



APPLICATION FOR CHANGE TO THE NOTIFICATION OF MEDICAL DEVICE

Medical Devices Branch

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 (hereinafter 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.

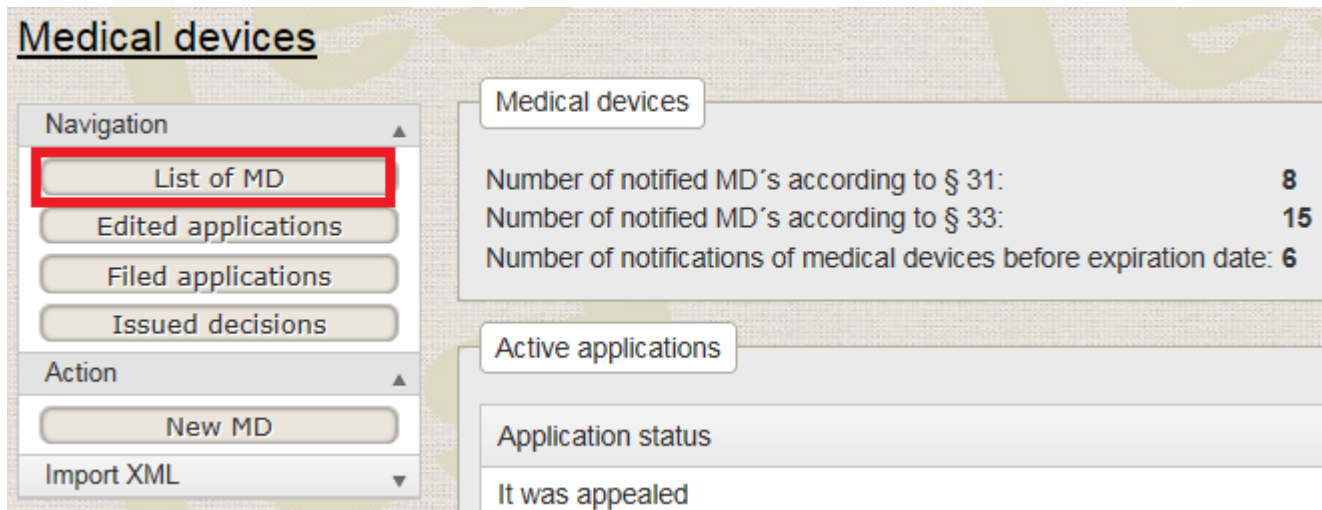
Principle of submitting the applications for MD change

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“



The screenshot shows the 'Medical devices' section of a web application. On the left, there is a navigation menu with the following items: 'List of MD' (highlighted with a red box), 'Edited applications', 'Filed applications', 'Issued decisions', 'New MD', and 'Import XML'. The main content area on the right is divided into two sections: 'Medical devices' and 'Active applications'. The 'Medical devices' section displays the following statistics:

Number of notified MD's according to § 31:	8
Number of notified MD's according to § 33:	15
Number of notifications of medical devices before expiration date:	6

The 'Active applications' section is currently empty, showing only the header 'Application status' and the text 'It was appealed'.

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

List of MD Medical devices

Search

MD name Catalogue No. Manufacturer Ref. No. Identification code

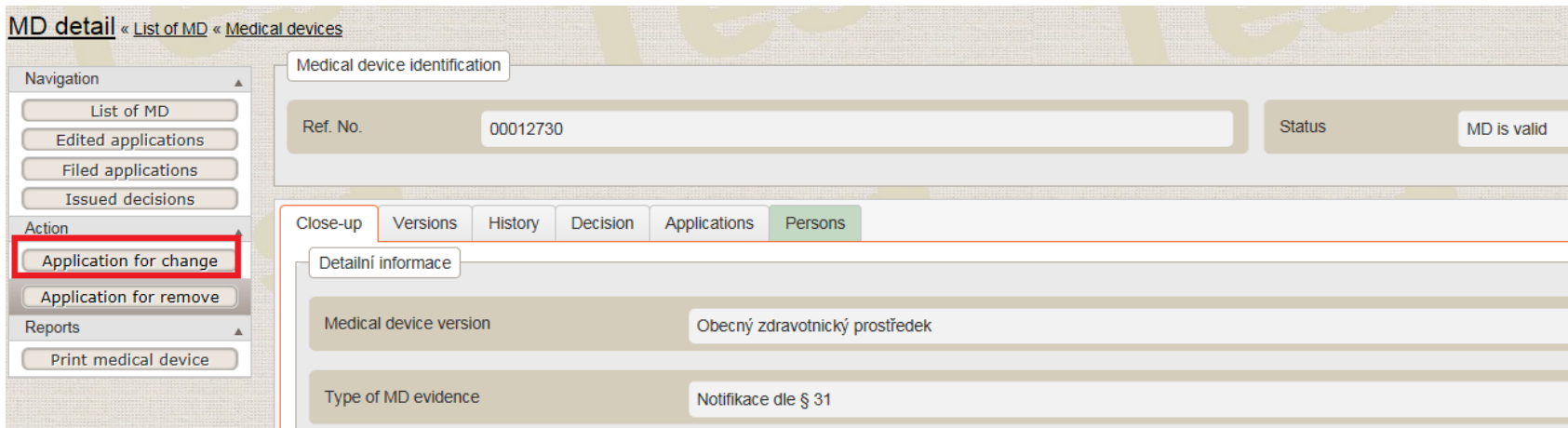
+ Advanced search

Search Delete

List of notified medical devices

	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	Ila		28. 03. 2021	2
Close-up	MD2	00000887 🚩	stujje	33	Ilb		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	Ila		13. 07. 2020	1
Close-up	Hroch 2	00001476 🚩	bbb	33	III		13. 07. 2020	2
Close-up	BMV	00001476 🚩	BMD	33	III		13. 07. 2020	2


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



The screenshot shows the 'MD detail' page in the SÚKL system. The breadcrumb trail is 'List of MD < Medical devices'. The left sidebar contains a 'Navigation' menu with 'List of MD', 'Edited applications', 'Filed applications', and 'Issued decisions'. Below it is an 'Action' menu where 'Application for change' is highlighted with a red box. Other actions include 'Application for remove', 'Reports', and 'Print medical device'. The main content area is titled 'Medical device identification' and shows 'Ref. No.' as 00012730 and 'Status' as 'MD is valid'. Below this is a tabbed interface with 'Close-up', 'Versions', 'History', 'Decision', 'Applications', and 'Persons' tabs. The 'Persons' tab is active, showing 'Detailní informace' with fields for 'Medical device version' (Obecný zdravotnický prostředek) and 'Type of MD evidence' (Notifikace dle § 31).

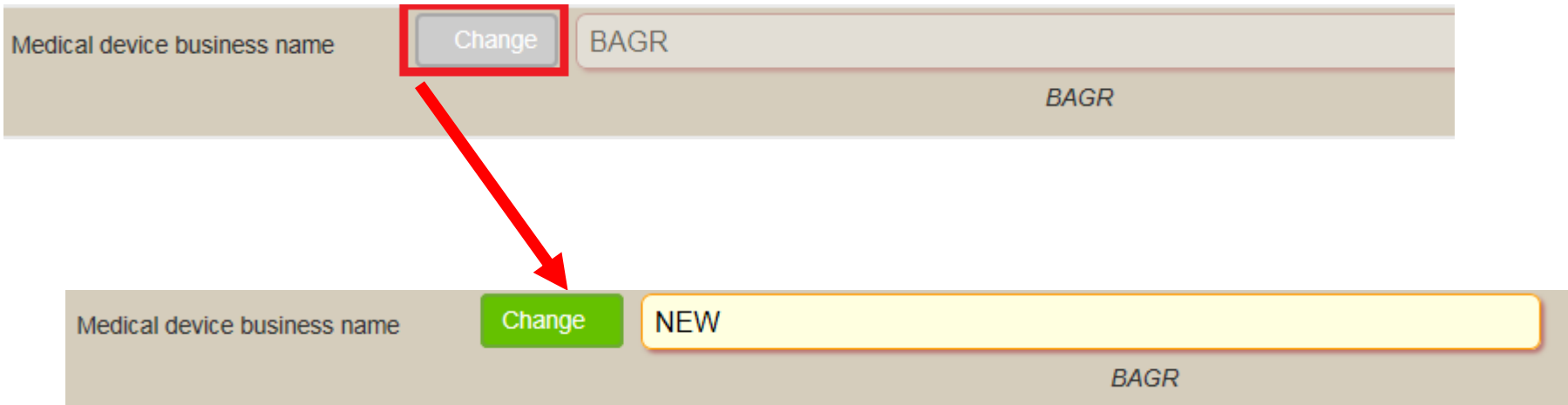
Completion of the application for MD change

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

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.



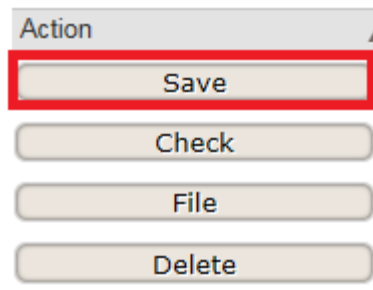
The image illustrates the process of activating a field for change in a web application. It shows two states of a form element:

- Top State (Inactive):** The label "Medical device business name" is followed by a grey "Change" button. To the right, the text "BAGR" is visible. Below this, the text "BAGR" is also visible.
- Bottom State (Active):** The label "Medical device business name" is followed by a green "Change" button. To the right, the text "NEW" is visible. Below this, the text "BAGR" is also visible.

A red arrow points from the grey "Change" button in the top state to the green "Change" button in the bottom state, indicating the transition from an inactive to an active state.

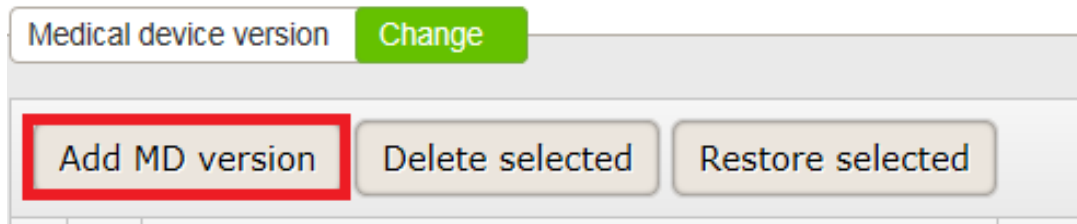
How to fill in the application for MD change

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“.




The screenshot shows a web interface with a header bar containing the text "Medical device version" and a green "Change" button. Below this, there is a row of three buttons: "Add MD version" (highlighted with a red border), "Delete selected", and "Restore selected".

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

<input type="checkbox"/>	Attachment type	Name
<input checked="" type="checkbox"/>	 The latest version of the operating manual in Czech language	Guidelines on Data Exchange


List of attachments

Change

Add attachment

Delete selected

Restore selected

<input type="checkbox"/>	Attachment type	Name
<input type="checkbox"/>	 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)

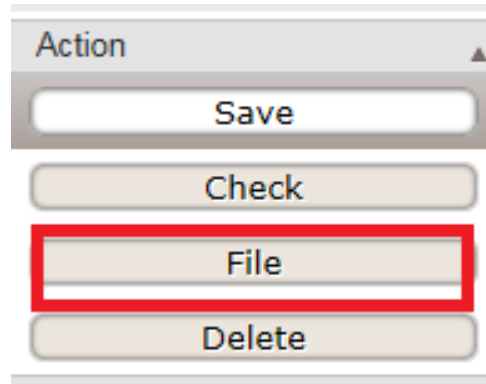
Select...

Další – specifikujte

Select...

Save

To file the application press the „File“ button.



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

Poučení ✕

V souladu s **§ 38 zákona č. 500/2004 Sb., správní řád**, ve znění pozdějších předpisů, **mají účastníci řízení a jejich zástupci právo nahlížet do spisu**. S právem nahlížet do spisu je spojeno **právo činit si výpisy a právo na to, aby správní orgán pořídil kopie spisu nebo jeho části**. Právo nahlédnout do spisu a další práva s tím spojená se uplatňují vůči tomu správnímu orgánu, který se spisem aktuálně disponuje (Státní ústav pro kontrolu léčiv, resp. Ministerstvo zdravotnictví České republiky).

Veškeré údaje jsou zpracovány pro účely Registru zdravotnických prostředků (RZPRO). S těmito údaji bude nakládáno pouze způsobem odpovídajícím příslušným ustanovením **zákona č. 101/2000 Sb., o ochraně osobních údajů a o změně některých zákonů**, ve znění pozdějších předpisů. K osobním údajům budou mít přístup **pouze oprávněné úřední osoby vázané mlčenlivostí**.

Prohlašuji, že všechny údaje uvedené v této žádosti jsou správné, úplné, zakládají se na pravdě a odpovídají aktuálnímu stavu. Jsem si vědom/vědoma, že **poskytnutí nepravdivých údajů je posuzováno jako správní delikt** dle zákona č. 268/2014 Sb., o zdravotnických prostředcích a o změně zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů.

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.

Žádost byla podána ✕

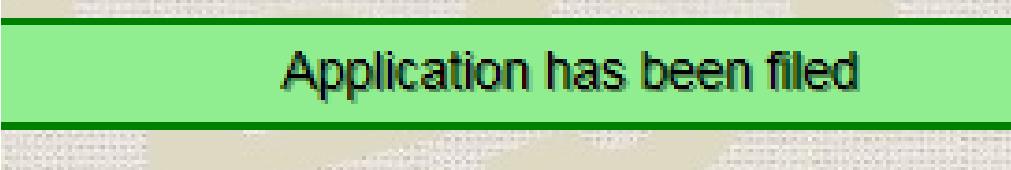
Platební předpis

V platebním předpisu najdete všechny potřebné náležitosti k zaplacení vyměřeného poplatku.

[Zobrazit](#) [Uložit](#)

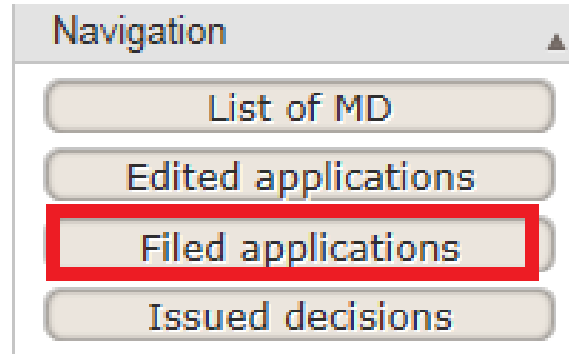
[OK](#)

Your application has been filed



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

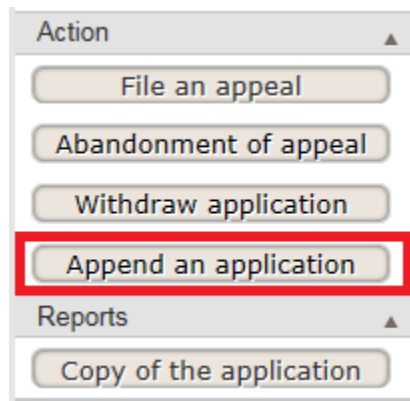
To append the application when you have received the call for completion, go to the the detail of the application

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

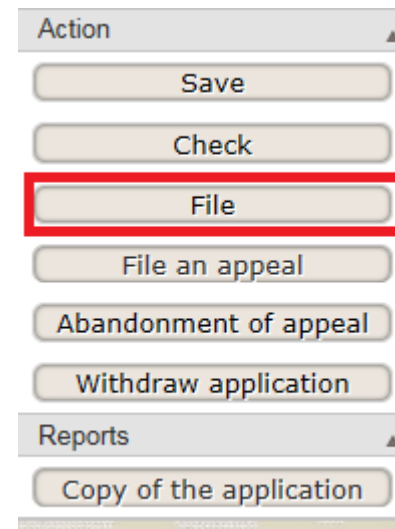
List of decisions and resolutions						
MD name	SIDC file number	Subject	Decision status	Decision type	Legal power	Plenipotentiary agency
Device...	sukls3436/2019	The request to change th...	Confirmed delivery	Call for completion		

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.

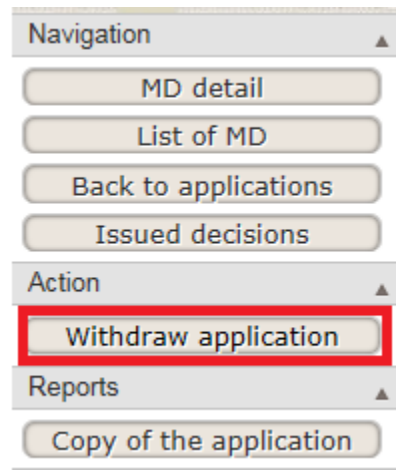
Notification of noncompliance

Should the applicant fail to append the application upon call for completion within the established timeline or fail to pay the administrative 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

- ⑥ **EDITING** – (reference number issued) you may edit (modify) the application
- ⑥ **SUBMITTED** – the application has been filed or appended to the Institute
- ⑥ **PROCESSED** – the application is being assessed by the assessor
- ⑥ **ACCEPTED** – the application 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 application within the predefined timeline set forth by the resolution, which is part of the call for completion
- ⑥ **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.
- ⑥ **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“.
- 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 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.**