



APPLICATION FOR EXTENSION OF MEDICAL DEVICE NOTIFICATION ACCORDING TO SECTION 36 OF THE ACT ON MEDICAL DEVICES

Medical Devices Branch

A medical device notification shall be effective for the period of five years of the date of coming legally into force of the decision on notification.

The notification may be repeatedly extended, always for the period of five years. The application for notification extension may be filed six months before the expiry of its validity, no longer, however, than two months prior to its expiry; Section 32 of the Act on Medical Devices (Act on MD) shall apply accordingly to the particulars of applications for notification extension as per Section 31; Section 34 of the Act on MD shall apply accordingly to the particulars of applications for notification extension as per Section 33.

The period of notification extension shall follow up on the last day of the originally established validity of the notification.

Note:

- ☞ Before filing the application for Medical device notification extension, the particulars of registered Medical device shall be verified to ensure that all data is up to date and valid.
- ☞ In case, the registered data is not valid, it shall be updated via the application for Medical device change (Manual Application for Medical device change) according to Section 35 par. 4 of the Act on MD. The application for Medical device extension shall be filed followingly.
- ☞ No data of a registered Medical device can be edited within the application for Medical device extension. By filing the application for Medical device extension the applicant confirms, that all data of the Medical device is valid and up to date.
- ☞ In the event that the application for Medical device extension is not filed until the date of medical device notification validity expiry, the **notification of medical device will be invalidated.**

Log in the Registry and access module Medical Devices



Click *List of Medical Devices (MD)* to access registered Medical devices

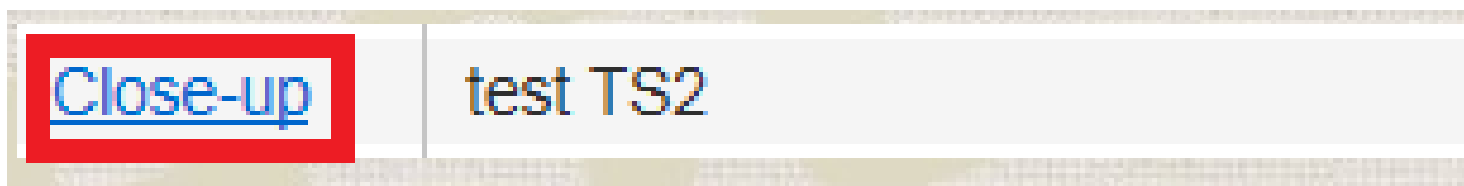


Medical device notification which is due to expire in 6 months bears a marking of a yellow triangle


ZP5	00011455 
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Click *Close-up* to access the Medical device detail



Six months prior the expiry of medical device validity the icon *Application for renewal* is activated (application for Medical device extension)

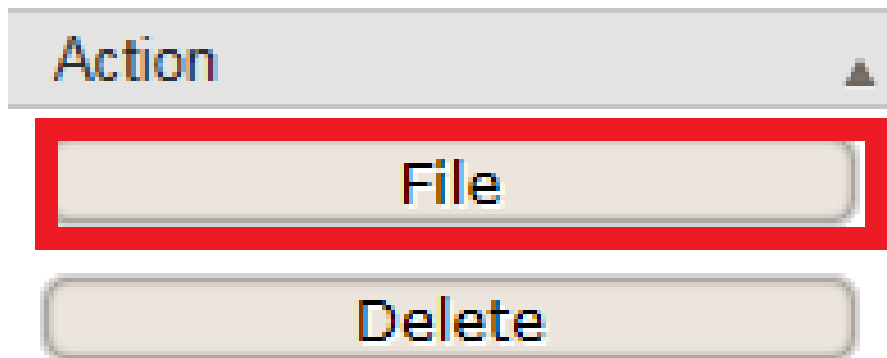


The screenshot displays the 'MD detail' page within a web application. The breadcrumb trail at the top reads 'MD detail << List of MD << Medical devices'. On the left side, there is a navigation menu with several sections: 'Navigation' (containing 'List of MD', 'Edited applications', 'Filed applications', and 'Issued decisions'), 'Action' (containing 'Application for renewal', 'Application for change', and 'Application for remove'), and 'Reports' (containing 'Print medical device'). The 'Application for renewal' button is highlighted with a red rectangular border. The main content area on the right is titled 'Medical device identification' and shows 'Ref. No.' as '00012917'. Below this, there are tabs for 'Close-up', 'Versions', 'History', 'Decision', and 'Applications'. The 'Close-up' tab is selected, showing 'Detailní informace' (Detailed information). This section includes 'Medical device version' (Obecný zdravotnický pr...) and 'Type of MD evidence' (Notifikace dle § 31).

Click *Application for renewal* to open the form of the application for Medical device extension

Subject	The request for an extension MD	Application status	Editing
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To file the application click *File*



**A notice is displayed. Confirm and click *File*.
Confirming the notice, the applicant declares that all registered Medical device data is valid and up to date.**

Note: the notice is not available in English

Poučení x

Podáním žádosti o prodloužení ZP potvrzují, že veškeré údaje vč. příloh na detailu zdravotnického prostředku jsou aktuální a platné. Aktualizaci údajů, pokud se od vydání rozhodnutí o notifikaci předmětného zdravotnického prostředku Ustavem změnily, jsem provedl/a formou podání žádosti o změnu údajů v souladu s §35 odst. 4 zákona č. 268/2014 Sb., o zdravotnických prostředcích a o změně zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů (ZoZP). Beru na vědomí, že nepodáním žádosti dle § 35 odst. 4 ZoZP při změně údajů se mohu dopustit přestupku, za který lze uložit pokutu až do výše 200.000,- Kč.

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 této žádosti jsou správné, úplné, zakládají se na pravdě a odpovídají aktuálnímu stavu a jsem si vědom svých zákonných povinností..

File

The application has been filed.

A screenshot of a notification or status message. It consists of a light beige background with a fine grid pattern. A horizontal green bar is centered across the middle, containing the text 'Application has been filed' in a black, sans-serif font.

Application has been filed

When filing an application for extension of a Medical device notified according to Section 31 of the Act on MD, payment prescription is generated. The payment shall be made under the variable symbol in the prescription.

Žádost byla podána x

Platební předpis

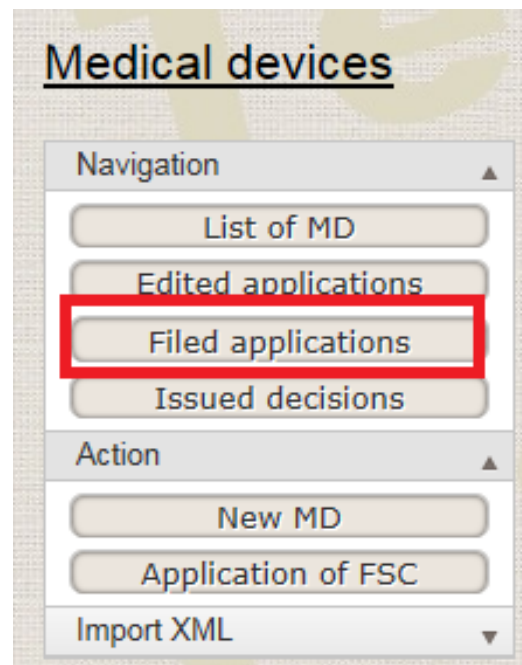
V platebním předpisu najdete všechny potřebné náležitosti k zaplacení vyměřeného poplatku.

Zobrazit

Uložit

OK

Status of the application may be checked under *Filed applications*



Application acceptance

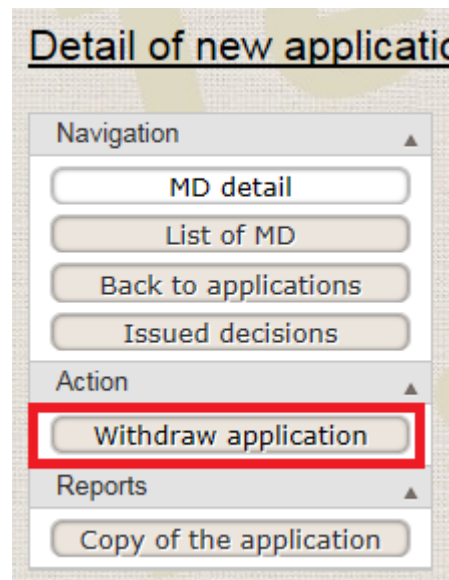
The Institute accepts the application for Medical device extension in case, all data of the registered Medical device is up to date and valid.

The validity of Medical device is extended by 5 years as of the date of coming legally into force of the decision on Medical device extension.

Application withdrawal

The application may be withdrawn at any moment since filing until the Decision is issued.

Attention – this step is irreversible!



Status 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 doubt contact the State Institute for Drug Control:

Methodology 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.

Expert requests:

email: ran@sukl.cz

tel. +420 272 185 600, Monday and Wednesday – 9:00 a.m.-11:00 a.m., 1:00 p.m – 3:00 p.m.