



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

Medical Devices Branch

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 than six months before the expiry of its validity, no later, however, than 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 activities 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 extension (of entity) the form for Announcing renewal is generated

Activities Please select activities

Activity extension (of entity) « List of filed notifications « Persons

|                                    |  |
|------------------------------------|--|
| <b>Administrative information</b>  |  |
| Subject                            | Announcing renewal                           |
| Application status                 | Editing                                      |
| <b>Information on the notifier</b> |  |
| Name                               | Ing. Miroslav Zemanerický a. s. - autorizace |
| ID No.                             | 0000571                                      |
| Contact person                     | Ing. Zemanerický                             |
| Registration number                | 0000571                                      |

**Navigation**

- Entity detail
- Back to notification
- Issued decisions

**Action**

- Save
- Delete
- File

**Reports**

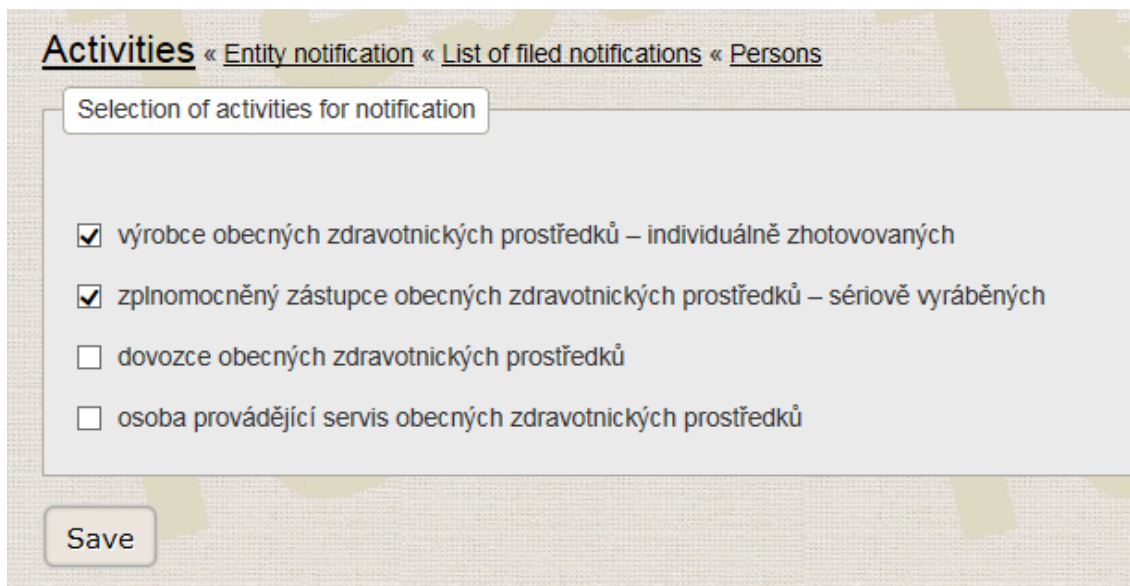
- Copy of the application

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

List of notified activities

Selection of activities for renewal

**When you click on Selection of activities for renewal, the list of registered activities whose validity 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.***



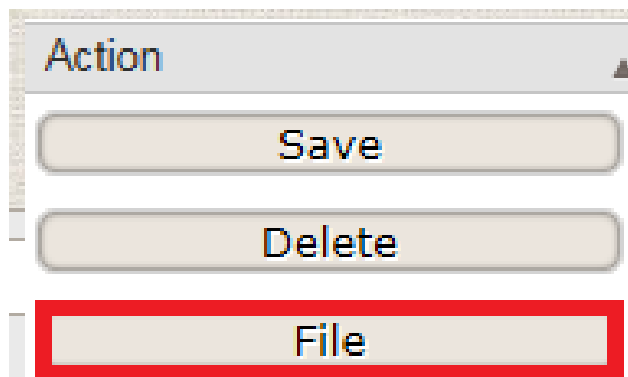
**Activities** « [Entity notification](#) « [List of filed notifications](#) « [Persons](#)

Selection of activities for notification

- výrobce obecných zdravotnických prostředků – individuálně zhotovovaných
- zplnomocněný zástupce obecných zdravotnických prostředků – sériově vyráběných
- dovozce obecných zdravotnických prostředků
- osoba provádějící servis obecných zdravotnických prostředků

Save

**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.***

**Poučení** ✕

Podáním ohlášení prodloužení činnosti potvrzují, že veškeré údaje na detailu osoby jsou aktuální a platné. Je mi známo, že osoba provádějící servis je povinna doložit k seznamu výrobců, pro jejichž zdravotnické prostředky provádí servis kopii dokladu o školení odborné údržby podle § 65 odst. 4 písm. b) nebo § 66 odst. 2 písm. b) zákona č. 268/2014 Sb., o zdravotnických prostředcích a o změně zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů (ZoZP) od každého výrobce nebo jím autorizované osoby a kopii autorizace této osoby výrobcem. Beru na vědomí, že nesplněním výše uvedené povinnosti o proškolení se jako osoba provádějící servis mohu dopustit přestupku dle § 90 odst. 2 ZoZP, za který lze uložit pokutu dle § 90 odst. 6 písm. b) ZoZP.

Veškeré údaje jsou zpracovány pro účely Registru zdravotnických prostředků (RZPRO). S těmito údaji bude nakládáno pouze způsobem odpovídajícím příslušným ustanovením zákona č. 101/200 SB., o ochraně osobních údajů a o změně některých zákonů, ve znění pozdějších předpisů. K osobním údajům budou mít přístup pouze oprávněné osoby vázané mlčenlivostí.

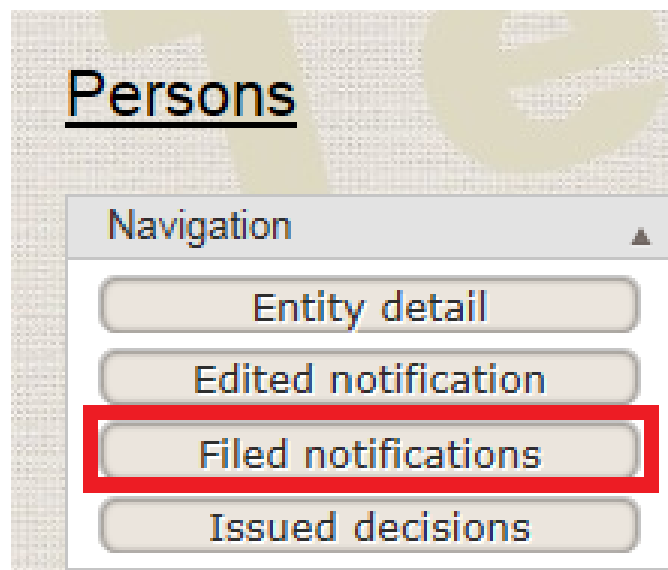
**Prohlašuji, že všechny údaje uvedené v tomto ohlášení jsou správné, úplné, zakládají se na pravdě a odpovídají aktuálnímu stavu a jsem si vědom svých zákonných povinností.**

**Your notification has been filed.**

A screenshot of a notification banner. It consists of a light beige background with a fine grid pattern. A solid green horizontal bar is centered across the middle, containing the text 'The notification was filed' in a black, sans-serif font.

The notification was 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 is 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

- ⑥ **EDITING** – (reference number issued) you may edit (modify) the notification
- ⑥ **SUBMITTED** – the notification has been filed or appended to the Institute
- ⑥ **PROCESSED** – the notification is being assessed by the assessor
- ⑥ **ACCEPTED** – the notification meets the legal requirements and the Institute has issued the decision
- ⑥ **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
- ⑥ **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.
- ⑥ **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 resolution has been issued, the application status changes to „cancellation administration“.
- ⑥ **CANCELLATION ADMINISTRATION** – see **THE APPLICATION WAS WITHDRAWN**.

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

- ⑥ **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](mailto:SZP_RZPRO_dotazy@sukl.cz) or  
tel. + 420 272 185 262 on Wednesdays between  
9:00 a.m. and 12:00 a.m.**