



REPUBLIC OF ESTONIA
HEALTH BOARD

A short guide for using the Estonian Medical Device Database

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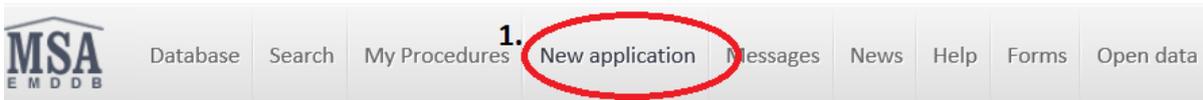
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Notification procedure through EMDDB

1. Gaining access to the EMDDB.
 - a. Logging into the EMDDB with the ID-card or by mobile-ID for Estonian citizens.
 - b. In exceptional cases we can make an account manually, so it is possible to log into the database with username and password. If this option is selected please write to us at mso@terviseamet.ee with the reason why would you need the EMDDB account.



2. After logging in, there is an option called "New application" (1). From there please select "Add new organisation" (2) and fill in the data fields with your represented company and click "Forwards" and "Submit". After that the application is submitted to the processor who has to confirm it.



List of procedures

-page-foretext-new-application

- ✓ Organisations
 - Add new organisation** 2.
- ✓ My personal data
 - Change your personal data
 - Change your password
 - Represent an organisation

3. Always check that the application status is "Presented". Otherwise it won't make it to the processor.

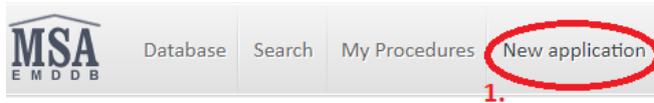
Add new organisation

✓ General application data

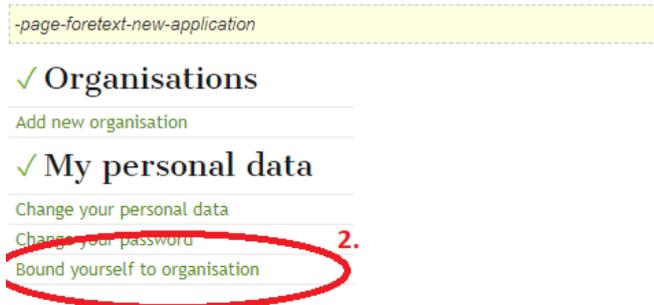
Status	Started	Submitted
Presented	06/21/2019	06/21/2019

Processor	Submitter	Applicant

4. If the organisation is added to the database then you will need to link yourself to it. For that please choose „New application“ -> „Bound yourself to organisation“ (as shown below).



List of procedures



List of procedures |

Bound yourself to organisation

✓ General application data

Status	Started
Not presented	06/09/2020

Submitter	Applicant

✓ Organisation main data

Register code
Juridical name
Address
Country
E-mail
Search organisation

Search the organisation that you want to bound to

✓ Persons data

Personal ID code or user name
Riik
Name

Add the signed authorisation letter (free form document) from the board member of the company to confirm that you have rights to represent the company in the database

✓ Add file(s)

Purpose of the file	Title	Fail (vali oma arvestist)	
		Vali fail Pole valitud	Remove

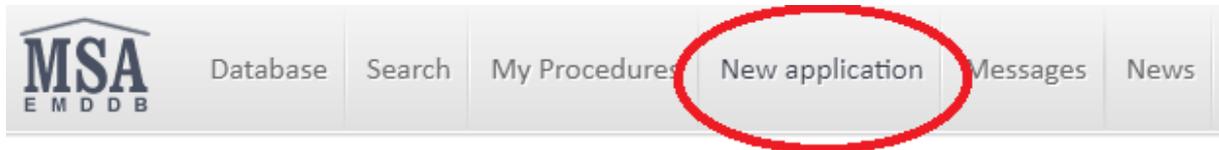
Add more

Forwards

Save Leave unfinished Cancel

Make sure to click **forwards** and **submit** and after that to check if the application status is „presented“. Otherwise the processor can't see and process it.

5. When you are connected with the organisation, then you should see more application options than before. To see these new options select from the menu ***new application***. You can choose ***notify about medical device distribution in Estonia*** or ***notify about placing medical device on the market*** (device made available on the market in the European Union for the first time through Estonia).



List of procedures

✓ Organisations

[Add new organisation](#)

[Change organisation data](#)

[Refresh organisation data](#)

[Bound person to organisation](#)

✓ My personal data

[Change your personal data](#)

[Change your password](#)

[Bound yourself to organisation](#)

[Remove yourself from organisation](#)

✓ Medical device

[Notify about medical device distribution in Estonia](#)

[Notify about placing medical device on the market](#)

6. Fill in the correct form with at least mandatory fields and attach the necessary documents.

Error message „**Tootja määramata!**“ - [click here to solve this error.](#)

List of procedures |

Notify about medical device distribution in Estonia

✓ General application data

Status	Started
Not presented	10/08/2020

Submitter	Applicant
Test	* Test

✓ Medical device data

MSA code
Name
device category
Risk class
Manufacturer
appliance
revised for EHIF

Only for registration of parallel distribution (linking yourself as a distributor for the device that is already in the database).

With these options you can add a manufactures and authorised representative data. Always use “Add existing organisation” first to check whether the company is already in the database. If not, use the ”Add new organisation” option.

✓ Bound organisation data

Roll	MSA andmebaasis	Asutuse andmed
Distributor	Juridical name	Test
Register code		
Short name		
Address		
Organisaton e-mail		
Organisations fax number		
Contact name		
Contact number	Kontaktisiku ametikoht	

Make sure that you have selected the right role for each block (manufacturer, authorised representative or distributor).

✓ Medical device data

Seadme klass	Medical device	Rohkem teavet seadmeklassi kohta ENG: help
Vali, kui seade on meditsiiniseade		
Risk class	I	Rohkem teavet riskiklassi kohta ENG: help

7. Make sure to click **forwards** and **submit** and after that to check if the application status is „**presented**“. Otherwise the processor can't see and process it.

Notify about medical device distribution in Estonia

✓ **General application data**

Status	Started	Submitted	Due date
Presented	10/08/2020	10/08/2020	10/22/2020

Processor	Submitter	Applicant
Processor name	John	Test company

 PDF

8. If the application is sent back to you (status „**Returned to applicant for editing**“), please open the application and read the clarification, make corrections accordingly and resubmit the application by clicking „forwards“ and „submit“. Make sure that the application status is „presented“. Otherwise the processor can't see and continue to process it.

Typical errors and shortcomings/FAQ

- Check that the application is submitted (status „presented“).
- Some of the required documents are missing. Documents required for the registration of medical devices are the following:
 - EC certificate (class I medical devices generally do not have it)
 - Declaration of conformity
 - Instructions for use in English
 - Instructions for use in Estonian
 - A copy of the packaging / labelling of the device as a surface layout (for lay-users one-to-one translation from the original packaging)
- Make sure that the EC certificate and the declaration of conformity match (reference to the EC certificate in the DoC).
- The number of the notified body is four digits.
 - Class I medical devices generally do not have this.
- If there is a device generic group code (GMDN), please include this in the application.
- The error message „**Tootja määramata!**“ (literal translation is „manufacturer not specified“) appears if you have not selected manufacturer data in the "Bound organisation data" block. To correct this error, fill in all the necessary roles in the "Bound organisation data" block. For this choose „Add existing organisation" (if there are devices already registered in the

EMDDB from the same manufacturer, meaning this company already exists in the database) or "Add new organisation" if you did not find the manufacturer under "add existing organisation" or the manufacturer data have changed). Once this is done, a new block will appear under " Bound organisation data " with the details of the organisation entered. The role for this new block must be "manufacturer".

✓ Bound organisation data

		<input type="button" value="Add existing organisation"/> <input type="button" value="Add new organisation"/>	
Roll	Distributer	MSA andmebaasis	Asutuse andmed
Register code		Juridical name	Test
Short name		Country	
Address		Address addition	
Organisaton e-mail		Organisation phone number	
Organisations fax number		Organisations webpage	
Contact name		Contact e-mail	
Contact number		Kontaktisiku ametikoht	
<input type="button" value="Change"/> <input type="button" value="Delete"/>			
Roll	Manufacturer	MSA andmebaasis	Asutuse andmed
Register code		Juridical name	
Short name		Country	
Address		Address addition	
Organisaton e-mail		Organisation phone number	
Organisations fax number		Organisations webpage	
Contact name		Contact e-mail	
Contact number		Kontaktisiku ametikoht	
<input type="button" value="Change"/> <input type="button" value="Delete"/>			

Required documents with the application

Class I medical devices (excluding sterile, measuring function and reusable surgical instruments, which have the same requirements as Class IIa, IIb and III medical devices)

- Declaration of conformity
- Instructions for use in English
- Instructions for use in Estonian
- A copy of the packaging / labelling of the device as a surface layout (for lay-user one-to-one translation from the original packaging)

Class IIa, IIb and III medical devices

- EC certificate (class I medical devices generally do not have it)
- Declaration of conformity
- Instructions for use in English
- Instructions for use in Estonian
- A copy of the packaging / labelling of the device as a surface layout (for lay-users one-to-one translation from the original packaging)