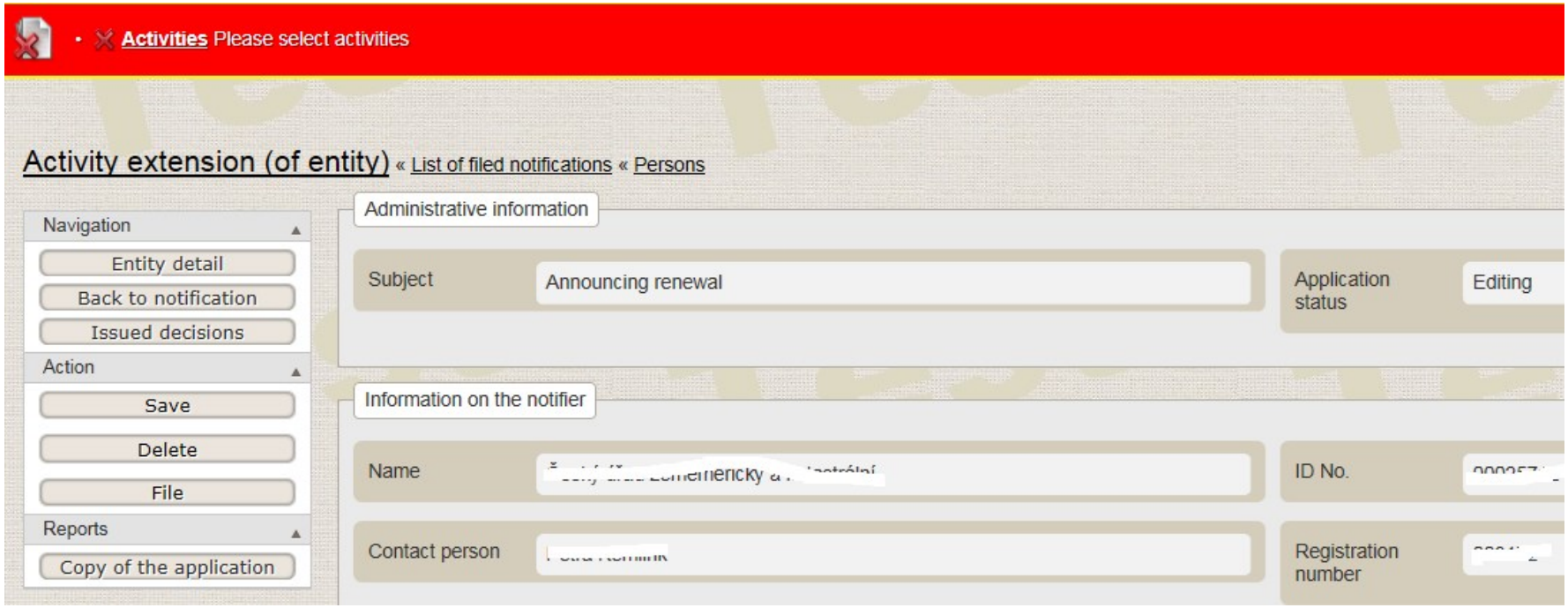
- **Person servicing medical devices** – list of manufacturers whose medical devices are serviced thereby, containing the bussiness or person name and address of its registered office, a copy of a certificate of specialised maintenance training as referred to by Section 65 par. 4 letter b) or Section 66 par. 2 letter b) of the Act on MD from each manufacturer or its authorised person and a copy of authorisation of such person by the manufacturer.

# Log in the Registry and access module Person



# The icon Activity extension (of entity) is available no sooner than 6 months before the expiry of activity validity

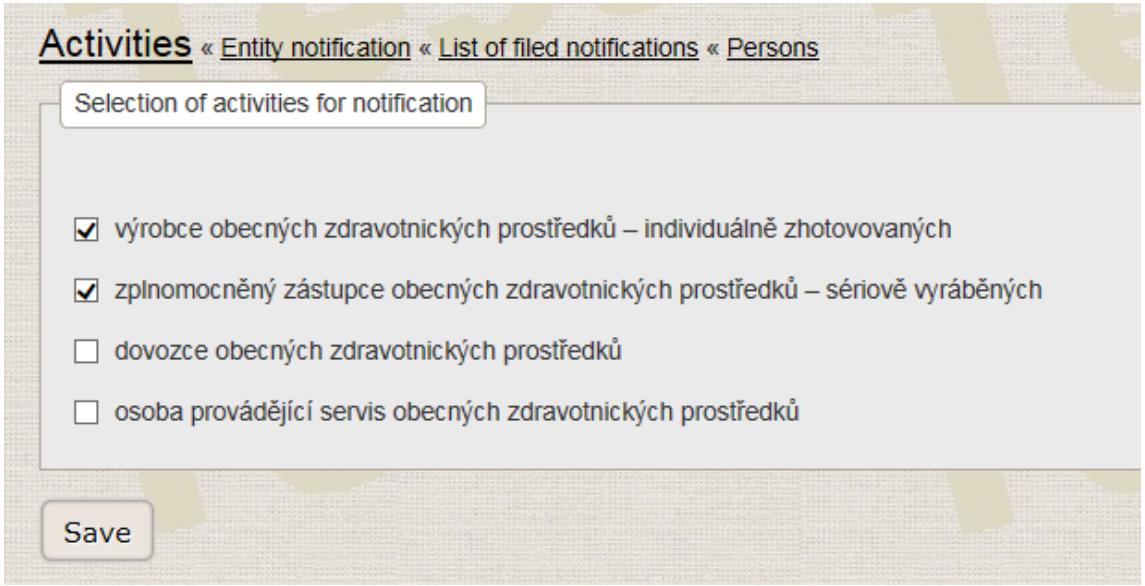
# When you click on Activity extenstion (of entity) the form for Announcing renewal is generated



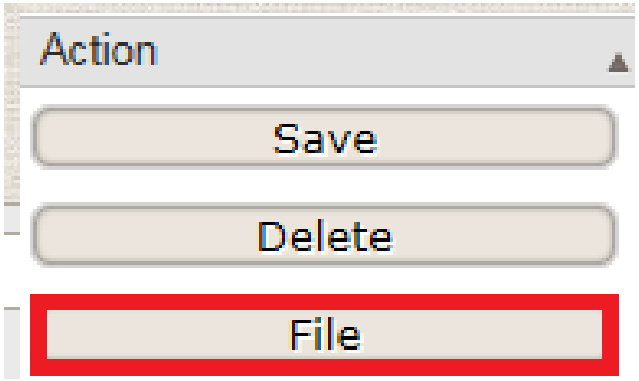
# Roll to the bottom of the page and click on Selection of activities for renewal

**When you click on Selection of activities for renewal, the list of registered activities whose validy shall expire within 6 months is displayed. Select the activities you desire to extend and confirm by Save.**

***Note: activity names are provided only in the Czech language.***

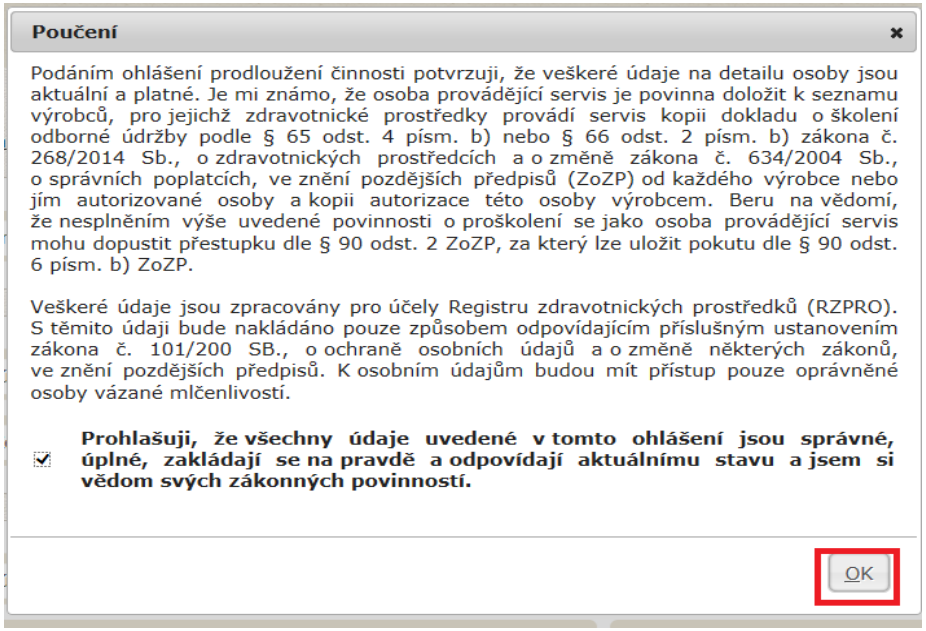


# To submit the notification click on File.



**A notice is displayed. Confirm by OK.**
**By confirming the notice, the notifier declares, that all registered data is valid and up to date.**

***Note: the notice is always displayed in Czech.***



# Your notification has been filed.

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

# Notification certification

The Institute shall grant the activity extension by issuing Certificate of compliance with notification duty, in case all registered data is valid and up to date.

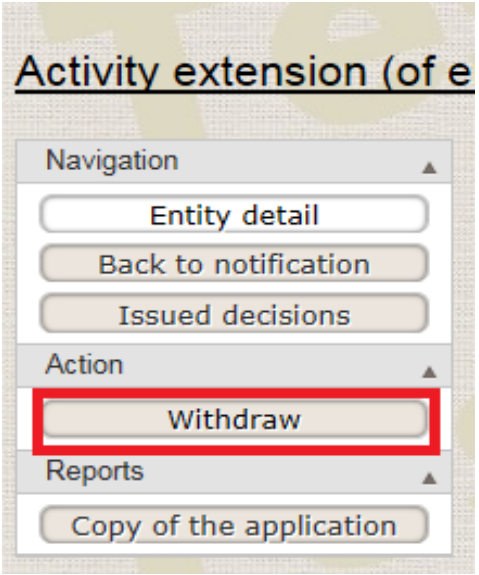
# Notification rejection

Should the Institute find, that registered data in not valid and up to date, the notification is rejected. Reasons for rejecting the notification are provided in the issued resolution. The invalid data have to be updated via Data change notification. Notification for activity extension shall be submitted followingly.

# 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.**