
SÚKL

APPLICATION FOR CHANGE TO THE NOTIFICATION OF MEDICAL DEVICE

Medical Devices Branch

25.9.2019

Section 35 par. 4 of the Act No 268/2014, Coll., on Medical Devices and on Amendments to Act No. 634/2004 Coll., on Administrative Fees (hereinafter referred to as „Act on MD“)

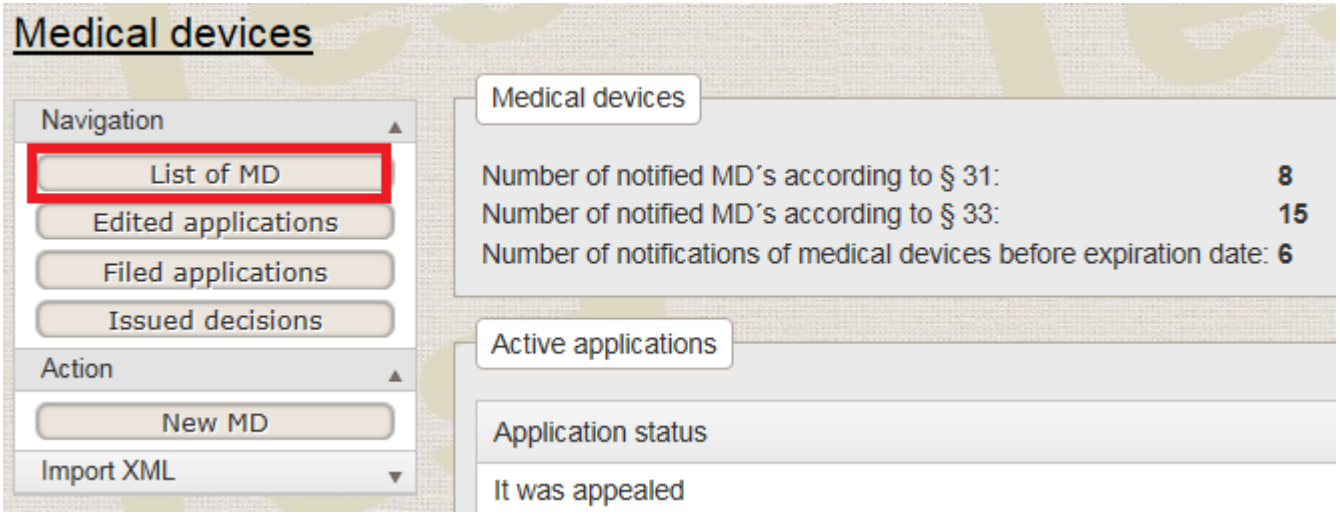
In case of changes to the data mentioned in the notification, the manufacturer, authorised representative, distributor or importer shall be obliged to submit an application for change to the notification (herinafter referred to as „application for MD change“) to the Institute in electronic format via the Registry of Medical Devices (hereinafter referred to as „RZPRO“) within 30 days. The application must include the registration number of the applicant, the file number of the medical device, and the identification code of each variant of the medical device, and the update of data which have been changed.

Principle of submitting the applications for MD change

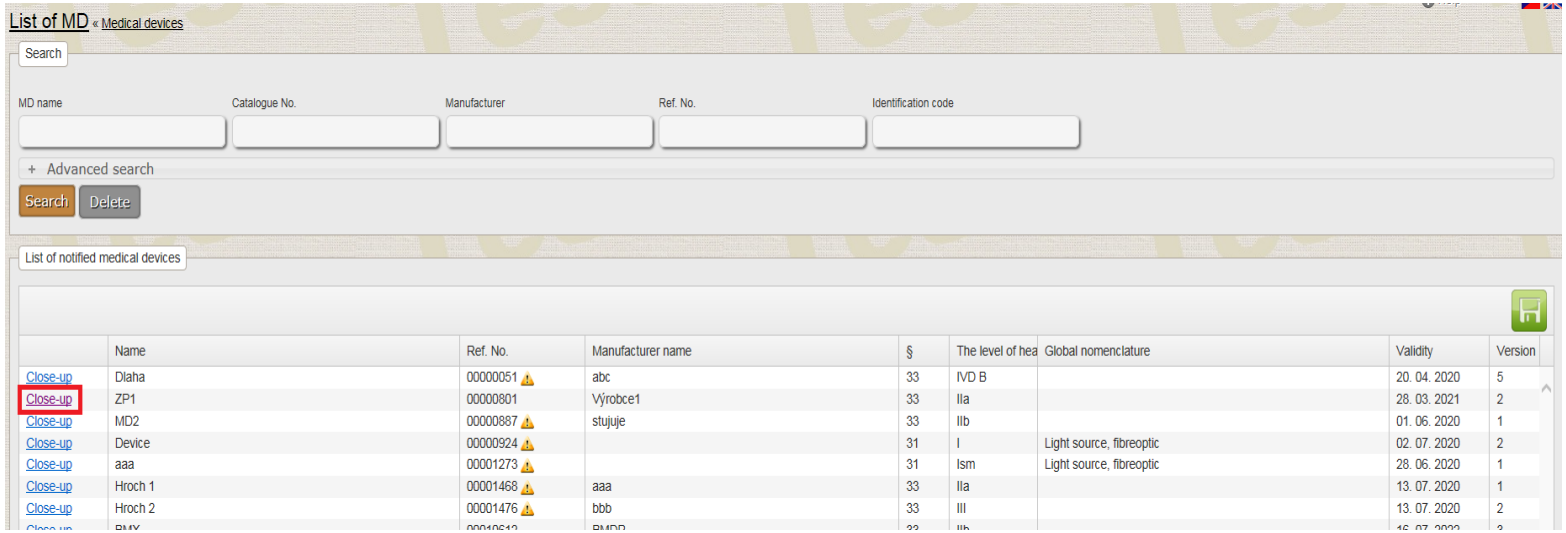
You may submit an unlimited number of applications for MD change, however not for the same subject (item). Unless, the application for change of particular item of the medical device has not been processed by the Institute, it is technically not possible to submit the application for change of the same item.

Once you are registered as manufacturer, authorised representative, distributor or importer, the module Medical Devices will be displayed after you log in the RZPRO. Applications requesting MD notification and change for MD notification are filed via this module.

To submit the application for MD change, select the particular MD from the „List of MD“

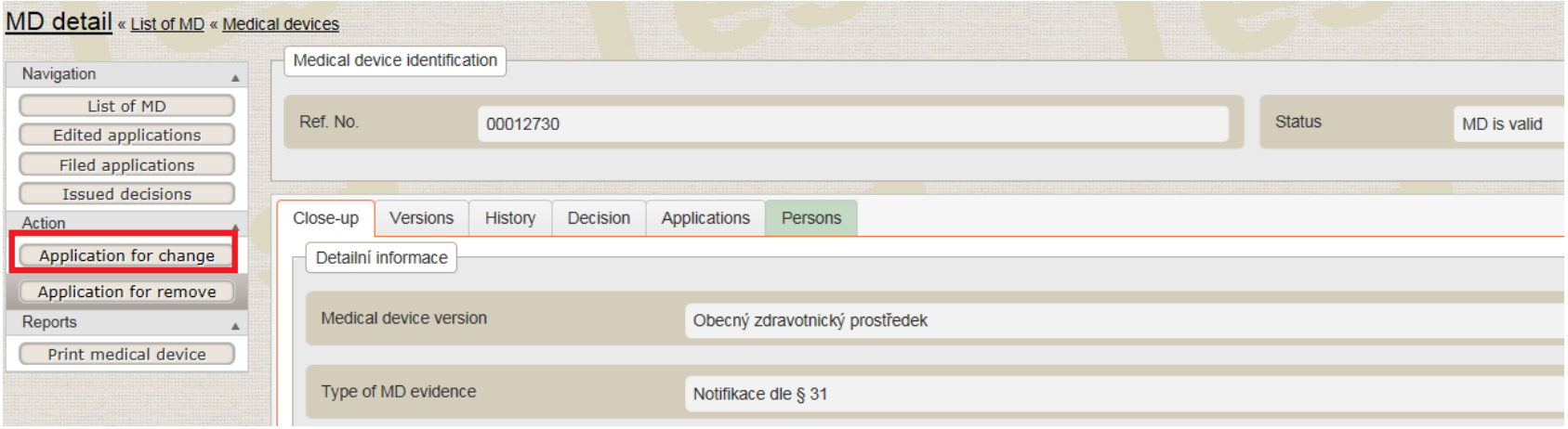


To access the MD detail click on the „Close-up“ button



	Name	Ref. No.	Manufacturer name	§	The level of hea	Global nomenclature	Validity	Version
Close-up	Dlaha	00000051	abc	33	IVD B		20. 04. 2020	5
Close-up	ZP1	00000801	Výrobce1	33	IIa		28. 03. 2021	2
Close-up	MD2	00000887	stujuje	33	IIb		01. 06. 2020	1
Close-up	Device	00000924		31	I	Light source, fibreoptic	02. 07. 2020	2
Close-up	aaa	00001273		31	Ism	Light source, fibreoptic	28. 06. 2020	1
Close-up	Hroch 1	00001468	aaa	33	IIa		13. 07. 2020	1
Close-up	Hroch 2	00001476	bbb	33	III		13. 07. 2020	2

To generate the application press the button „Application for change“

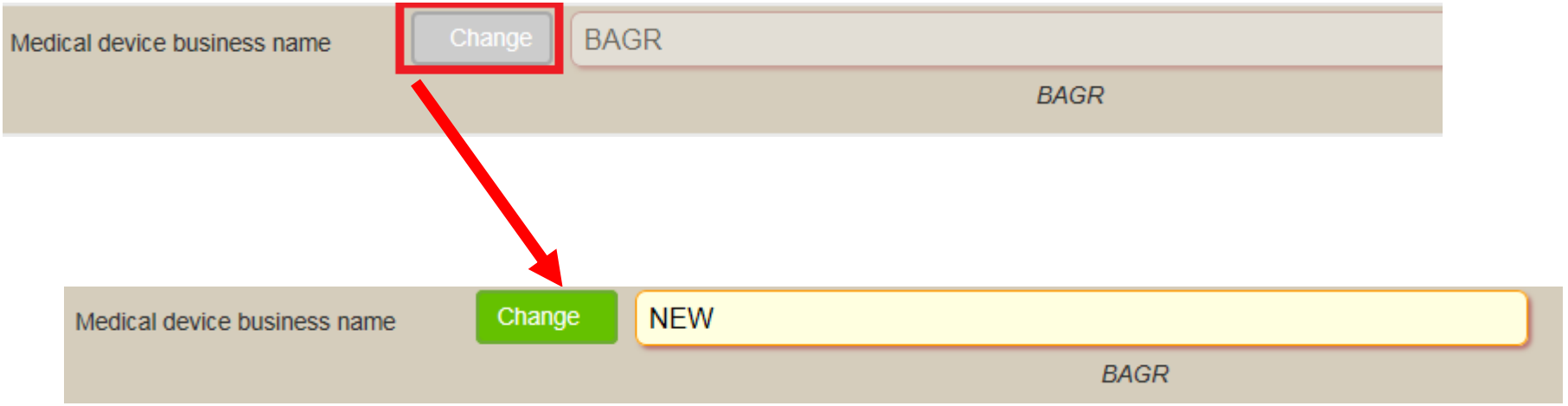


Completion of the application for MD change

Enter the summary of all changes carried out within the application in the field „Reason for change“

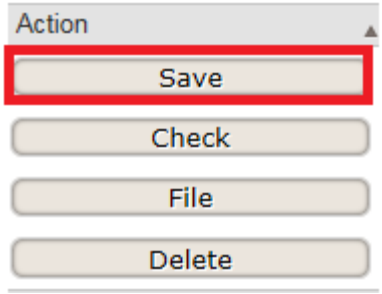
How to fill in the application for MD change

To activate the field for change press „Change“ button. The green colour of the button indicates that it is possible to change the item.



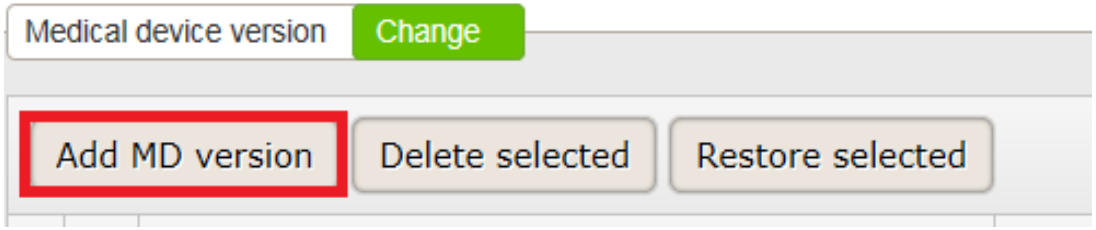
How to fill in the application for MD change

It is recommended to save the changes continuously as they are made by pressing the „Save“ button placed in the „Action menu“.



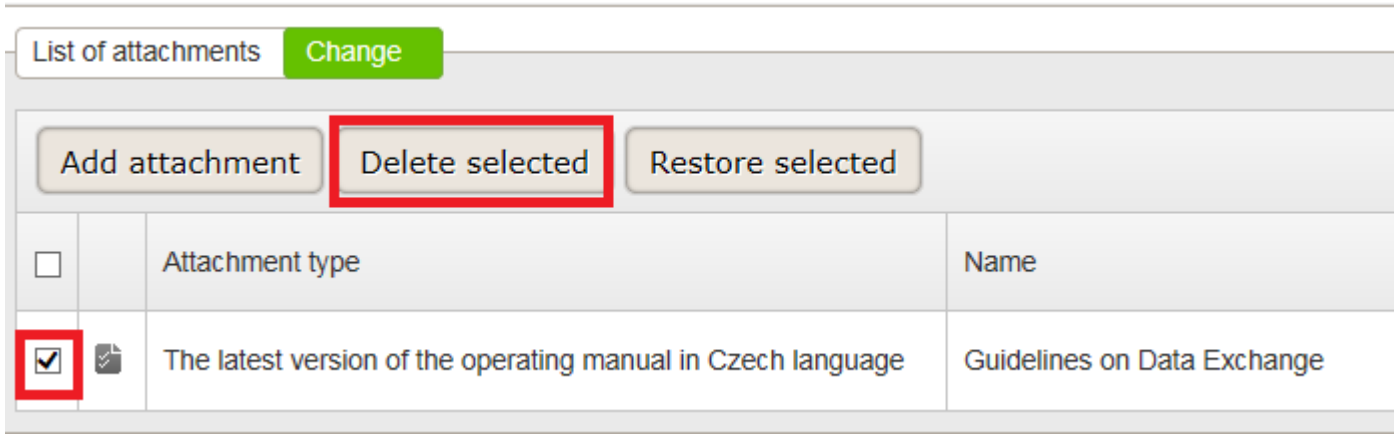
Adding / deleting MD version (variant)

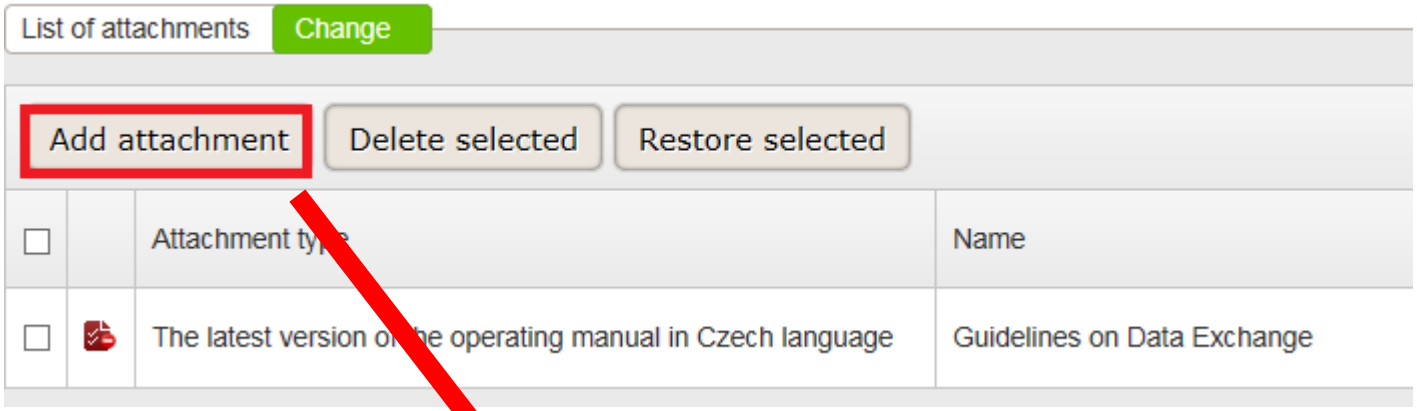
In case you wish to add / delete MD variants in Medical device, activate the „Medical Device version“ field and continue to edit the field „Medical device version“.

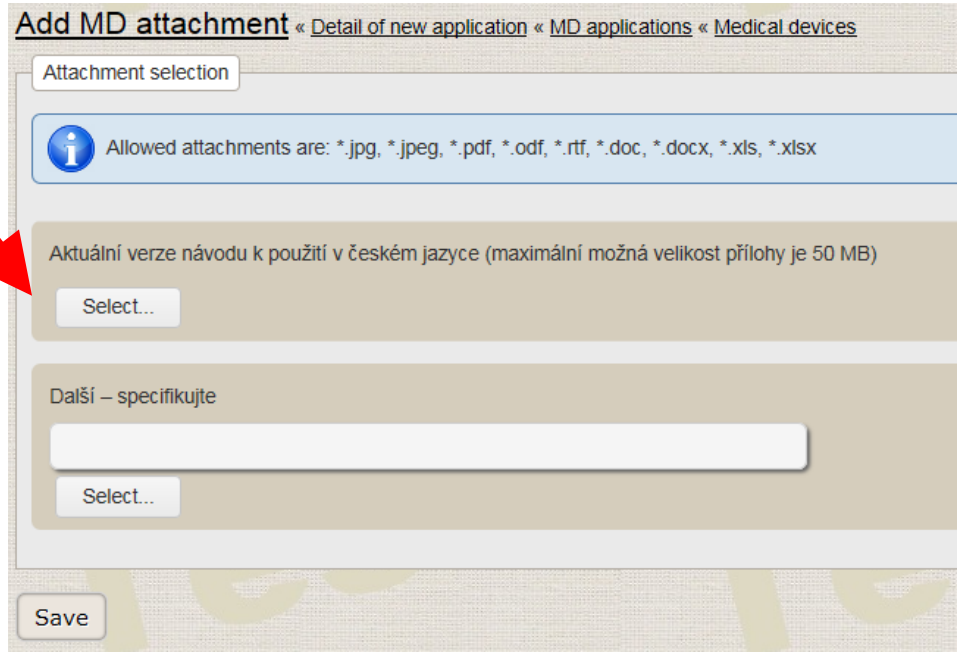


Change of attachments

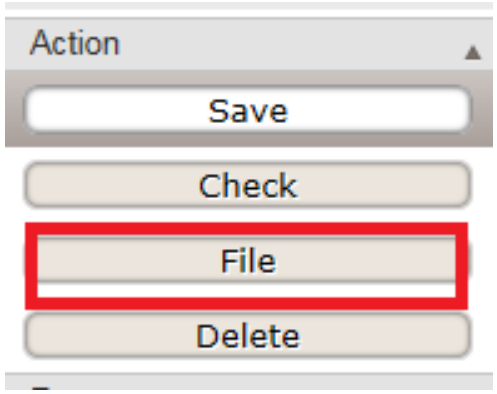
In case of attachment change, first delete the selected attachments and then continue by adding a new one.



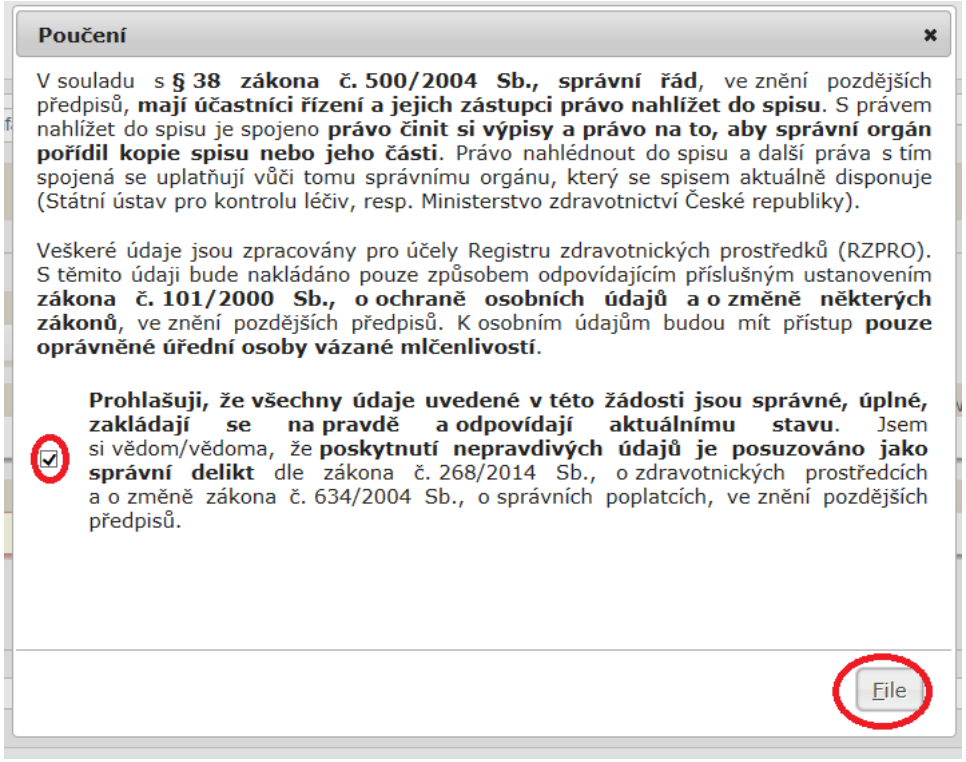

List of attachments
Change
Add attachment
Delete selected
Restore selected
Attachment type
Name
The latest version of the operating manual in Czech language
Guidelines on Data Exchange


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

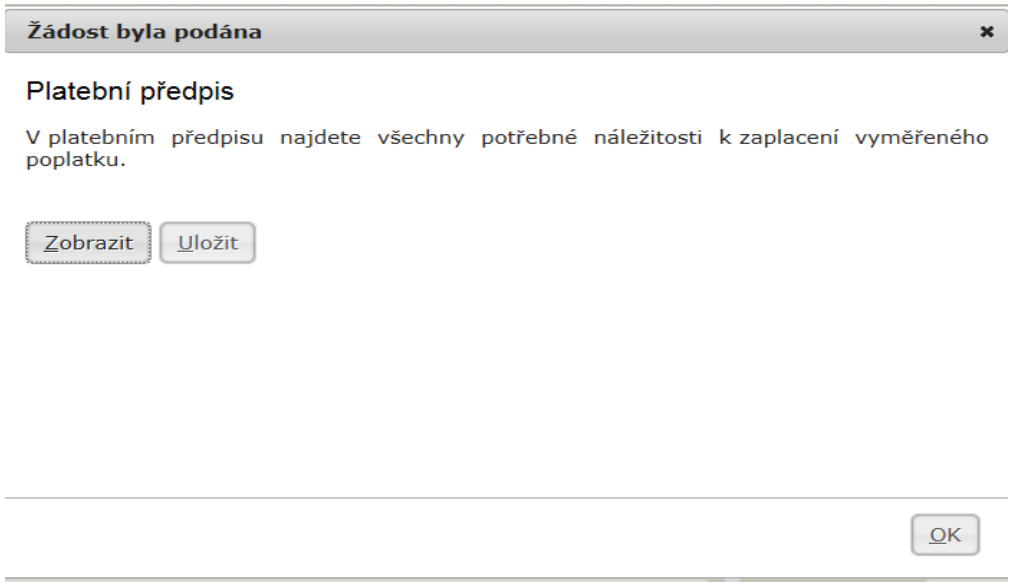
To file the application press the „File“ button.



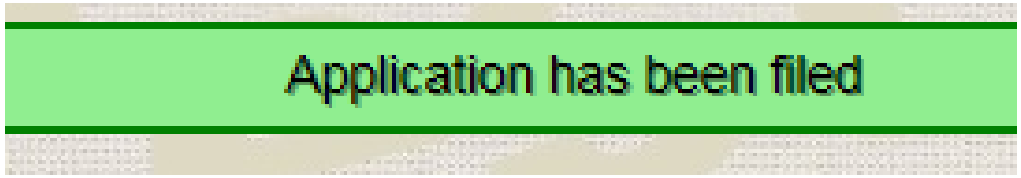
An informative notice is displayed, cofirm by clicking on „File“



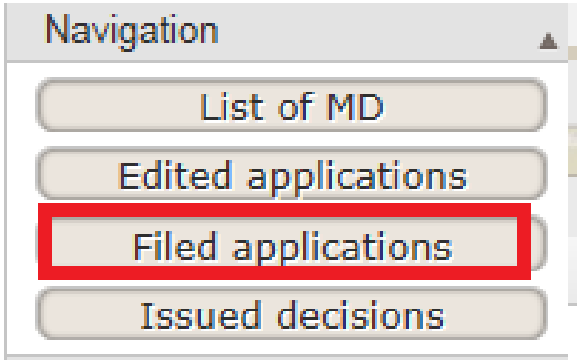
In case the medical device is notified according to Section 31 of the Act on MD, the payment order is generated. The payment should be made without any delay. After the payment is made you will be sent the payment receipt.



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 stipulated by Section 32 and 34 of the Act on MD, you will be invited to eliminate the shortcomings within a reasonable timeline.

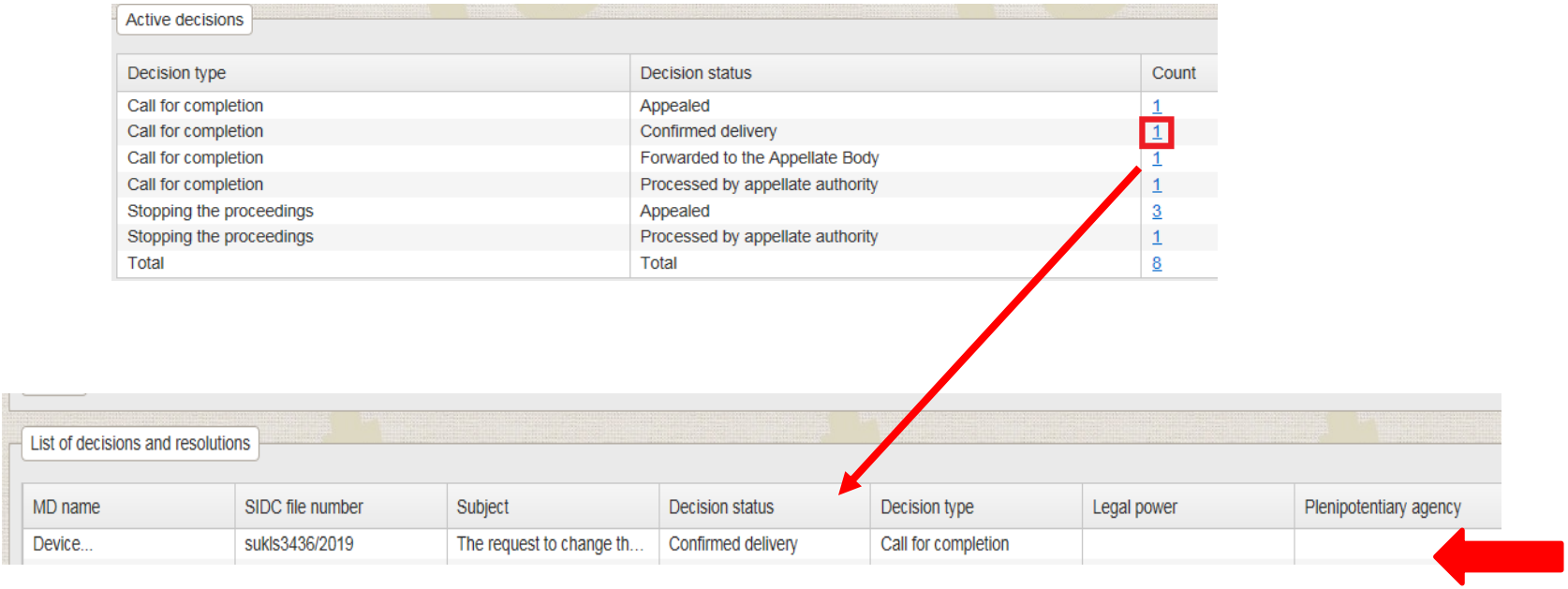
Call for completion will be displayed in the Medical Devices module under „Active decisions“

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 the application upon call for completion 1/2

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



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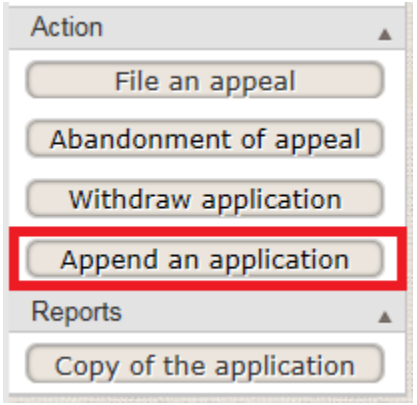
Stopping the proceedings	Appealed	3
Stopping the proceedings	Processed by appellate authority	1
Total	Total	8

List of decisions and resolutions

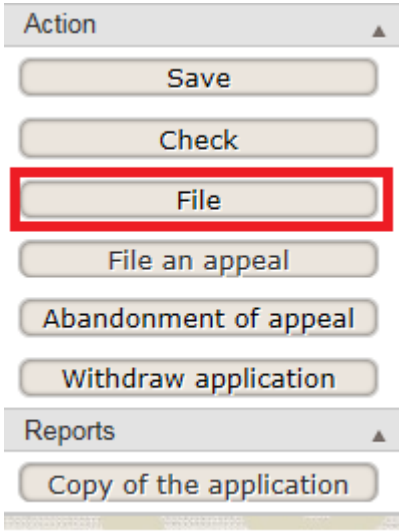
MD name	SIDC file number	Subject	Decision status	Decision type	Legal power	Plenipotentiary agency
Device...	sukls3436/2019	The request to change th...	Confirmed delivery	Call for completion		

Append the application upon call for completion 2/2

1. Press „Append an application“ button



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



Acceptance of the application

In case the application meets the particulars stipulated by Section 35 par. 4 of the Act on MD, the Certificate on Medical device change is issued by the Institute.

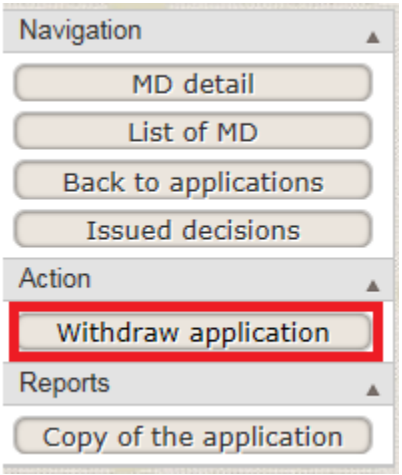
Notification of noncompliance

Should the applicant fail to append the application upon call for completion within the established timeline or fail to pay the admininstrative fee or withdraw the application, the Institute issues the Notification of noncompliance.

Application withdrawal

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

Attention – this step is not reversible!



Status of the application 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 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.

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In case of confusion, please address the State Institute for Drug Control:

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

For expert requests:
email: onzp@sukl.cz nebo tel. +420 272 185 600
on Mondays and Wednesdays 9:00 - 11:00 a. m. and 1:00 - 3:00 p. m.