
SÚKL

APPLICATION FOR NOTIFICATION OF MEDICAL DEVICE – DISTRIBUTOR / IMPORTER

Medical Devices Branch

The Distributor or Importer of a **medical device (MD)** shall be obliged to submit an application for notification of the MD to the State Institute for Drug Control (hereinafter „Institute“) no later **than 15 days** of the date of its placement on the market or supply to the market in the Czech Republic according to the transitory provisions of Section 74 par. 5 of the Act No. 89/2021 Coll., on Medical Devices.

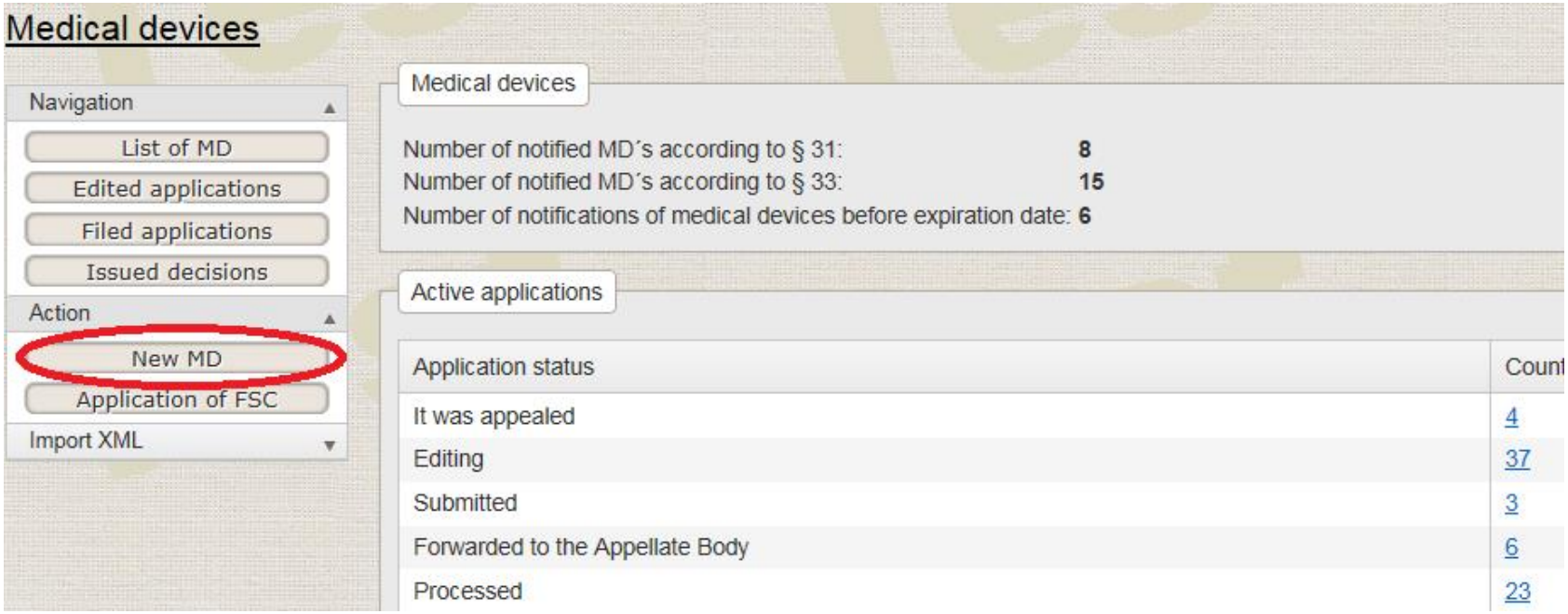
The Distributor or Importer of a **diagnostic medical device in vitro (IVD)** shall be obliged to submit an application for IVD notification according to Section 33 of the Act No. 268/2014 Coll., on diagnostic medical Devices in vitro.

The application is submitted via the Registry of Medical devices (hereinafter „RZPRO“).

The notification duty of a person handling medical devices is stipulated by Section 26 of the Act No. 268/2014 Coll. on Medical Devices in version valid until May 25th, 2021. Following the submission of a notification of a person and payment of administrative fee, the Certificate of compliance of notification duty is issued and the Module Medical Devices enabling the submission of an application for medical device notification, is made available.

Once, you are registered as Distributor or Importer, the module Medical Devices is displayed, when logged in the RZPRO.

The application form for MD notification is displayed by pressing „New MD“ button.



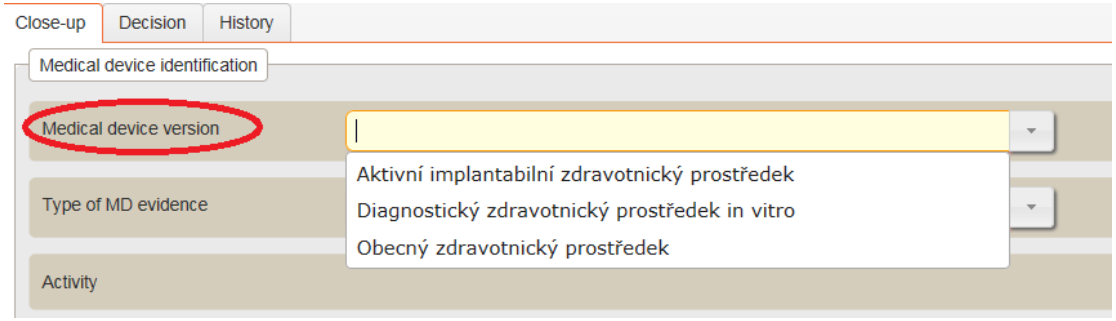
Select one of the options in the field „Medical Device version“ – ie. Obecný zdravotnický prostředek (Medical device), Aktivní implantabilní zdravotnický prostředek (active implantable medical device), Diagnostický zdravotnický prostředek in vitro (in vitro diagnostic Medical device).

The obligation to apply for MD/IVD notification shall not be applicable to risk class I medical devices, custom made medical devices, and in vitro diagnostic medical devices, which do not belong to list A and B and which are not medical devices intended for self testing.

To select the option Medical device, you have to be registered as distributor / importer of serially manufactured Medical Devices.

To select the option Active implantable Medical device, you have to be registered as distributor / importer of active implantable Medical Devices.

To select the option In vitro diagnostic Medical device, you have to be registered as distributor / importer of in vitro diagnostic Medical Devices.



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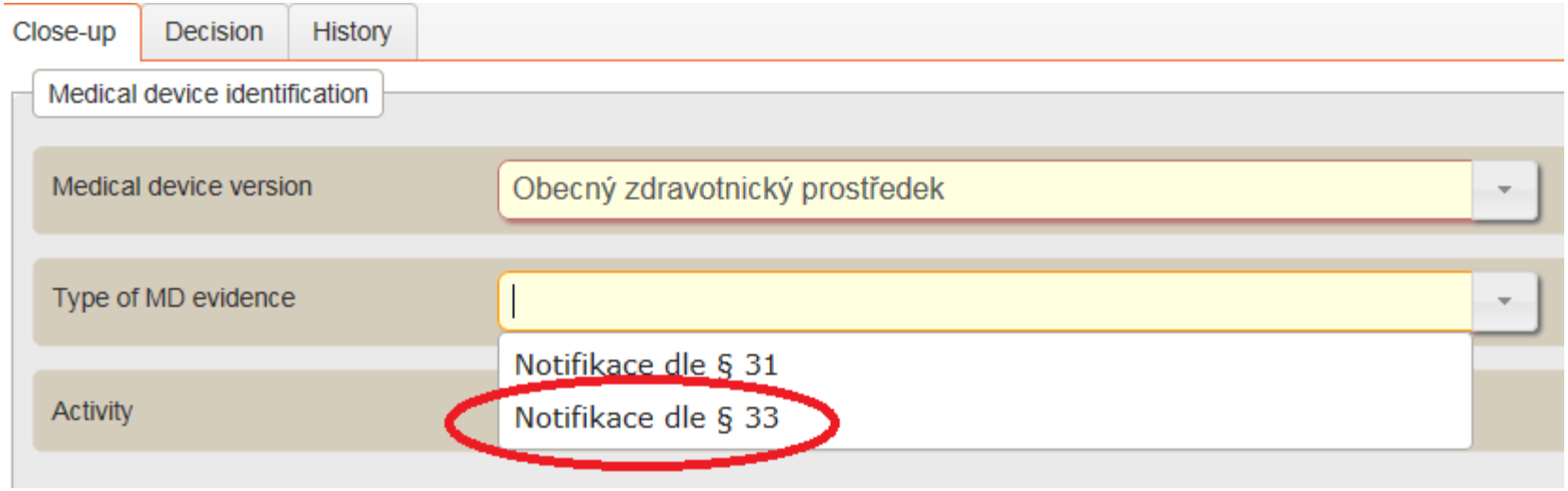
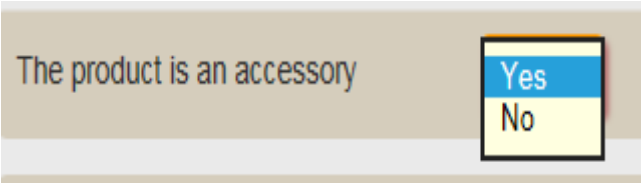
Click on § 33 in the field „Type of MD evidence“.



Choose the activity, under which the application is being filed ie. Distributor or Importer

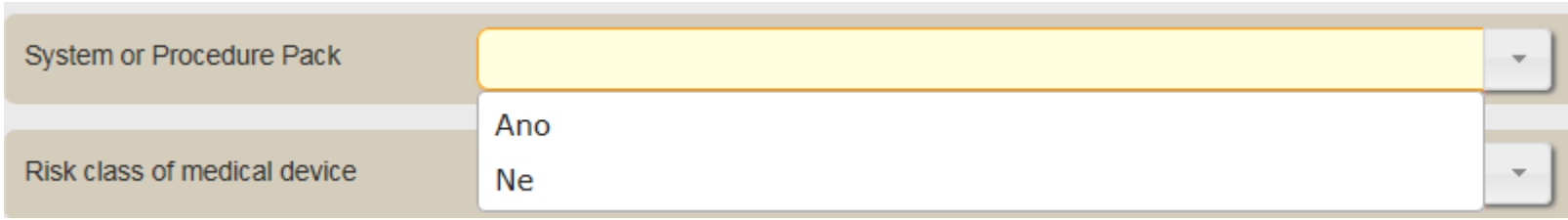
Fill in the field „Medical device business name“ in accordance with the attached Instructions for Use (hereinafter „IFU“) and provide it in the language of the IFU. Do not translate the MD business name into Czech, should it be provided in a different language.

Select if the MD is an accessory in the field „The product is an accessory“. This information shall be in compliance with the attached documents.

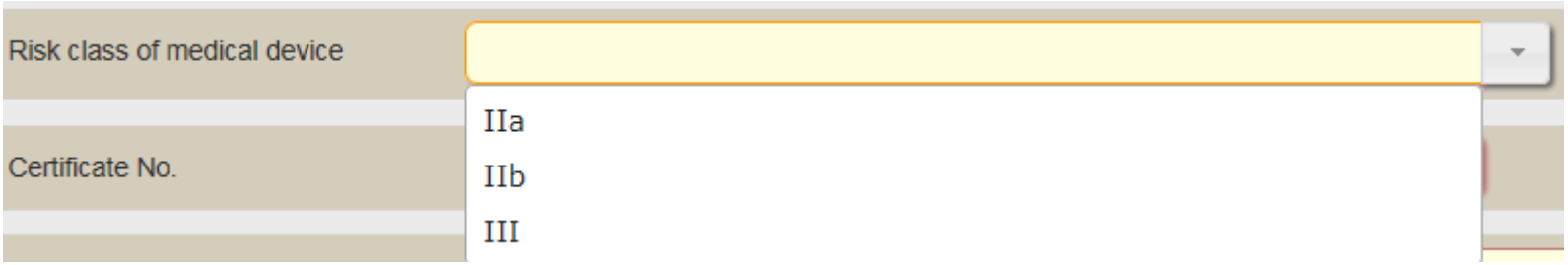


If the MD is a System / Procedure Pack, select Ano (yes) in case of Medical device or active implantable Medical device application.
In case of in vitro diagnostic medical device application select from the options System / Procedure pack.

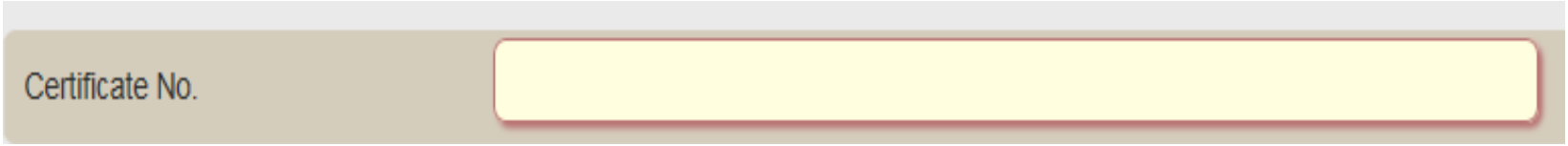
The information is provided in the IFU.



Select risk class of the MD. The information on risk class is available in EC certificate or Declaration of Conformity issued by the manufacturer.



Fill in the EC Certificate number of the certificate issued by the notified body. The information shall be provided by the manufacturer or authorised representative.

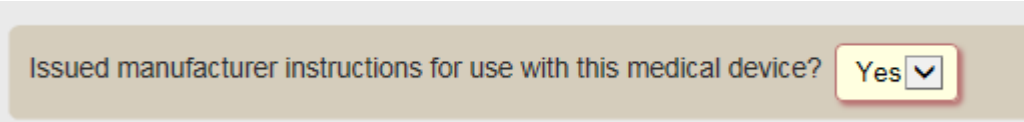


Select the notified body that issued the EC certificate of the concerned MD.

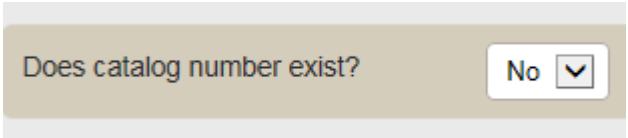
Fill in the intended purpose in compliance with the text provided in the attached IFU. The intended purpose shall comply with the Medical device definition.

Intended purpose of medical device in Czech

In case you have chosen risk class IIa, select if the IFU has been issued by the manufacturer. If you select „yes“, make sure to attach the IFU. IFU is not required in MD risk class IIa, if the manufacuturer has established that it is not necessary for its safe use.



Select yes / no in the field „Does catalogue number exist?“. Catalogue number is provided for each MD variant. In case you select option yes, catalogue numbers and appendix names must be filled in. In case you select option no, the field catalogue number has to remain unfilled. The field Catalogue number shall be filled in if it exists accoridng the attached documents.



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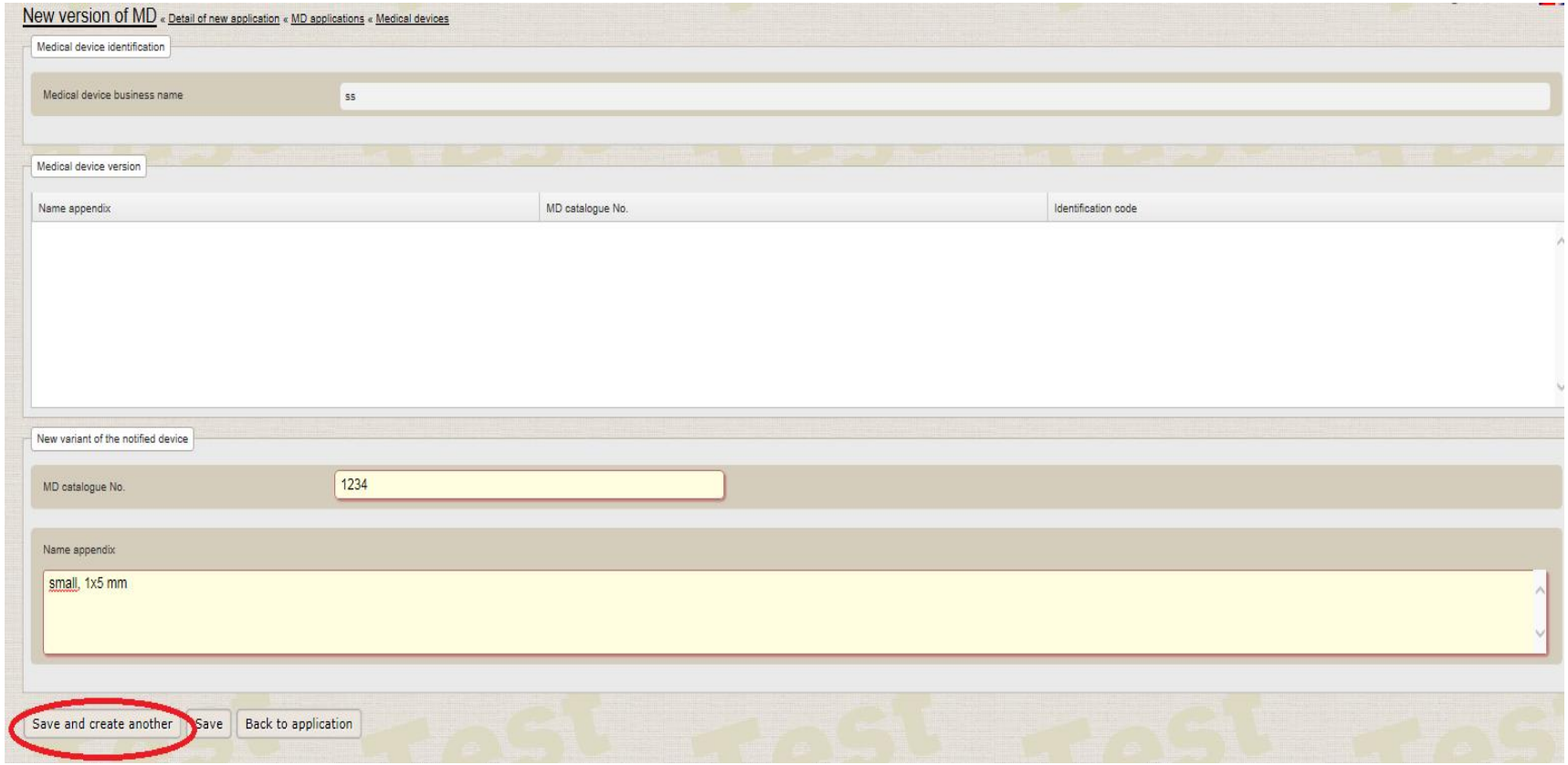
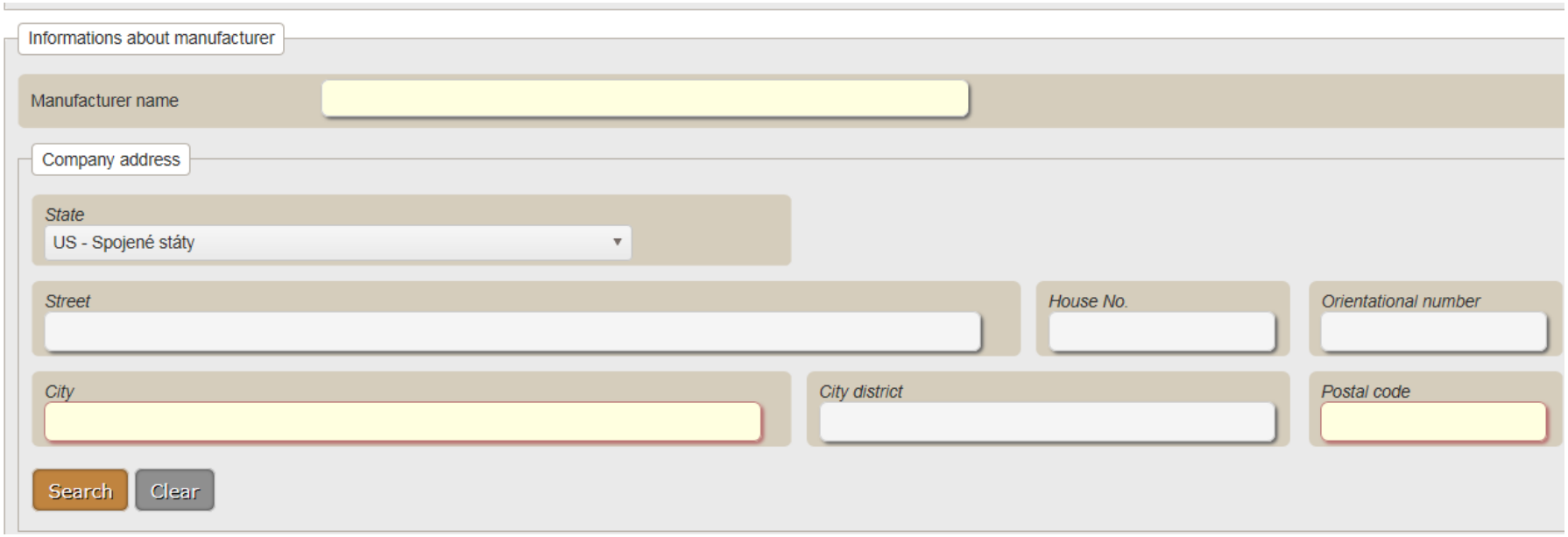
- In case MD variants exist, fill in all the existing variants placed on the market, by filling in the catalogue number and appendix names.
- Appendix name is a unique marking of each existing MD variant specifying variant distinction.
- In case various variants are filled in, appendix name shall be filled with each MD variant. In case of more variants, confirm the variant by clicking on „Save and create another“.
- In case MD exists in only one variant and it has been marked by catalogue number, you may fill in MD business name into the field „Appendix name“.


New version of MD « Detail of new application « MD applications « Medical devices
Medical device identification
Medical device business name
ss
Medical device version
Name appendix
MD catalogue No.
Identification code
New variant of the notified device
MD catalogue No.
1234
Name appendix
small, 1x5 mm
Save and create another
Save
Back to application

Fill in the „Manufacturer name“. In case the manufacturer has been already recorded in RZRPO, the data will be filled in automatically.



The current version of the IFU in Czech must be attached to the application. It is not mandatory to attach the IFU, in case it has been selected no, in the field „Issued manufacturer instructions for use with this Medical device?“.

The allowed attachment formats are doc, docx, rtf, pdf, odf, jpg, jpeg, xls and xlsx. The maximum size of the attahed IFU shall not exceed 50 MB.


Add MD attachment « Detail of new application « MD applications « Medical devices
Attachment selection
Allowed attachments are: *.jpg, *.jpeg, *.pdf, *.odf, *.rtf, *.doc, *.docx, *.xls, *.xlsx
Aktuální verze návodu k použití v českém jazyce (maximální možná velikost přílohy je 50 MB)
Select...
Další – specifikujte
Select...
Save

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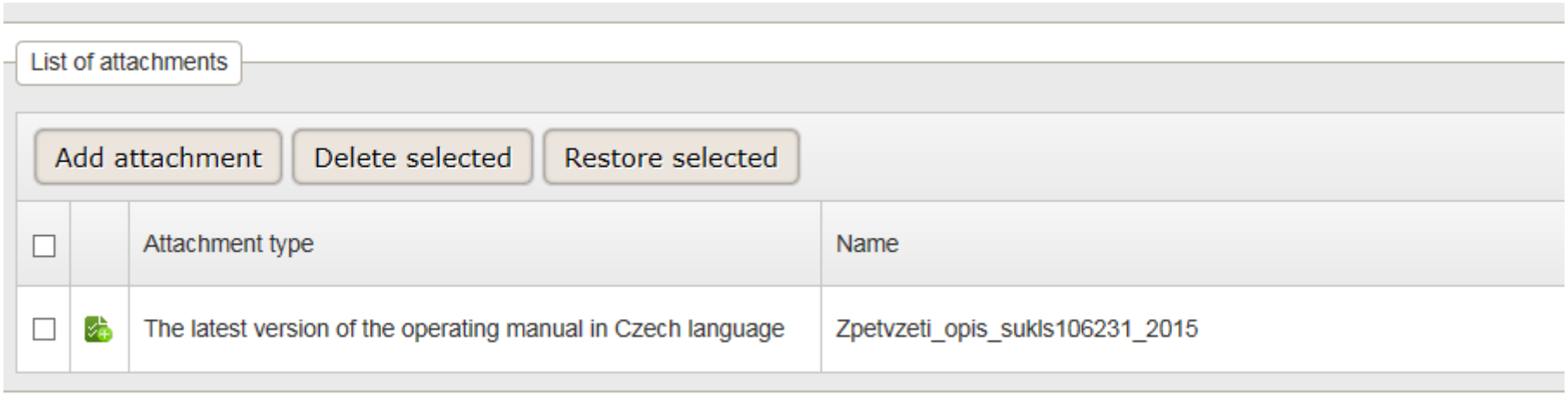
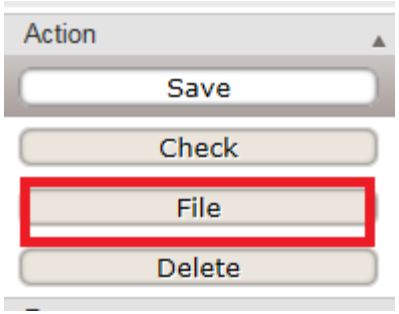
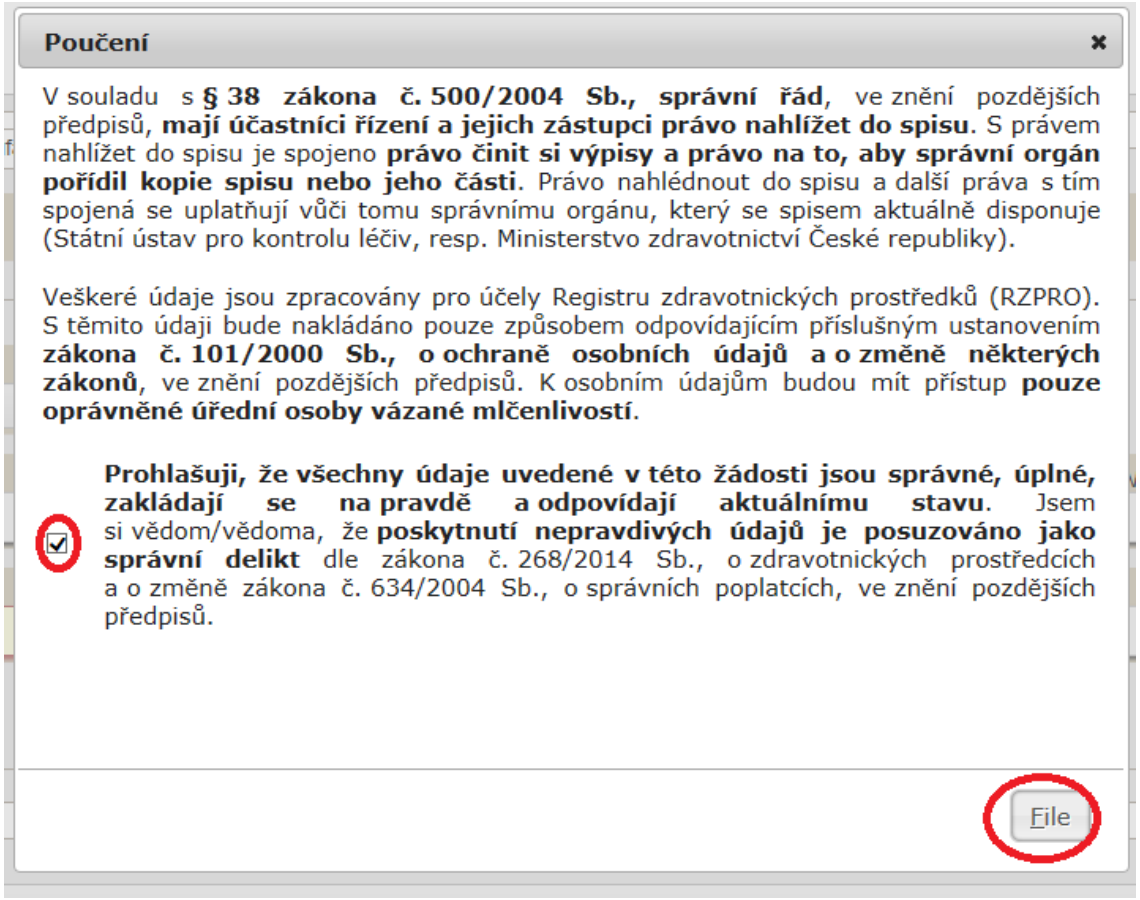
The uploaded documents will be tagged by a green symbol.



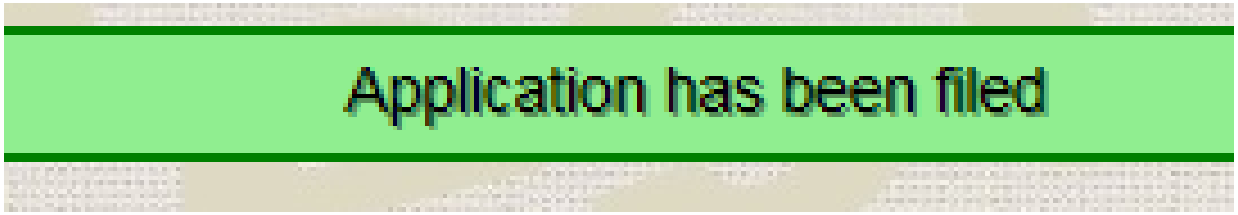
To file the application press the „File“ button.



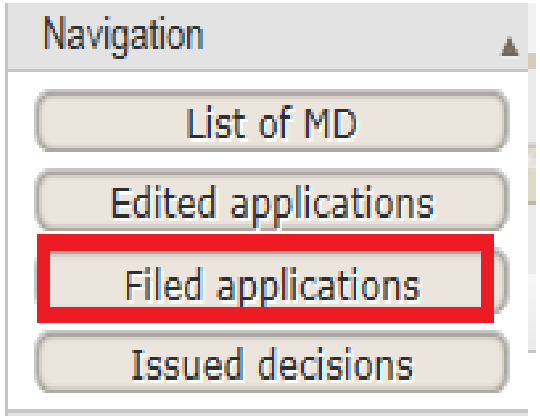
An informative notice is displayed, cofirm by clicking on „File“



Your application has been filed



You may check the status of your application under „Filed applications“.



Call for completion

Should the application fail to meet the particulars, you will be invited to eliminate the shortcomings within a reasonable timeline.

Call for completion will be displayed in the Medical Devices module under „Active decisions“

Active decisions

Decision type	Decision status	Count
Call for completion	Appealed	1
Call for completion	Confirmed delivery	1
Call for completion	Forwarded to the Appellate Body	1
Call for completion	Processed by appellate authority	1
Stopping the proceedings	Appealed	3
Stopping the proceedings	Processed by appellate authority	1
Total	Total	8

Append application upon call for completion 1/2

To append the application when you have received the call for completion, enter the detail of the application

Active decisions

Decision type	Decision status	Count
Call for completion	Appealed	1
Call for completion	Confirmed delivery	1
Call for completion	Forwarded to the Appellate Body	1
Call for completion	Processed by appellate authority	1
Stopping the proceedings	Appealed	3
Stopping the proceedings	Processed by appellate authority	1
Total	Total	8

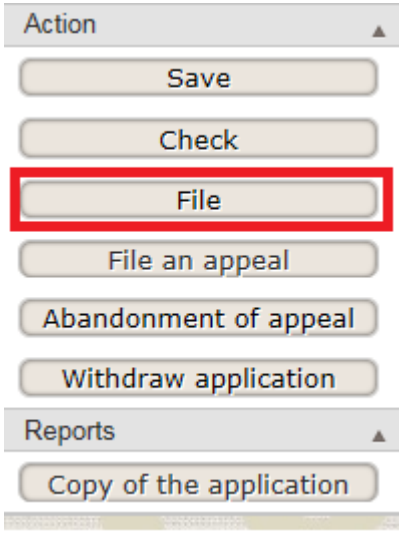
List of decisions and resolutions

MD name	SIDC file number	Subject	Decision status	Decision type
ss	sukls2806/2019	Request new MD	Confirmed delivery	Call for completion

Append application upon call for completion 2/2

1. Press „Append an application“ button

2. To file the completion of the application, press „File“ button



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„Notification according to Section 33 par. 2)

Where the MD has been already notified, any other distributor or importer of the concerned MD shall be obliged to notify the Institute of the fact that this MD is also distributed or imported thereby. This notification is filed by the distiributor or importer electronically via RZPRO by submitting the *data change notification* within the Module Person.

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Application confirmation

Notification of MD is completed by the coming legally into force of the decision on notification. The applicant is delivered the decision on MD notification via post or data box. No appeal may be filed against the decision, which is granted to the applicant in full extent.

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Application rejection

If the Institute learns that the product is not a medical device or that the attachment of the CE mark has been unauthorised, it shall decline the application. The applicant is delivered a resolution on procedure rejection via post or data box.

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Termination of a procedure

In case, the applicant e. g.:

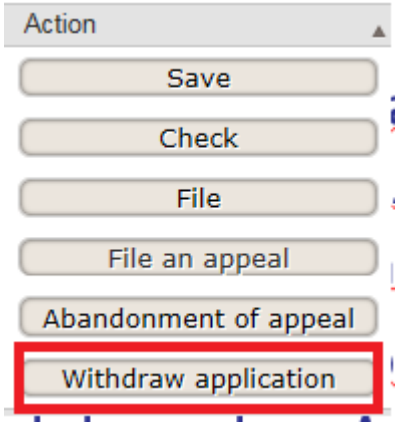
- fails to eliminate the substantial defects of the application within the predefined timeline
- takes the application back (withdraws)

The Institute terminates the procedure according to Section 66 par. 1 od the Administrative Code. In such case, the applicant is delivered resolution on procedure termination.

Application withdrawal

The applicant may take the application back at any time until the decision is issued.

Attention – this step is not reversible!



Status in RZPRO

- **EDITING** – (reference number issued) you may edit (modify) the application
- **SUBMITTED** – the application has been filed or appended to the Institute
- **PROCESSED** – the application is being assessed by the assessor
- **ACCEPTED** – the application 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 application within the predefined timeline set forth by the resolution, which is part of the call for completion
- **STOPPED** – you have not appended the application 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 application 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“.
- **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 confusion, contact the Institute:

email: SZP_RZPRO_dotazy@sukl.cz or
tel. 272 185 262 on Wednesdays from 9:00 to 12:00 CET