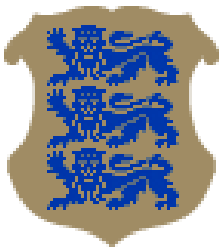


REPUBLIC OF ESTONIA
HEALTH BOARD

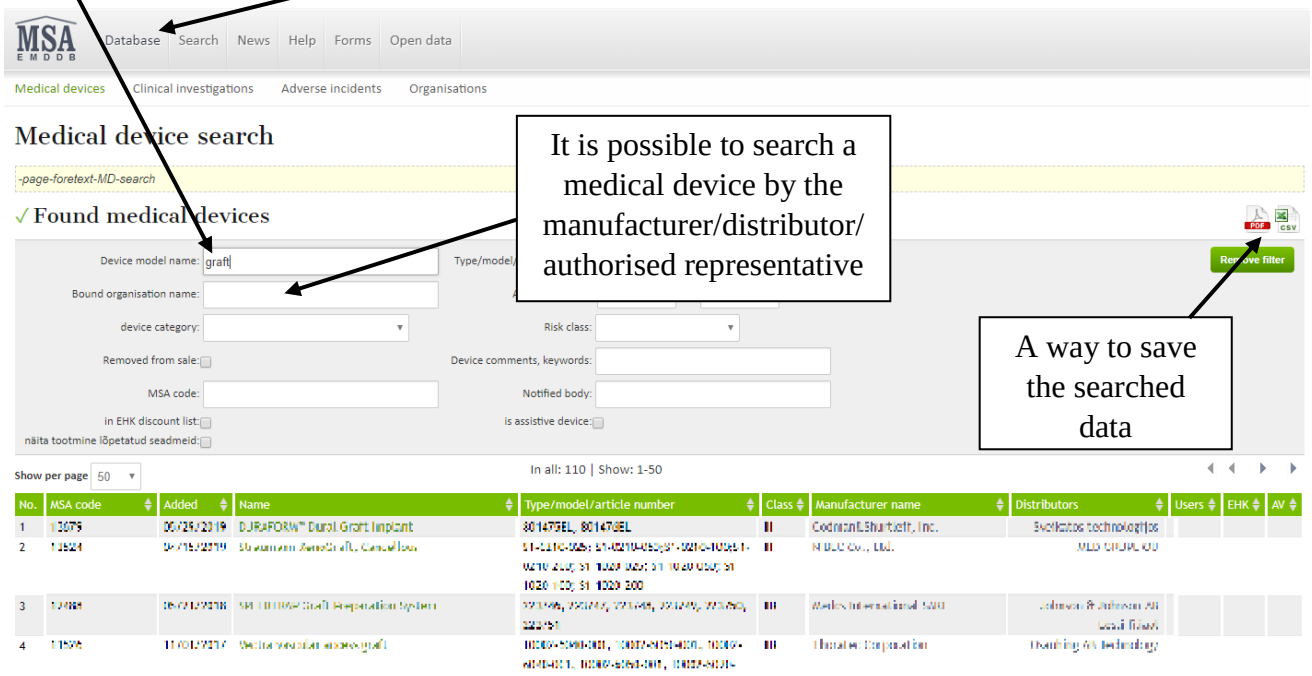
# A short guide for using the Estonian Medical Device Database

# Contents

# Searching for a medical device from the database

The Estonian Medical Device Database (EMDDB) web address is https://msa.sm.ee/eng.

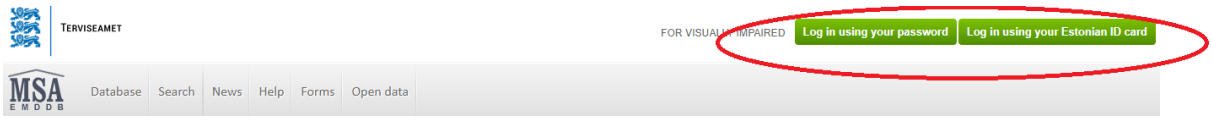
The easiest way to search for a medical device is to use ***database*** and searching by ***device model name***.



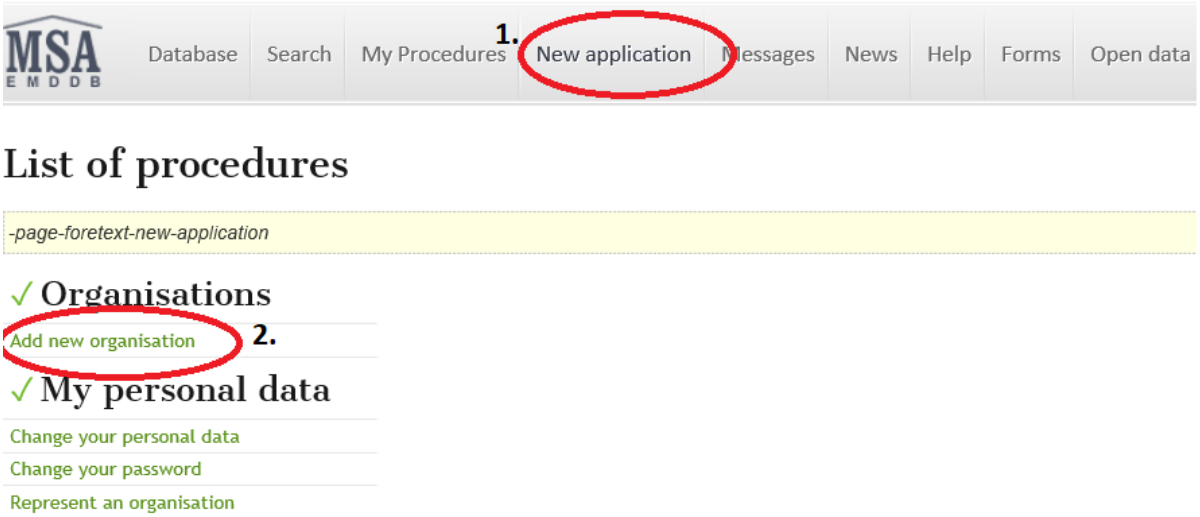

Other search options such as device type, risk class etc. can be applied for a more advanced search.

# Notification procedure through EMDBB

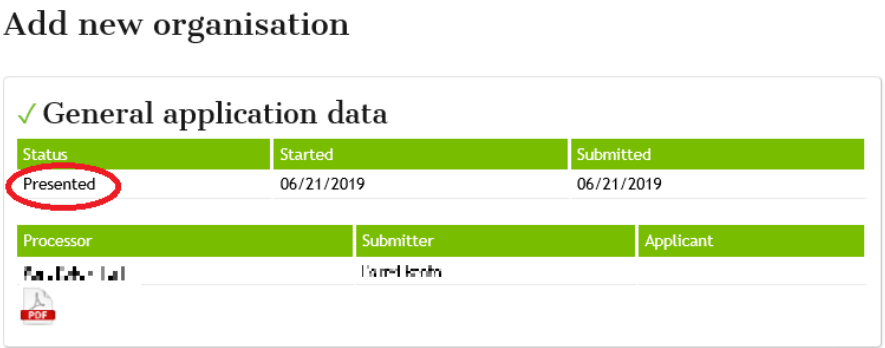
1. Gaining access to the EMDDB.
    a. Logging into the EMDDB with the ID-card or by mobile-ID for Estonian citizens.
    b. In exceptional cases we can make an account manually, so it is possible to log into the database with username and password. If this option is selected please write to us at mso@terviseamet.ee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



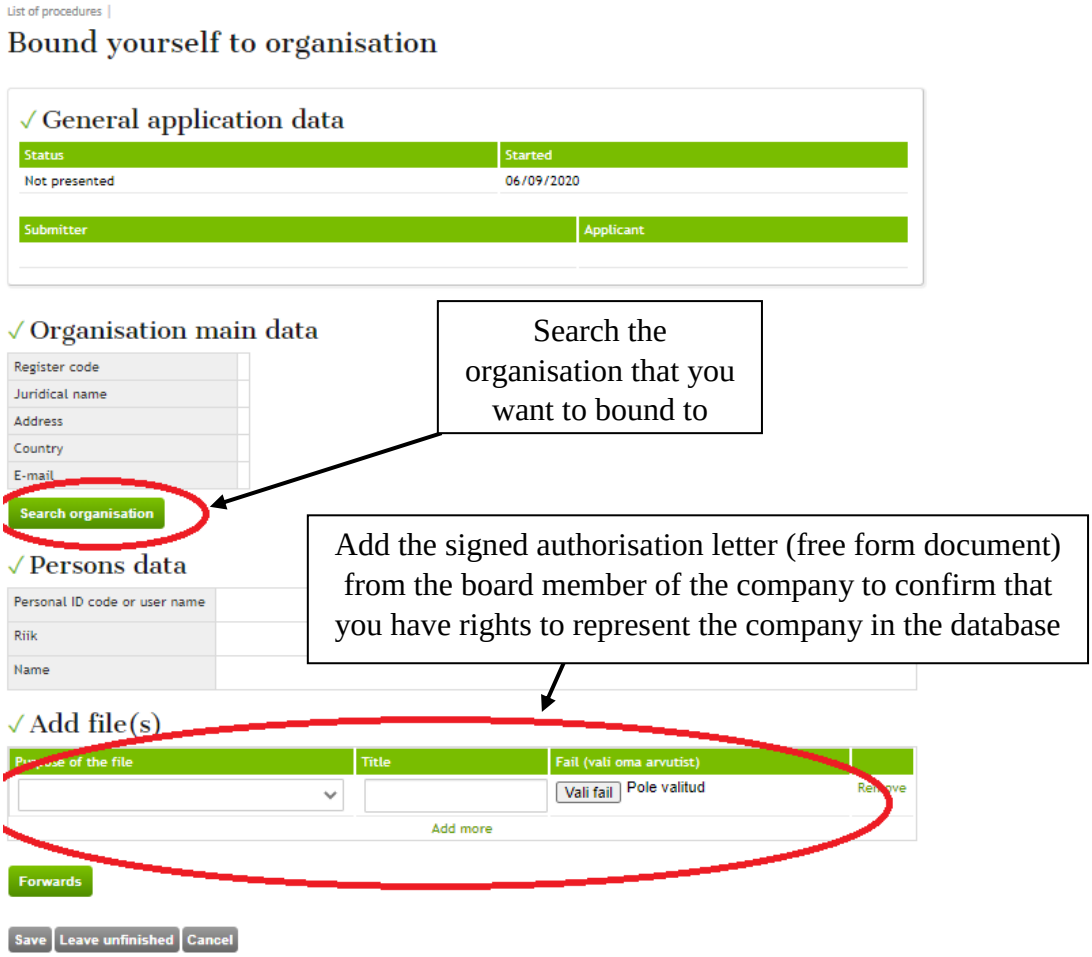

2. After logging in, there is an option called “New application” (1). From there please select “Add new organisation” (2) and fill in the data fields with your represented company and click “Forwards” and “Submit”. After that the application is submitted to the processor who has to confirm it.




3. Always check that the application status is “Presented”. Otherwise it won’t make it to the processor.



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).

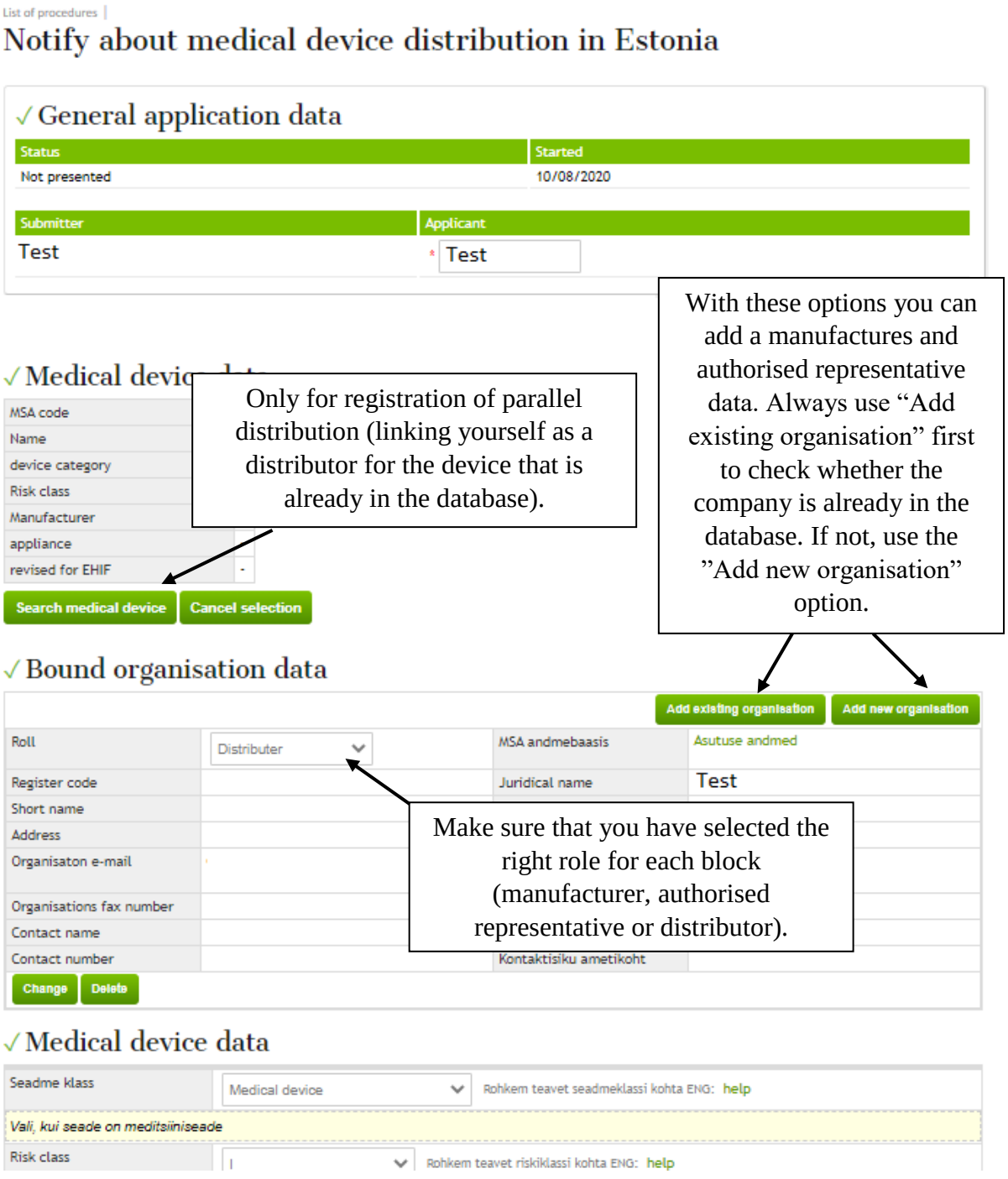




Make sure to click ***forwards*** and ***submit*** and after that to check if the application status is „presented“. Otherwise the processor can’t see and process it.

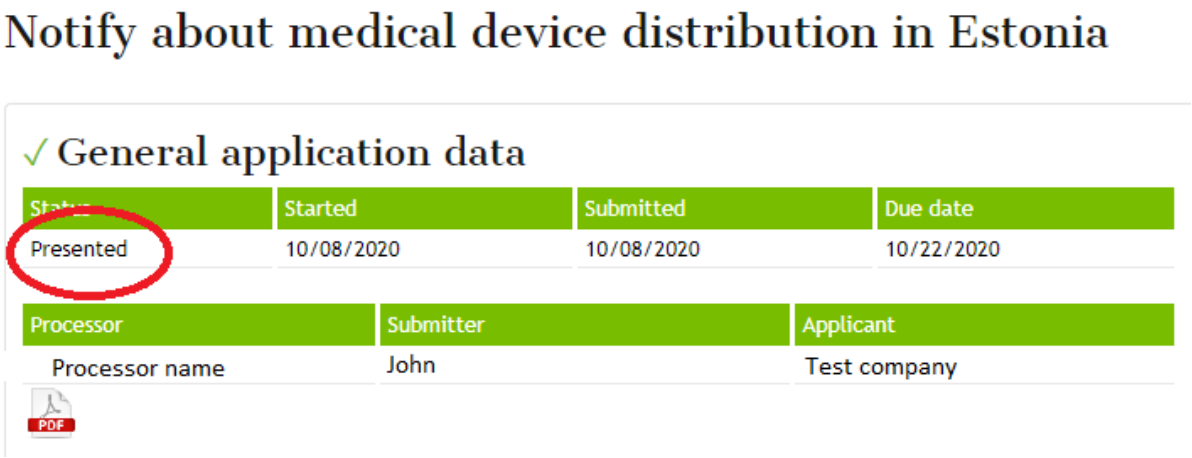
5. When you are connected with the organisation, then you should see more application options than before. To see these new options select from the menu ***new application***. You can choose ***notify about medical device distribution in Estonia*** or ***notify about placing medical device on the market***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

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.*



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.

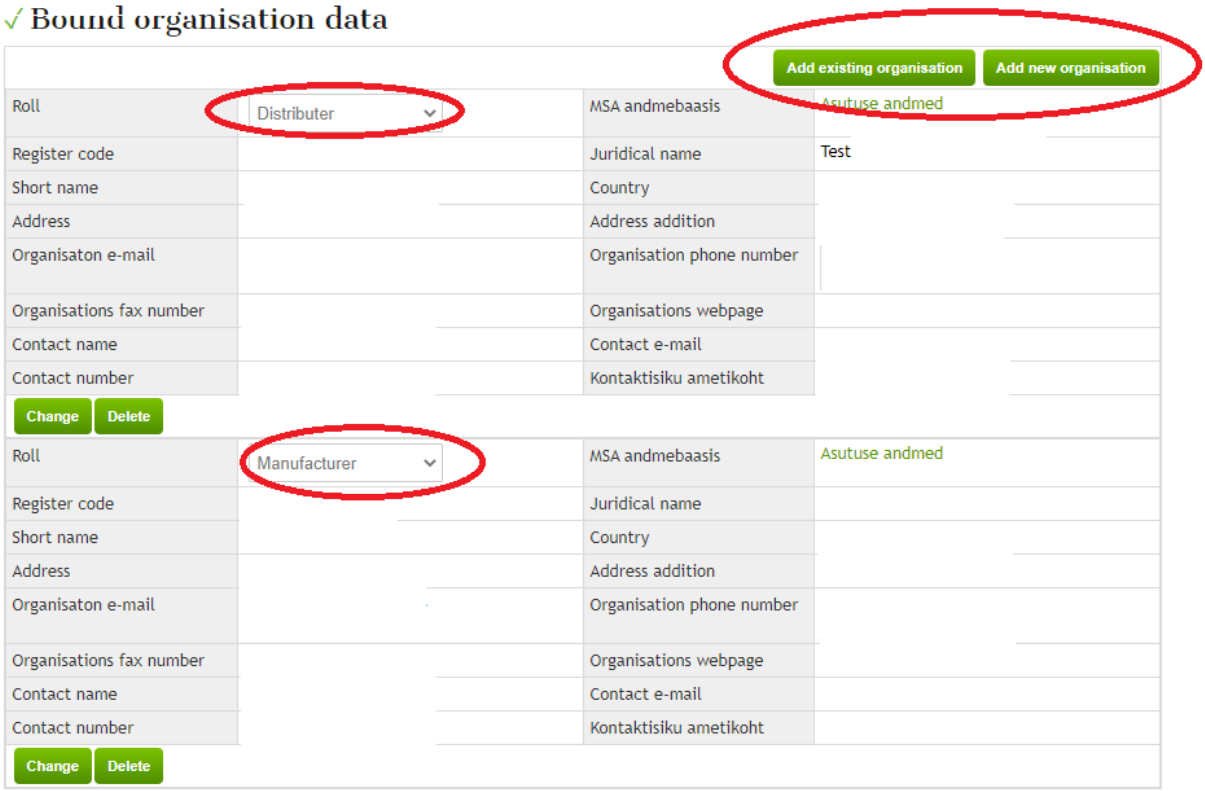



8. If the application is sent back to you (status „**Returned to applicant for editing** “), please open the application and read the clarification, make corrections accordingly and resubmit the application by clicking „forwards“ and „submit“. Make sure that the application status is „presented“. Otherwise 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".




## 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)