SÚKL

STÁTNÍ ÚSTAV
PRO KONTROLU LÉČIV
Šrobárova 48
100 41 Praha 10
Telefon: +420 272 185 111
Fax: +420 271 732 377
E-mail: posta@sukl.cz
Web: www.sukl.cz

Manual no. 1 – First-time login to the Registry of Medical Devices and notification of a person or operation

In compliance with Section 26, paragraphs 1 to 5, the manufacturer, authorised representative, importer, distributor, and servicing person are obliged to notify the Institute of their operation prior to the commencement of such operation. **This obligation does not apply to importers and distributors of risk class I medical devices and in vitro diagnostic medical devices not belonging to List A or List B and not intended for self-testing.** A sponsor of a clinical investigation conducted at the premises of a provider of healthcare services established within the territory of the Czech Republic must notify its activity to the Institute prior to the commencement of the clinical investigation.

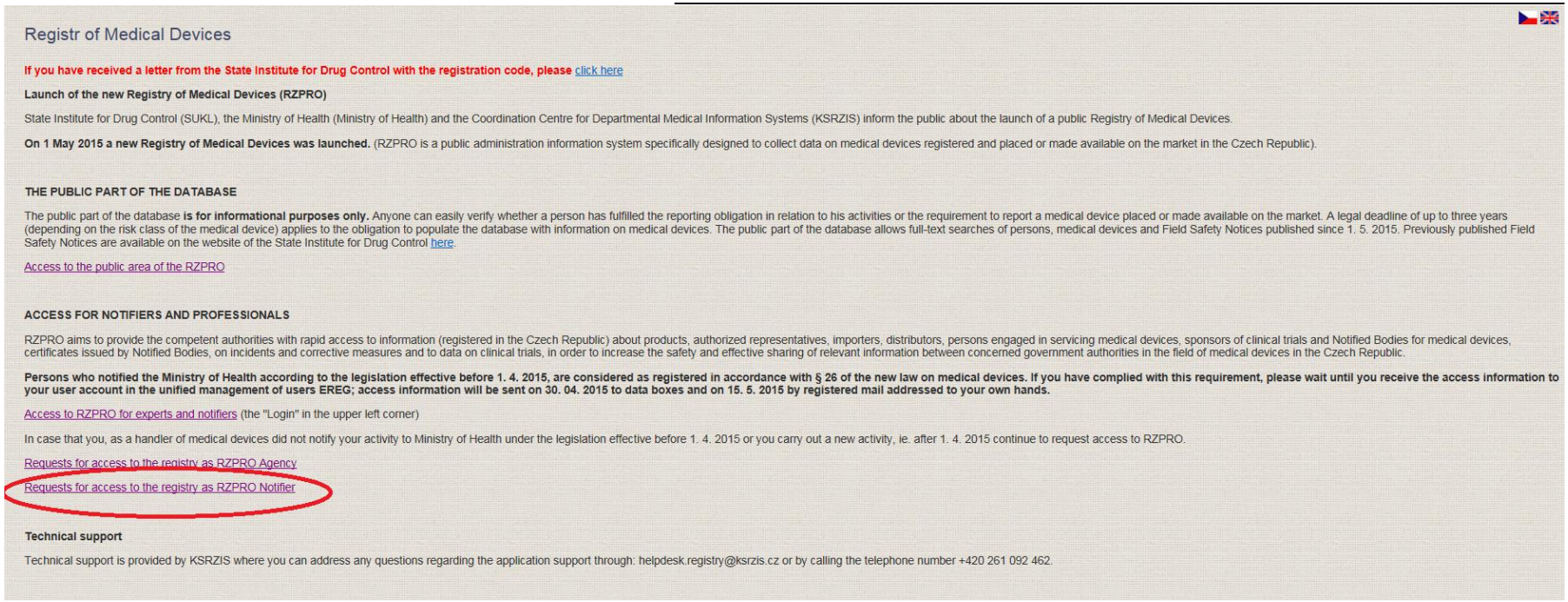
The notification of operation is subjected to administrative fee in the amount of 2,500 CZK:
The administrative fee shall be payable for the acceptance of:

- notification of operation of a manufacturer of serially manufactured medical devices;
- manufacturer of custom-made medical devices;
- authorised representative referred to by the Act on Medical Devices;
- medical device distributor;
- person servicing medical devices;
- importer of medical devices;
- sponsor of a clinical investigation of a medical device.

Please follow this Manual if you are a person handling medical devices who:

- **intends to commence operation which is subject to notification as referred to under Section 26 of the Act on Medical Devices; or**
- **has not filed notification of extended registration by 31 March 2016 despite having been obliged to do so (Section 97, paragraph 3 of the Act on Medical Devices).**

The first-time login to the Registry of Medical Devices has to be preceded by a submission of a request for access to the RZPRO. If you have not completed this step, please first visit the website at www.rzpro.cz and click on the link "*Request for access to the Registry as RZPRO Notifier*").



Registr of Medical Devices

If you have received a letter from the State Institute for Drug Control with the registration code, please click here

Launch of the new Registry of Medical Devices (RZPRO)

State Institute for Drug Control (SUKL), the Ministry of Health (Ministry of Health) and the Coordination Centre for Departmental Medical Information Systems (KSRZIS) inform the public about the launch of a public Registry of Medical Devices.

On 1 May 2015 a new Registry of Medical Devices was launched. (RZPRO is a public administration information system specifically designed to collect data on medical devices registered and placed or made available on the market in the Czech Republic).

THE PUBLIC PART OF THE DATABASE

The public part of the database **is for informational purposes only.** Anyone can easily verify whether a person has fulfilled the reporting obligation in relation to his activities or the requirement to report a medical device placed or made available on the market. A legal deadline of up to three years (depending on the risk class of the medical device) applies to the obligation to populate the database with information on medical devices. The public part of the database allows full-text searches of persons, medical devices and Field Safety Notices published since 1. 5. 2015. Previously published Field Safety Notices are available on the website of the State Institute for Drug Control here.

Access to the public area of the RZPRO

ACCESS FOR NOTIFIERS AND PROFESSIONALS

RZPRO aims to provide the competent authorities with rapid access to information (registered in the Czech Republic) about products, authorized representatives, importers, distributors, persons engaged in servicing medical devices, sponsors of clinical trials and Notified Bodies for medical devices, certificates issued by Notified Bodies, on incidents and corrective measures and to data on clinical trials, in order to increase the safety and effective sharing of relevant information between concerned government authorities in the field of medical devices in the Czech Republic.

Persons who notified the Ministry of Health according to the legislation effective before 1. 4. 2015, are considered as registered in accordance with § 26 of the new law on medical devices. If you have complied with this requirement, please wait until you receive the access information to your user account in the unified management of users EREG; access information will be sent on 30. 04. 2015 to data boxes and on 15. 5. 2015 by registered mail addressed to your own hands.

Access to RZPRO for experts and notifiers (the "Login" in the upper left corner)

In case that you, as a handler of medical devices did not notify your activity to Ministry of Health under the legislation effective before 1. 4. 2015 or you carry out a new activity, ie. after 1. 4. 2015 continue to request access to RZPRO.

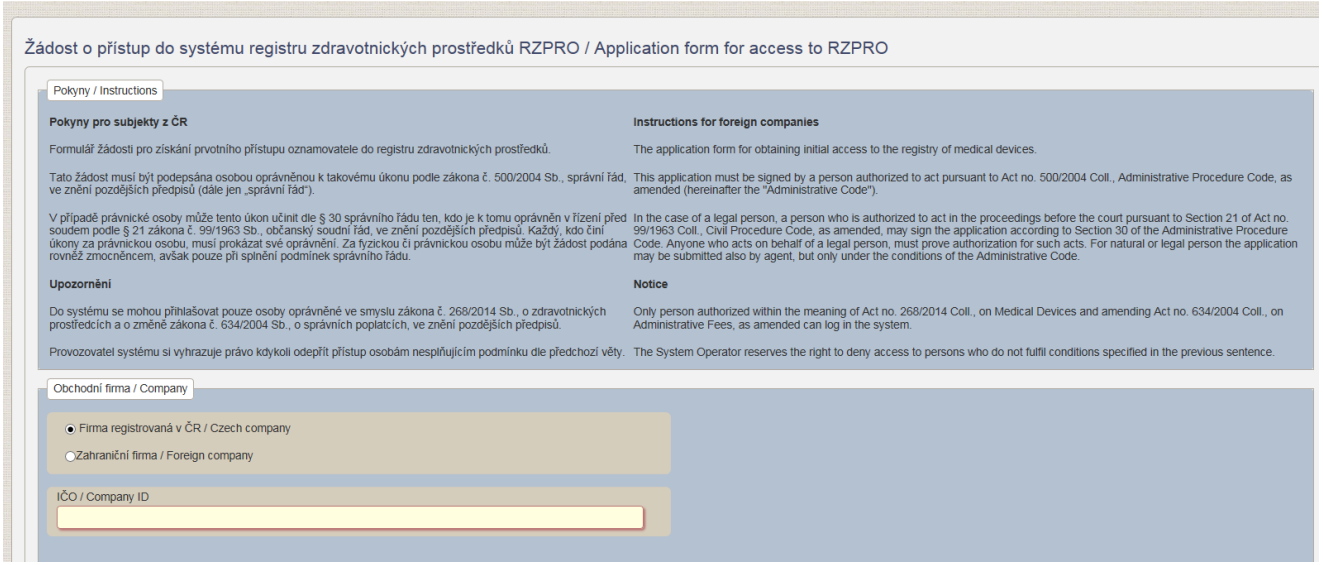
Requests for access to the registry as RZPRO Agency

Requests for access to the registry as RZPRO Notifier

Technical support

Technical support is provided by KSRZIS where you can address any questions regarding the application support through: helpdesk.registry@ksrzis.cz or by calling the telephone number +420 261 092 462.

Upon filling in the application, you will receive an e-mail message with your login details.

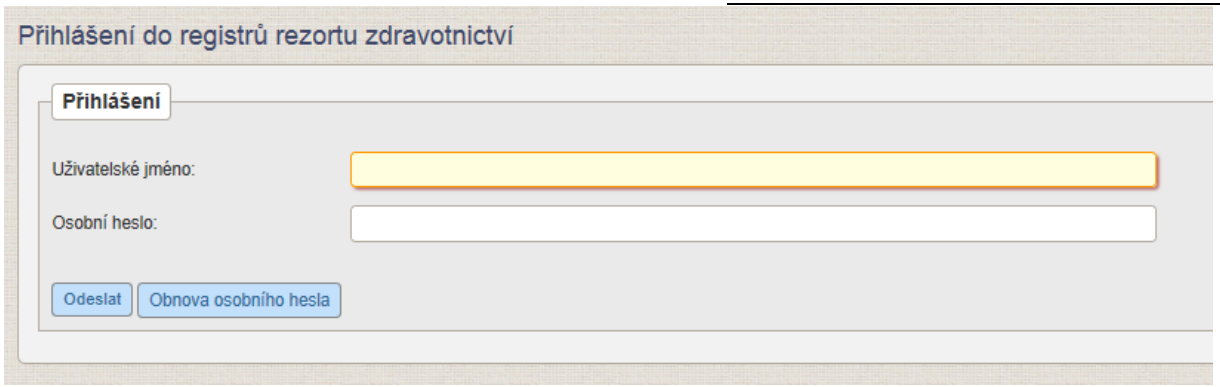


If you have completed this step, please continue as outlined herein.

1) In your internet browser (ideally Microsoft Internet Explorer 9, 10, 11 or Mozilla Firefox), open www.rzpro.cz.

2) Approximately in the middle of the page, you will see a hyperlink with the word “Access to RZPRO for experts and notifiers”. Click on this heading.

3) The following page asking you to log into your user account will be displayed. Fill in the details you have received in the e-mail message. The user name is usually composed of the first six characters of your surname and the first character of your name.



4) Once you fill in the required data, click on the *"Odeslat"* (Submit) button. Thereafter, check your mobile phone or e-mail, where a one-time code will be sent. The one-time code is of limited validity. Should it expire, click on the "Zpět na odeslání jednorázového kódu" (*Back to one-time code provision)* button.

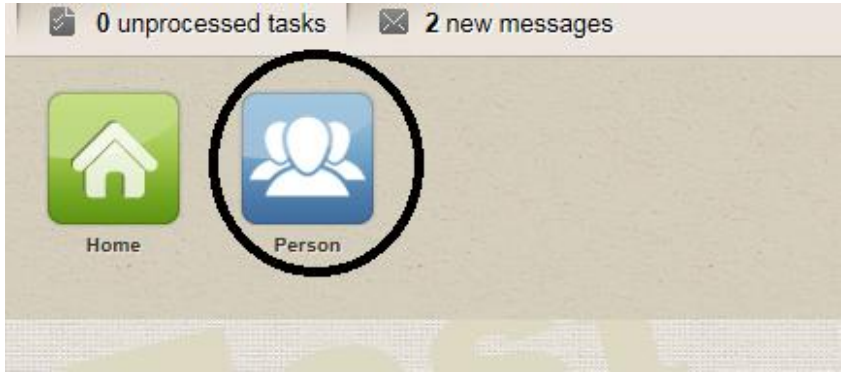
5) The following page will be displayed:

The word "SMS" in the green field may be also replaced with the word "e-mail", depending on what login channel you have set up.

6) Shortly thereafter, a one-time code will be sent to your phone number. Type the code into the "Jednorázový kód" *(One-time code)* field and click on "Odeslat" (*Submit*).

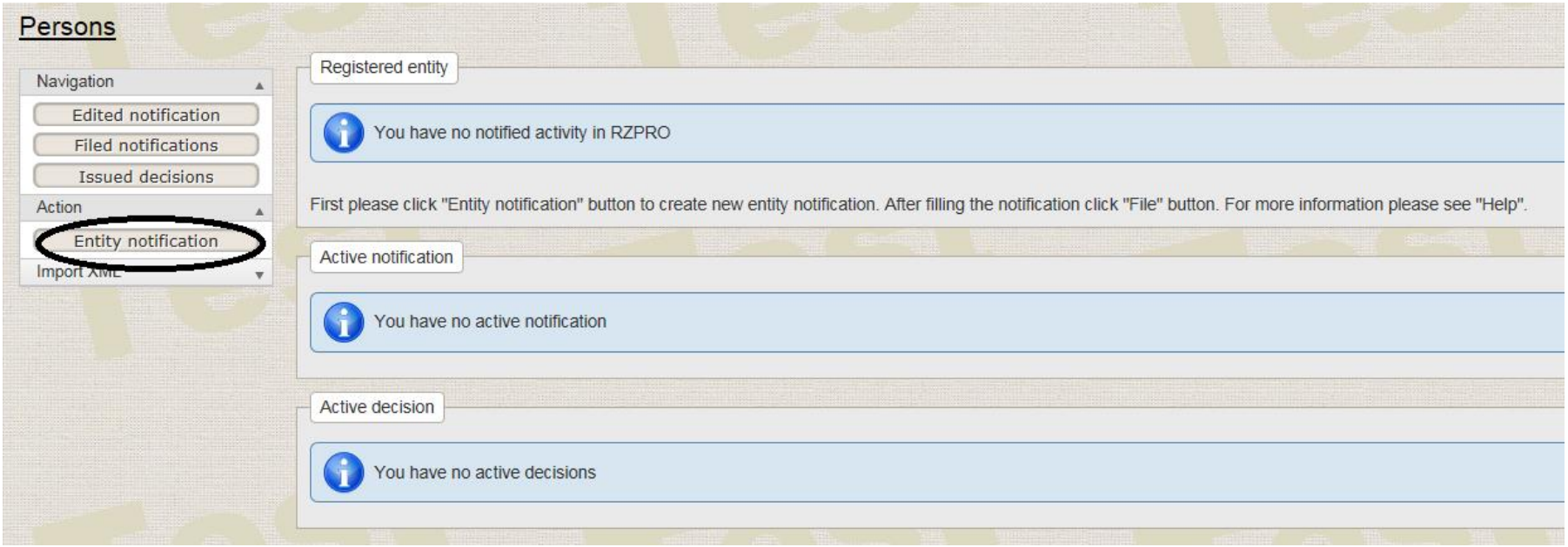
7) The following page will be displayed. On this page, click on the green frame reading “RZPRO”.

8) The following page will be displayed. Click on the image reading “Person”.

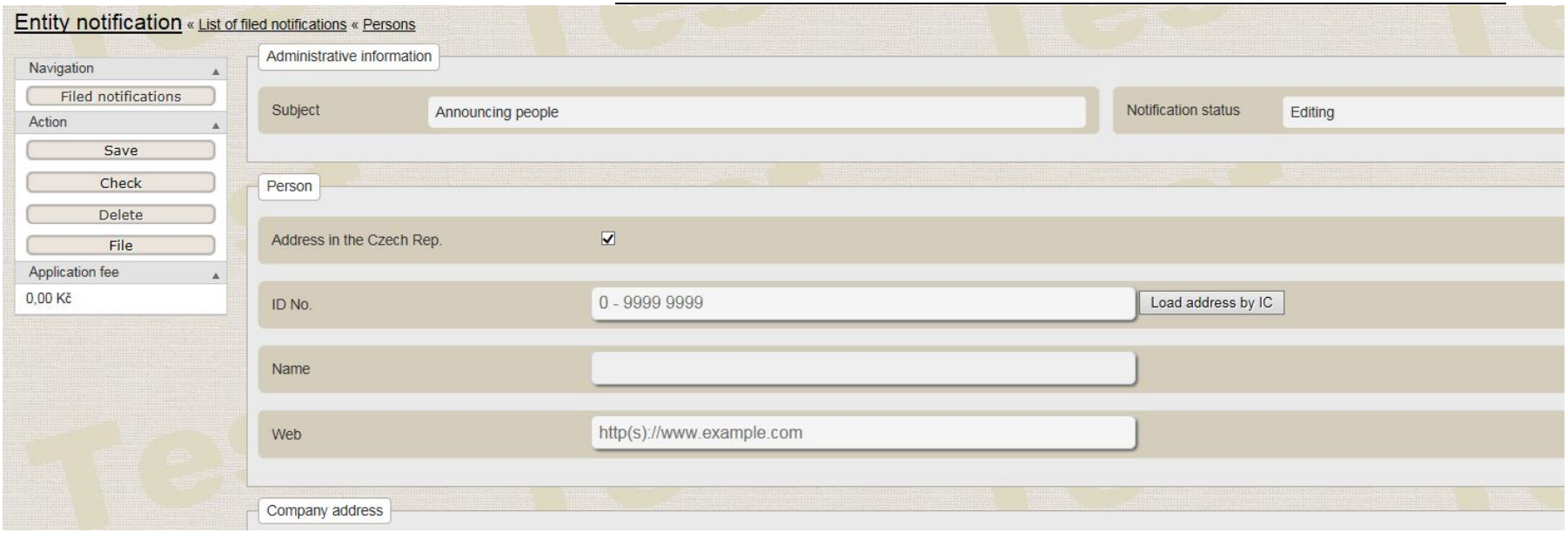


9) The following images illustrate the procedure of filing a notification of a new person, i.e. a person who intends to commence initial operation on the Czech market or a person who failed to meet their notification duty referred to under Section 97, paragraph 3 of the Act on Medical Devices by 31st March 2016.

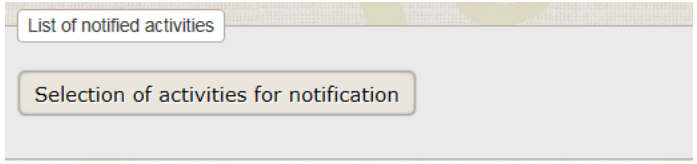
10) The following page will be displayed. Click on the "Entity notification" in the left section of the page.



11) A form to be completed will be displayed. Fields highlighted in yellow are mandatory.

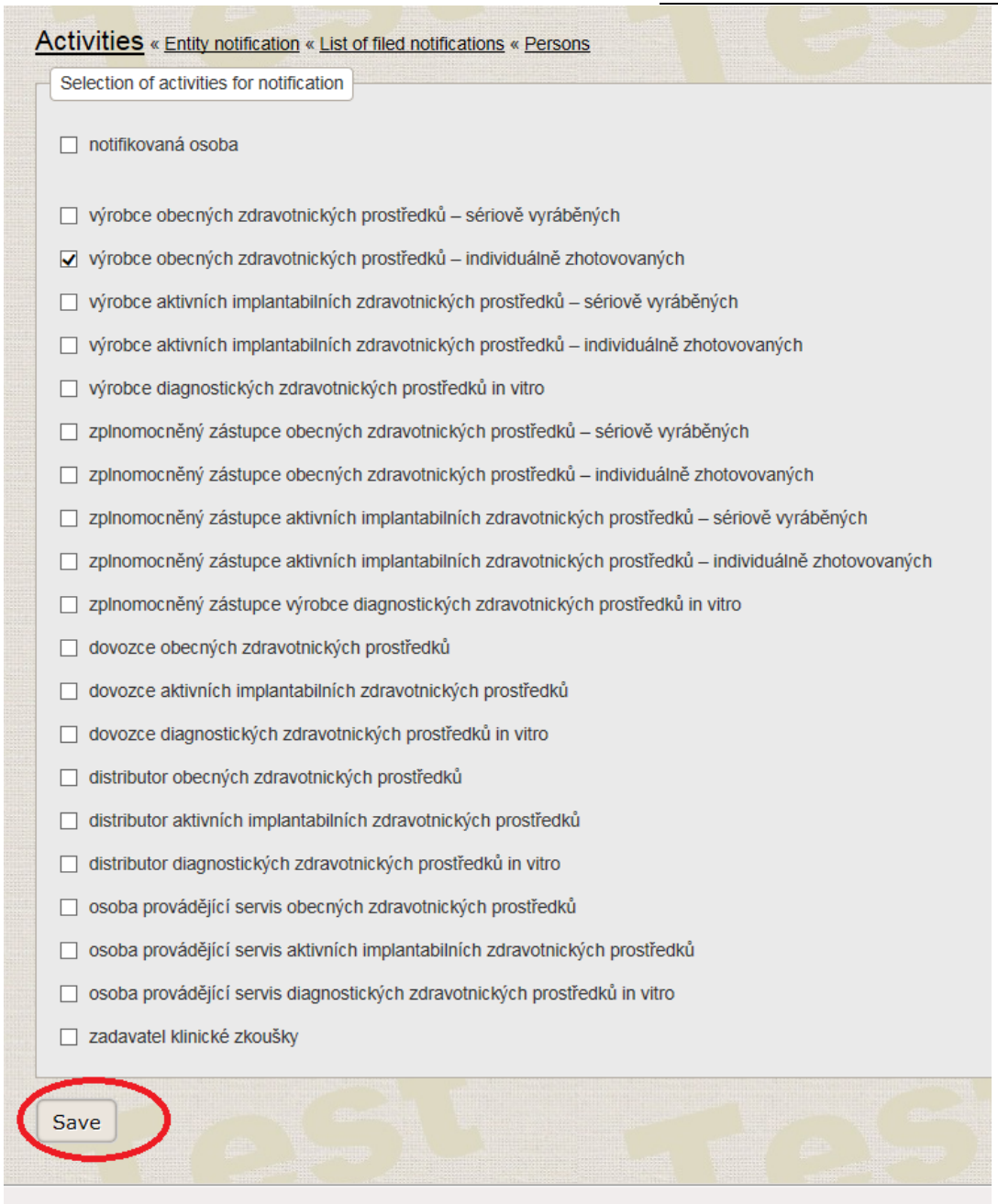


12) Once you complete the form, you will see a "Selection of activities for notification" button in the bottom part of the screen.



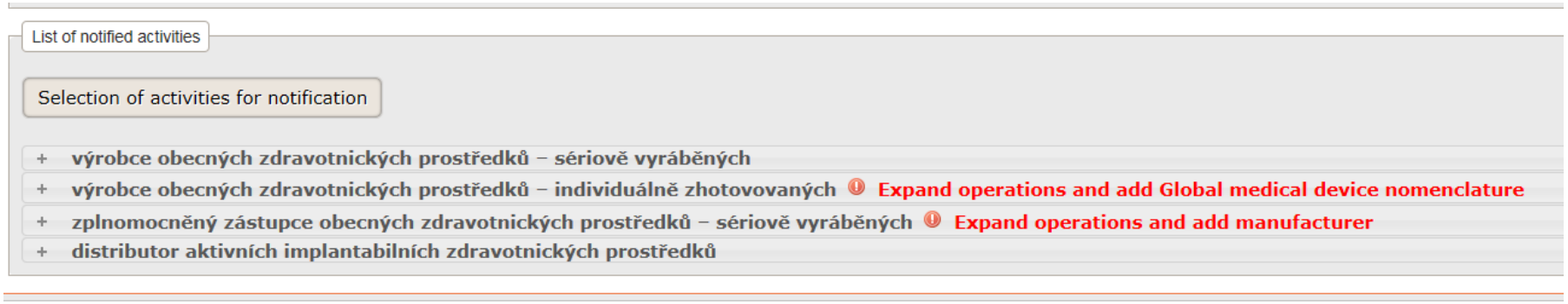
13) Click the button and select all of the operations applicable to you and press the “Save” button.

SÚKL
STÁTNÍ ÚSTAV PRO KONTROLU LÉČIV
Šrobárova 48
100 41 Praha 10
Telefon: +420 272 185 111
Fax: +420 271 732 377
E-mail: posta@sukl.cz
Web: www.sukl.cz



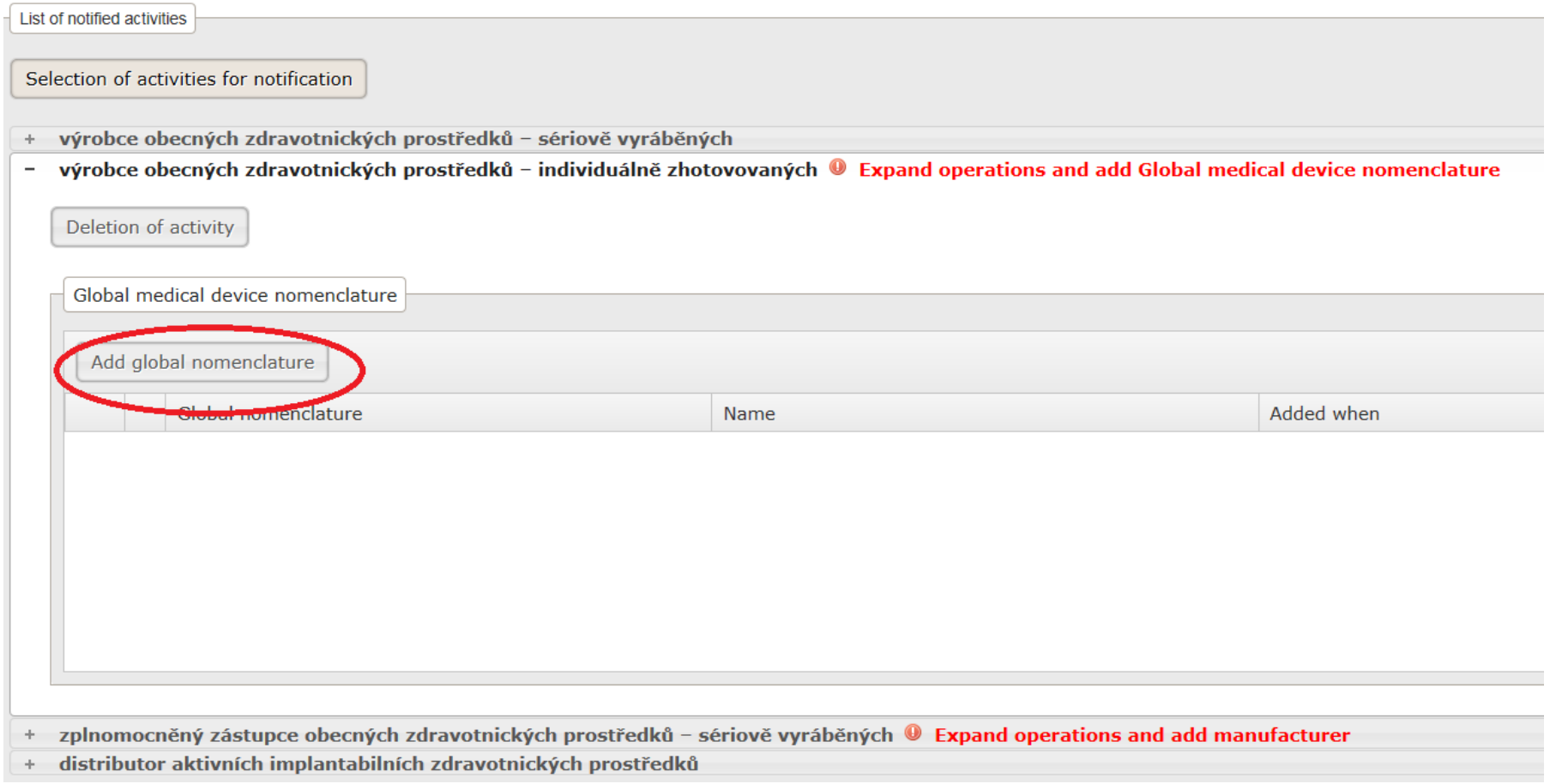
Steps 14-23 apply to manufacturers of custom-made medical devices, authorised representatives, and servicing persons. Others should continue with Step 24.

14) If you are a manufacturer of custom-made medical devices, open the activity and add the GMDN code. If you are an authorised representative or a servicing person, open the respective activity and add the manufacturer. Others should continue with Step 24.

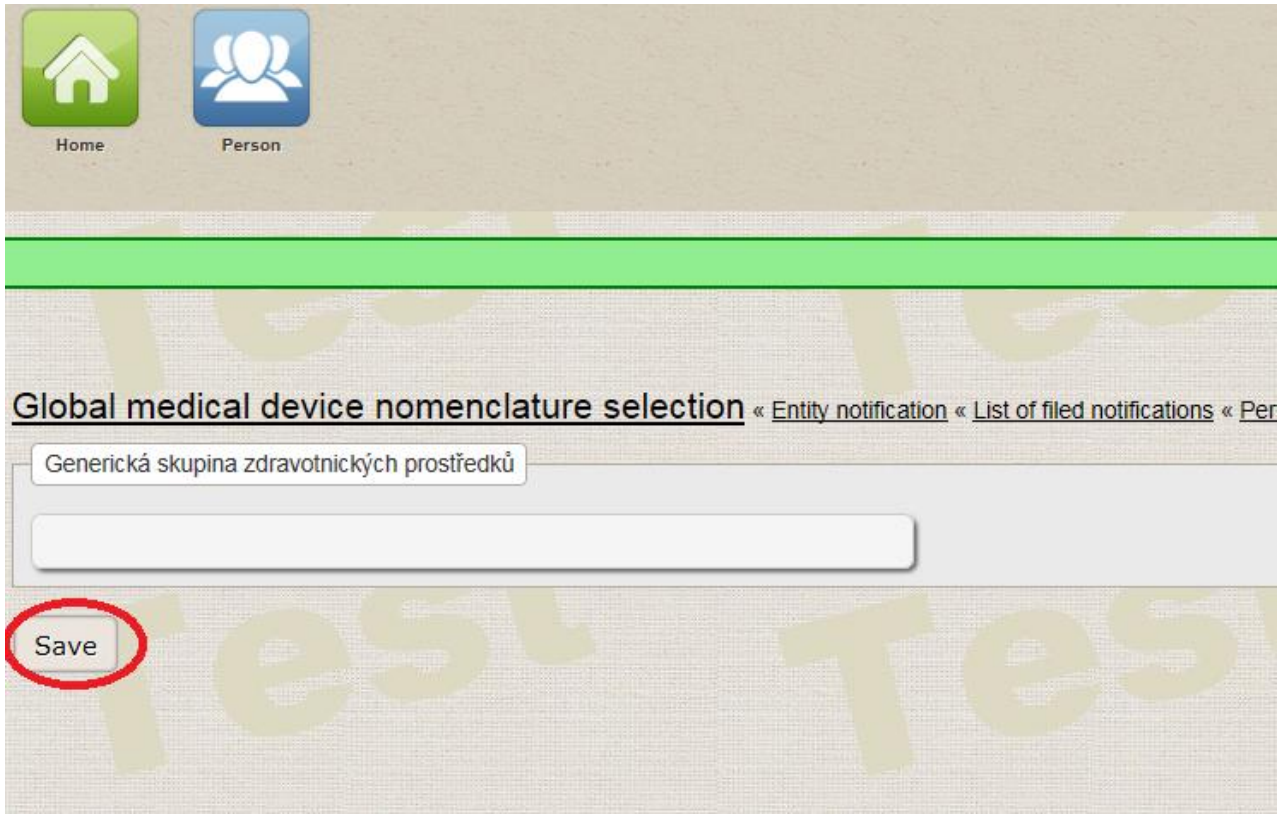


Steps 15 and 16 apply solely to manufacturers of custom-made medical devices (others should continue with Step 17).

15) The GMDN code may be added by opening the activity of the manufacturer of custom-made medical devices and by clicking on the "Add global nomenclature" button. Medical devices are classified according to the Global Medical Device Nomenclature (GMDN) indicating the generic group of medical devices. Generic groups of medical devices are defined on the basis of a numeric code and name as per the internationally acknowledged Global Medical Device Nomenclature. This code may be obtained from www.gmdnagency.org.

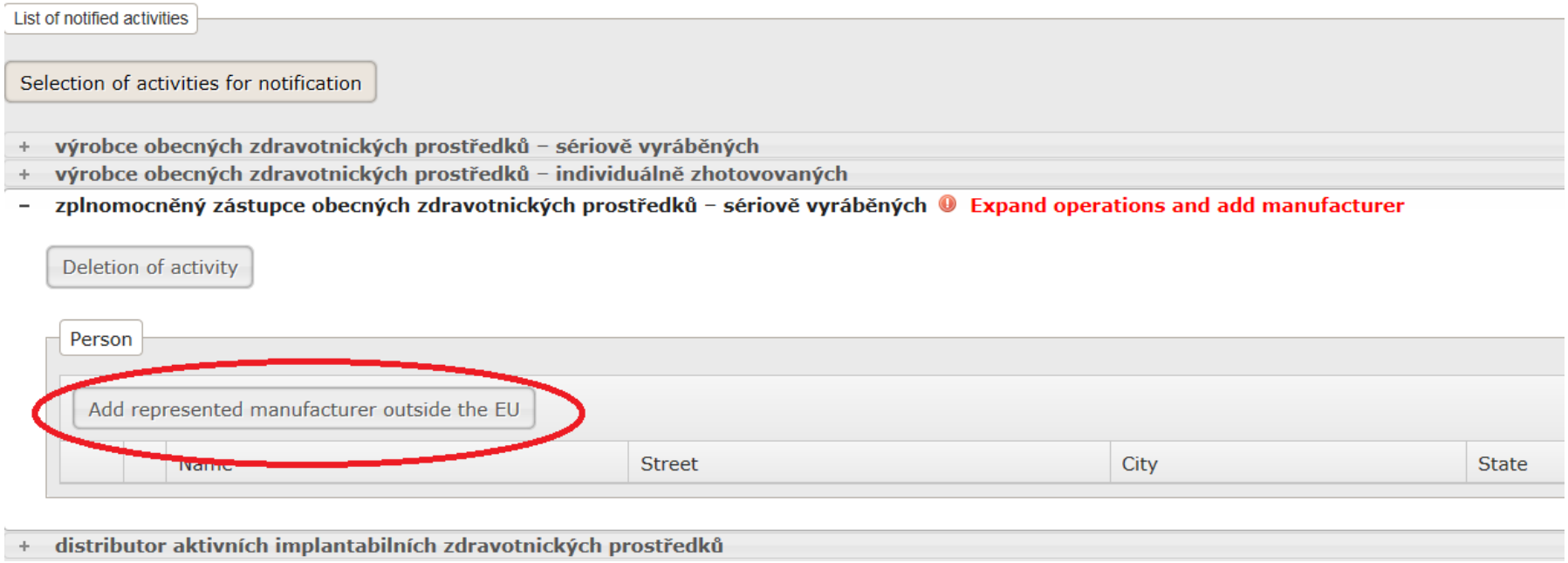


16) Enter the GMDN code and press the “Save” button.

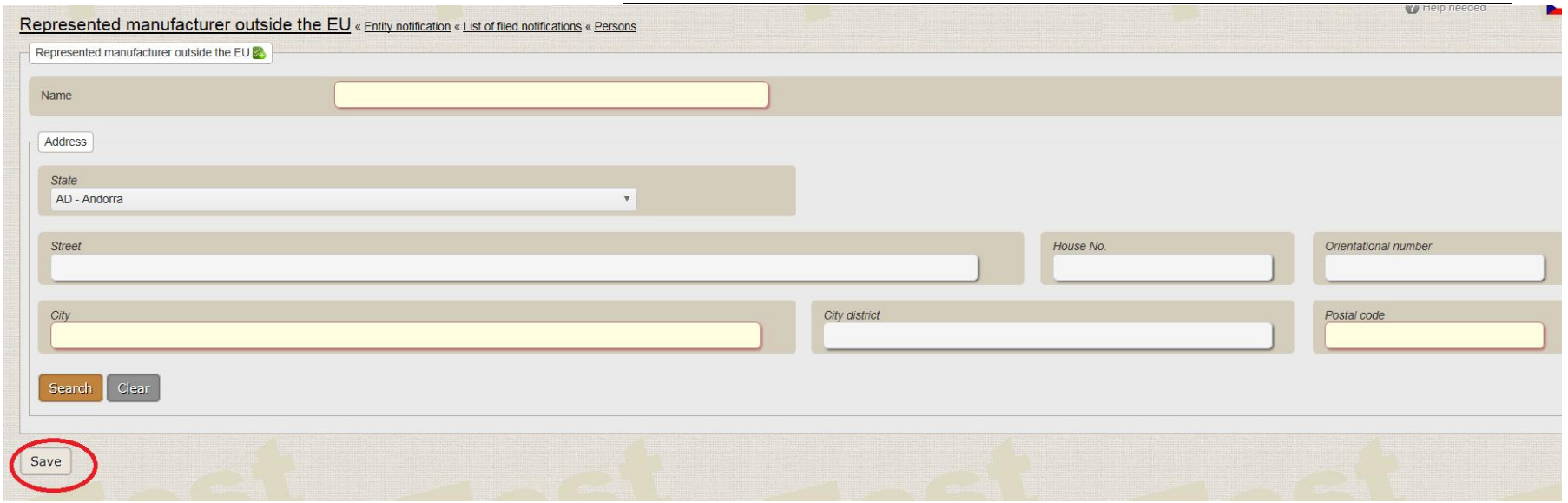


Steps 17 and 18 apply to authorised representatives (others should continue with Step 19).

17) To add a manufacturer to the activity of an authorised representative, open this activity and click on the "Add represented manufacturer outside the EU" button.

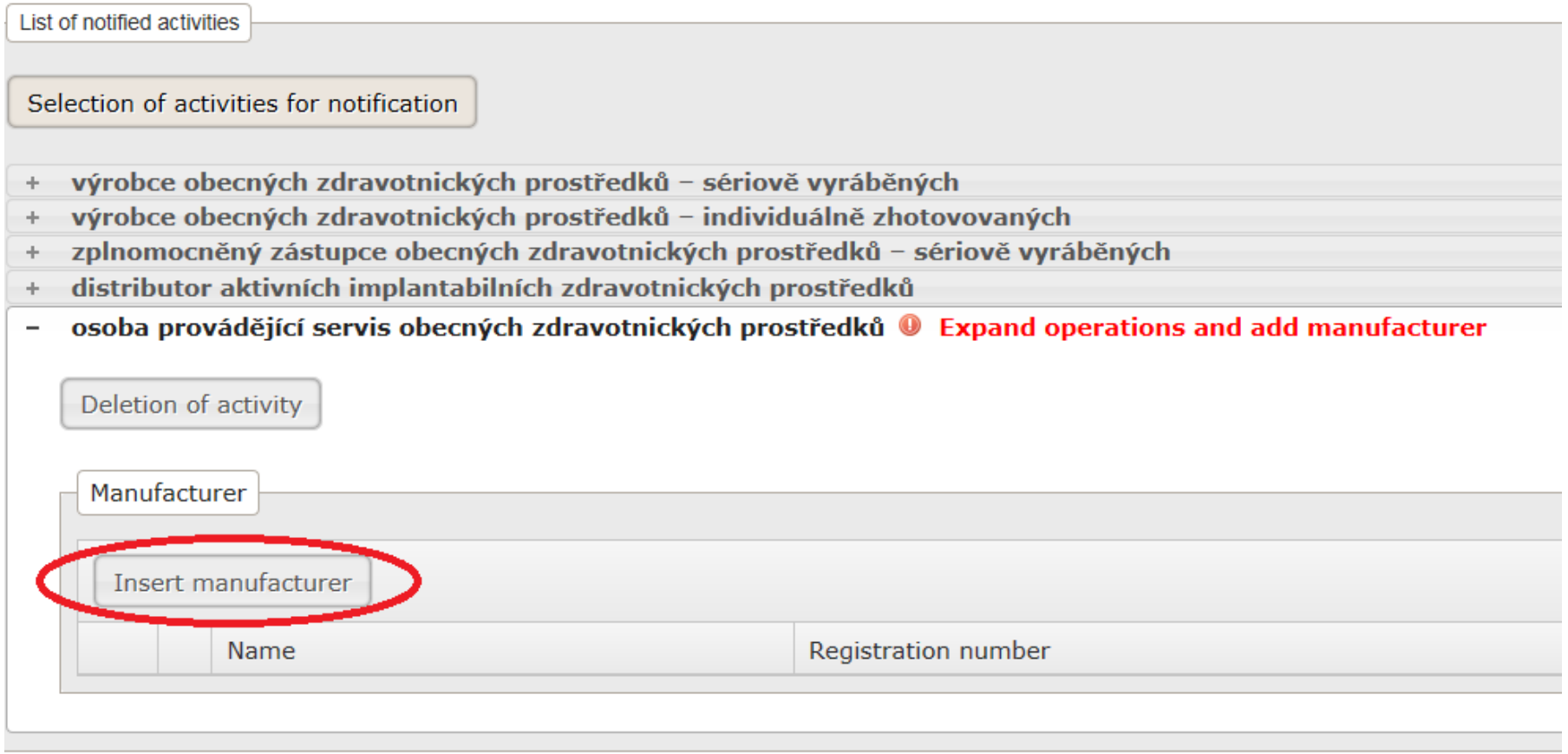


18) Thereafter, complete the data about the manufacturer outside the EU manually. The fields highlighted in yellow are mandatory. When the data are completed, press "Save".

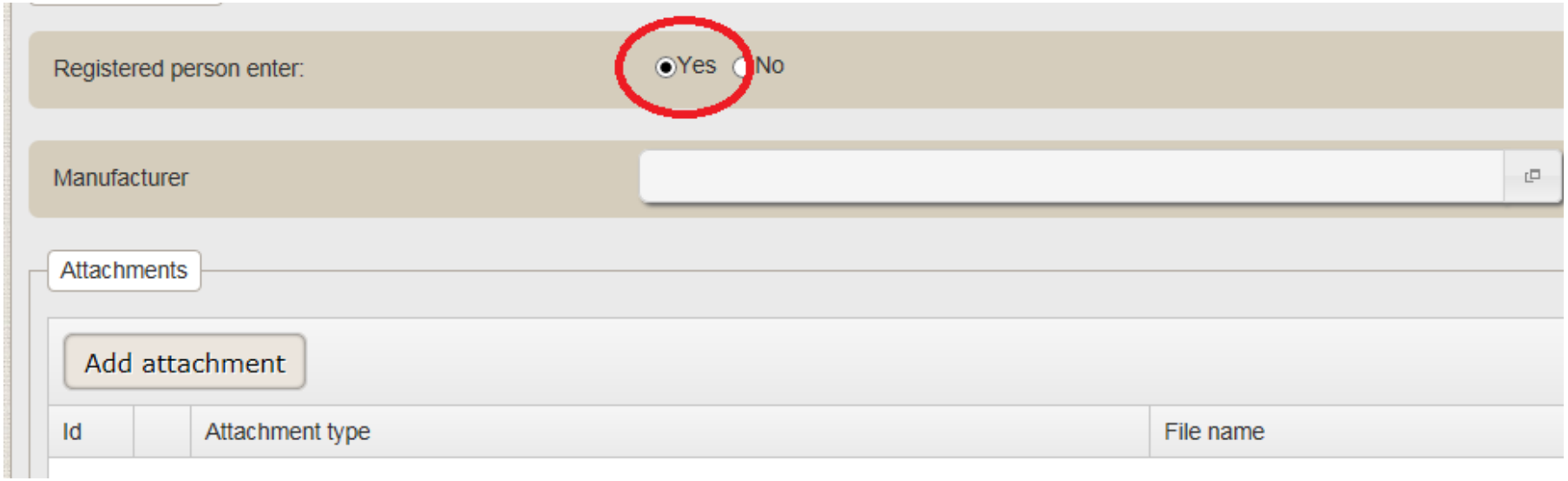


Steps 19 to 23 apply to servicing persons (others should continue with Step 24).

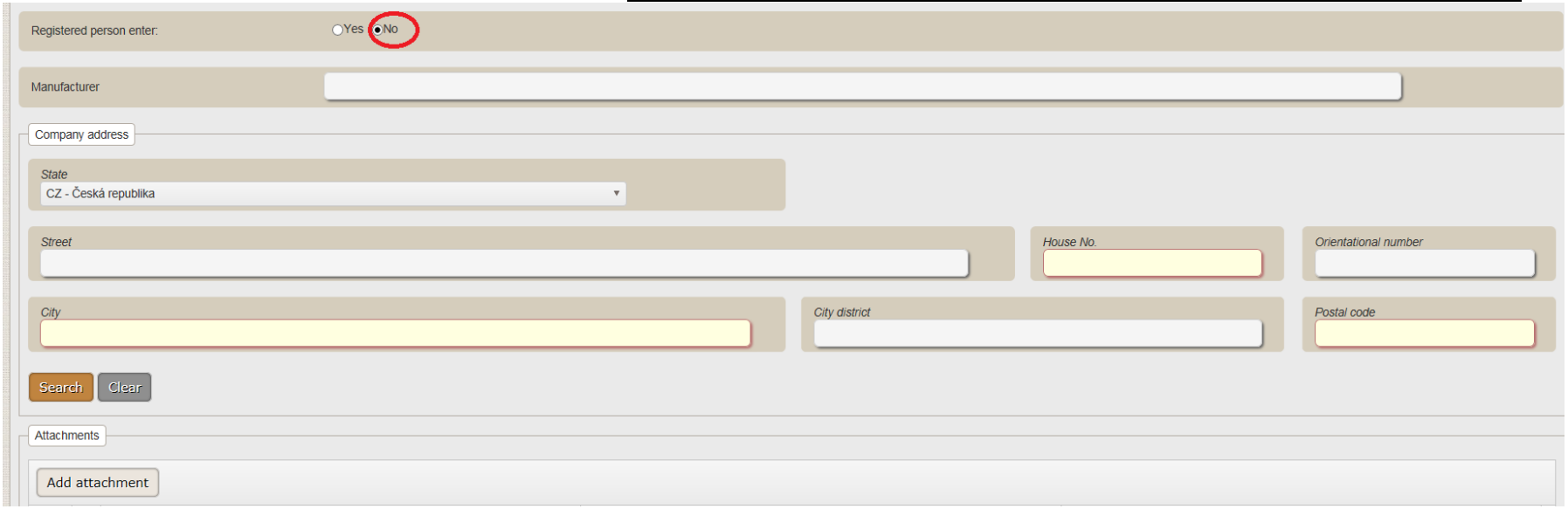
19) To add a manufacturer to the activity of a servicing person, open this activity and click on the "Insert manufacturer" button. **In compliance with Section 28, paragraph 1(e) of the Act on Medical Devices, it is necessary to complete the manufacturer´s name and address of its registered office in the following format: street, house no, city, and country.**


List of notified activities
Selection of activities for notification
+ výrobce obecných zdravotnických prostředků – sériově vyráběných
+ výrobce obecných zdravotnických prostředků – individuálně zhotovovaných
+ zplnomocněný zástupce obecných zdravotnických prostředků – sériově vyráběných
+ distributor aktivních implantabilních zdravotnických prostředků
– osoba provádějící servis obecných zdravotnických prostředků
Expand operations and add manufacturer
Deletion of activity
Manufacturer
Insert manufacturer
Name
Registration number

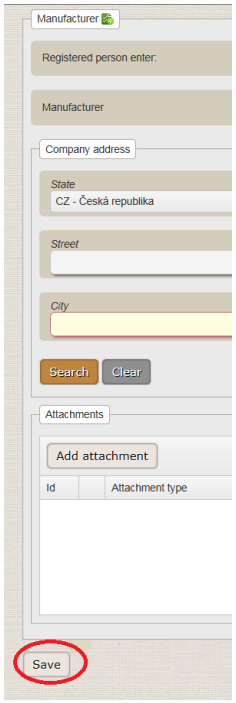
20) When you click on the "Insert manufacturer" button, a window to be completed will be displayed. You can try to select the manufacturer from the list by ticking "Yes" and selecting the manufacturer from the list.



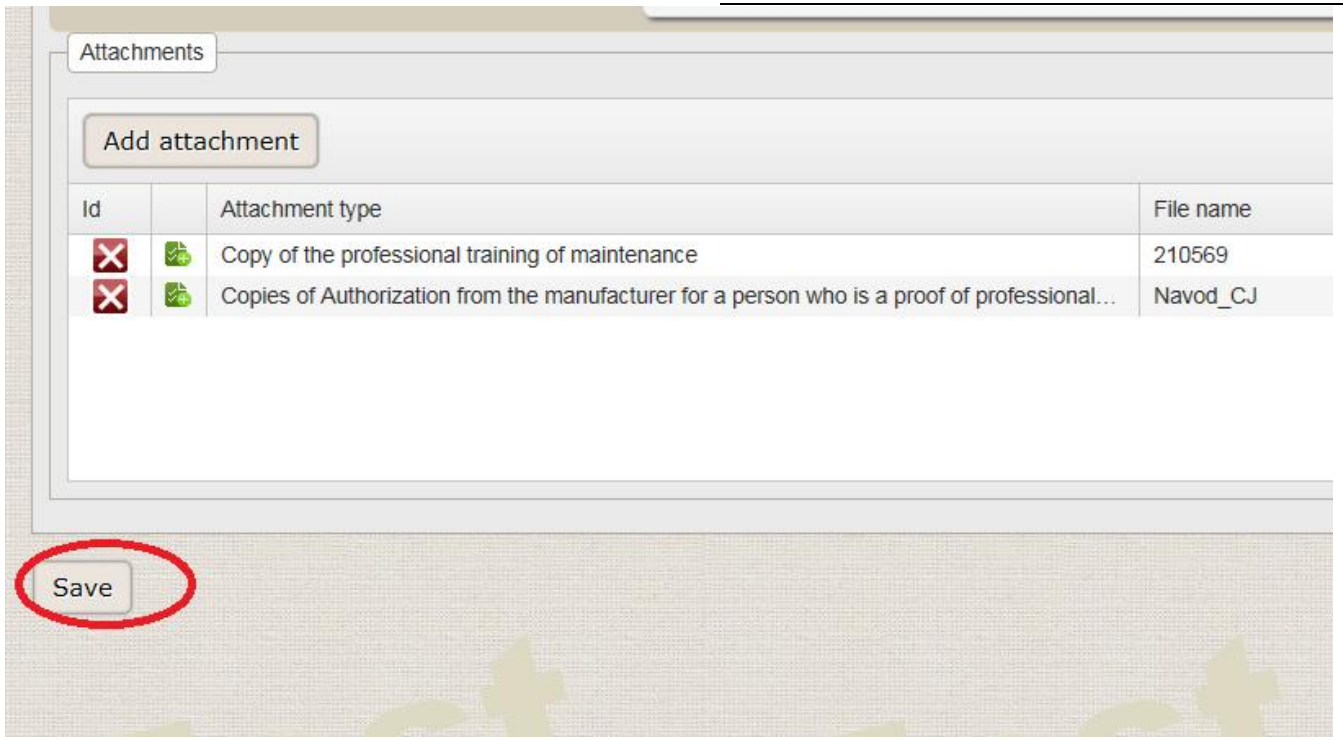
21) If you cannot locate the manufacturer in the list, leave the defaulted "No" and fill in the manufacturer manually. **In compliance with Section 28, paragraph 1(e) of the Act on Medical Devices, it is necessary to complete the manufacturer´s name and address of its registered office in the following form. Th fields highlighted in yellow are mandatory.**



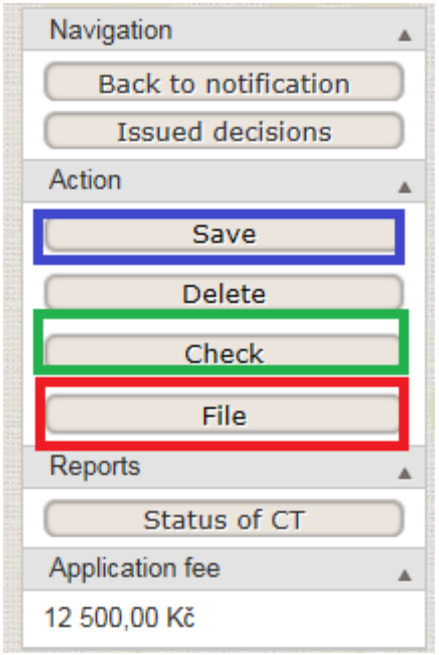
22) Thereafter, click on the “Save” button.



23) Then it is necessary to upload the attachment. Pursuant to Section 28, paragraph 2(e), a notification of a servicing person must include also a **copy of a document evidencing completion of professional maintenance and repairs training** as referred to under Section 65, paragraph 4(b) or Section 66, paragraph 2(b) of the Act on Medical Devices. The copy may be attached by pressing the "**Add attachment"** button. Thereafter, click on the "**Save"** button. The "Add attachment" button may be clicked on repeatedly, which allows for the upload of the necessary number of attachments. If you do not have a copy of the training document from the manufacturer, but from the person authorised by the manufacturer, it is necessary to add a **copy of authorisation of this person by the manufacturer** to the copy of the training document issued by the authorised person. The copy of authorisation of the person authorised by the manufacturer is to be attached in the same manner, i.e. by pressing the "Add attachment" and "Save" buttons.



24) Once the notification is completed, you may choose from the following actions.

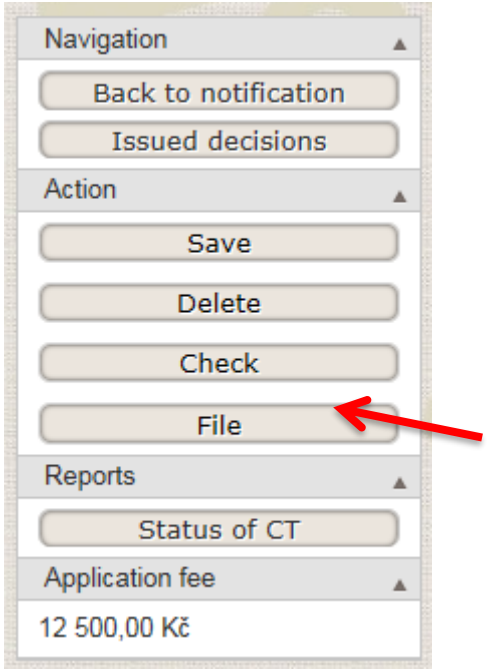


Save: the notification will be saved in the Edited status, you may go back to it and complete it. The notification has not been filed.
Check: the notification will be checked by the system to see whether it contains all of the technical particulars necessary for the submission. The notification has not been filed.

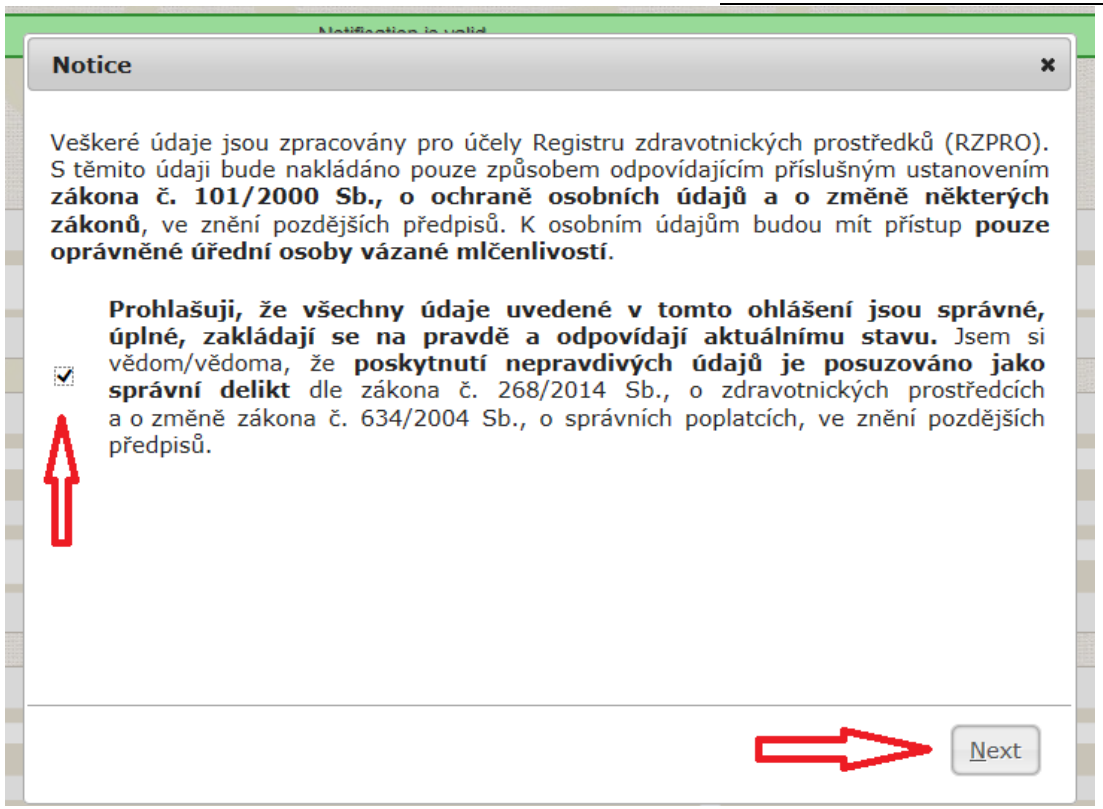
File: this button serves for the submission of the notification, and only then it will be copied to the RZPRO system as filed.

25) When you click on the “Check” button, the “Notification is valid” message will come up. At this moment you know that all of the mandatory fields have been completed and that the data you have entered are in the correct format.

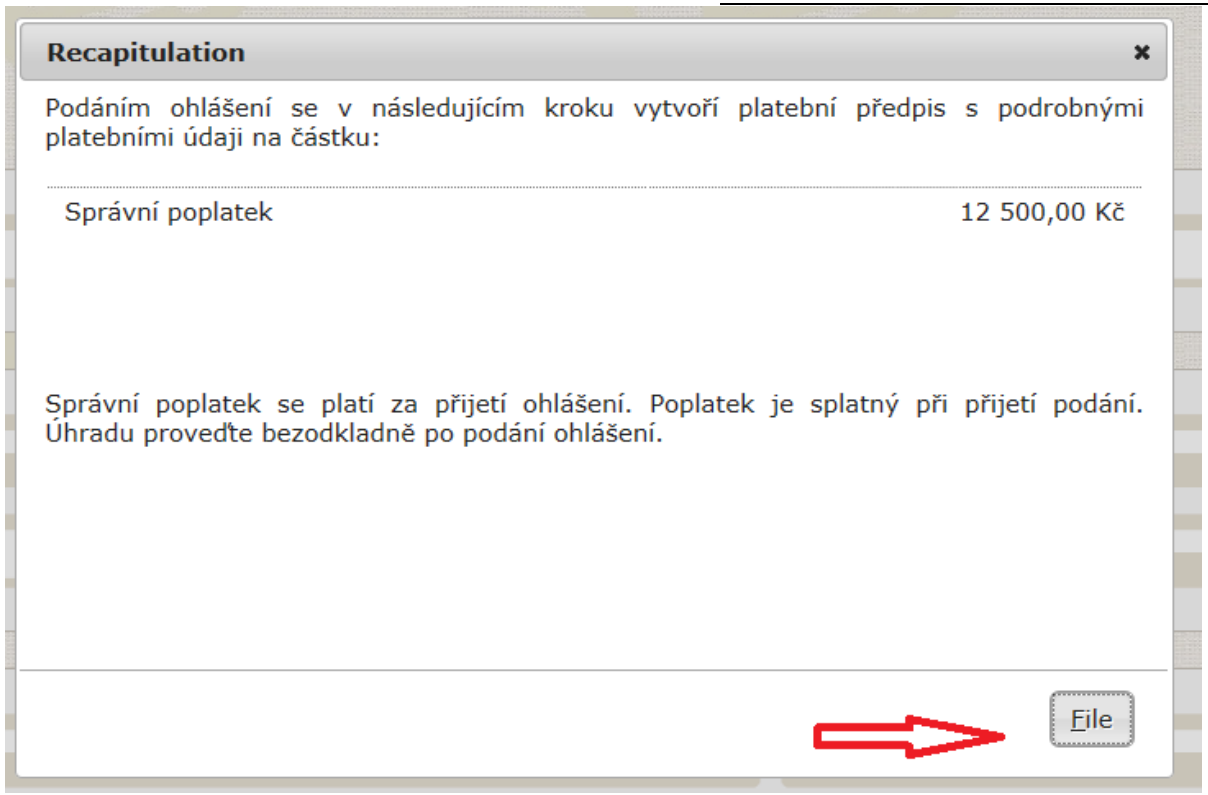
26) Now your notification is formally OK. To file your notification with the State Institute for Drug Control, click on the “File” button in the left part of the screen in the “Action” section.



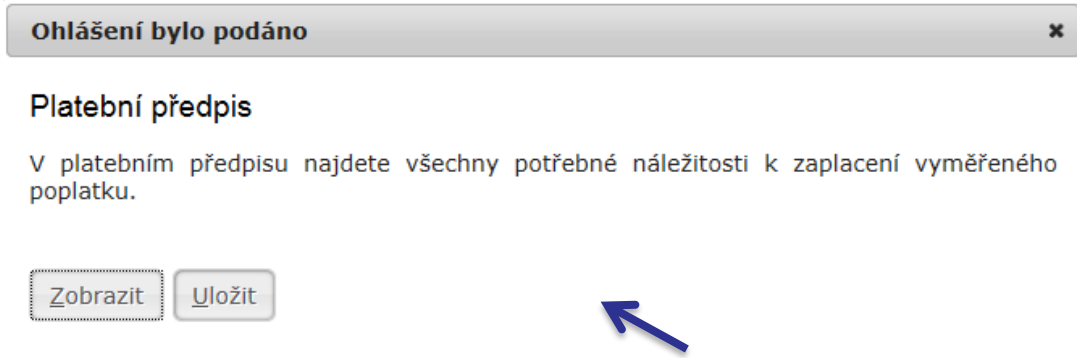
27) Thereafter a window with an advice will be displayed. Please read the advice and express your consent therewith by ticking the checkbox and pressing the “Next” button.



28) When you click the “Next” button, payment information will be generated. Click on the “File” button to confirm your consent therewith.

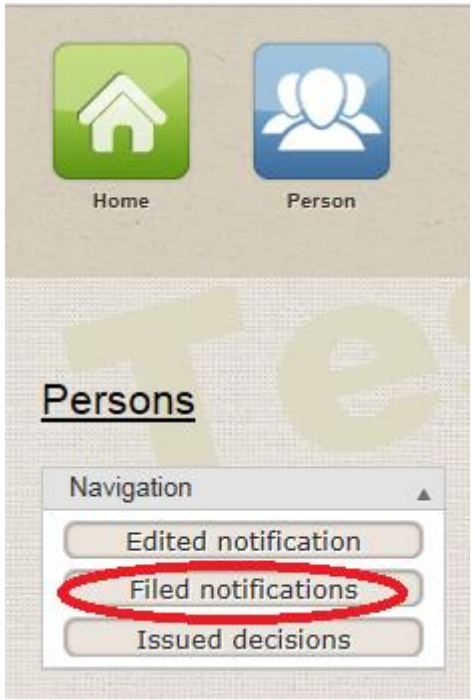


29) When you click on the "File" button, a payment charge will be generated. Please save the charge and make the payment according to the instructions provided in the payment charge.



30) The display of the following message **confirms that your notification of operation has been filed.**

31) This completes the notification submission procedure. You can track the status of your notification in RZPRO following login, if you click on the "Filed notifications" button.



In the list of the filed notifications you can see the status of your notification:

Main statuses in RZPRO:

EDITACE (EDITING)– (a file no. has been allocated), the notification may be edited (amended), the notification (requested supplement to notification) has been filed.
PODÁNO (FILED) – the notification or requested supplement to notification has been filed with the Institute.
ZPRACOVÁVÁNO (IN PROCESS) – the notification or requested supplement to notification is being assessed by the respective officer.
ZPRACOVÁNO (PROCESSED) – the notification or requested supplement to notification has been assessed and confirmation forwarded for signature.
PŘIJATO (ACCEPTED) – the notification has all of the particulars required by the law and the Institute has issued a confirmation.

VÝZVA K DOPLNĚNÍ (REQUEST FOR SUPPLEMENT) – you have received a request for additional information in respect of the notification; it is necessary to respond to the request within the timeline set forth in the resolution, which forms part of the request for supplement.
ZASTAVENO (SUSPENDED) – you have not provided the supplement to the notification within the predefined timeline therefore, the Institute cannot issue the confirmation, of which you will be advised by the Institute in your data mailbox or via a postal service operator.
ŽÁDOST BYLA VZATA ZPĚT (REQUEST WITHDRAWN) – you have withdrawn your notification. The confirmation hence cannot be issued. You are informed to this effect by means of a notice sent to your data mailbox or via a postal service operator. Once the notice is issued, the status of the notification will change to "Cancelled submission".
STORNO PODÁNÍ (CANCELLED SUBMISSION) – see status "REQUEST WITHDRAWN".

The list of **EDITED (NOT FILED)** notifications displays only the status of:

EDITACE (EDITING) – (file no. has not been allocated), the notification has not been submitted to the Institute, it is still on your side and you can amend it.

Should you have any questions regarding the submission of notifications, please contact SÚKL via:

e-mail at: SZP_RZPRO_dotazy@sukl.cz or

tel. at: 272 185 600.

Should you encounter technical problems when filing your notification, please contact petra.remesova@sukl.cz

Medical Device Branch

03/06/2018