MEDECA Software System

User Guide

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Introduction

This guide has been developed to help applicants navigate the MEDECA software system and use its features more effectively. The guide is divided into two main parts to provide a comprehensive overview. The first section focuses on a detailed description of the system's user interface, including navigation elements, page structure and how application information is displayed. The second part covers the practical steps involved in uploading documentation and submitting an application, including detailed instructions for linking files to each of the criteria.

The aim of this guide is to make the whole process easier for you and to ensure that all the necessary steps for managing your application are clear and straightforward. We hope that the information and guidance contained in this document will help you to better navigate the MEDECA software system and manage your applications more efficiently.

If you have any questions or encounter any problems using the system, please do not hesitate to contact us. You can find the contact information on the last page of this manual. We are ready to provide the support you need to ensure that your experience with the MEDECA software system is as comfortable as possible.

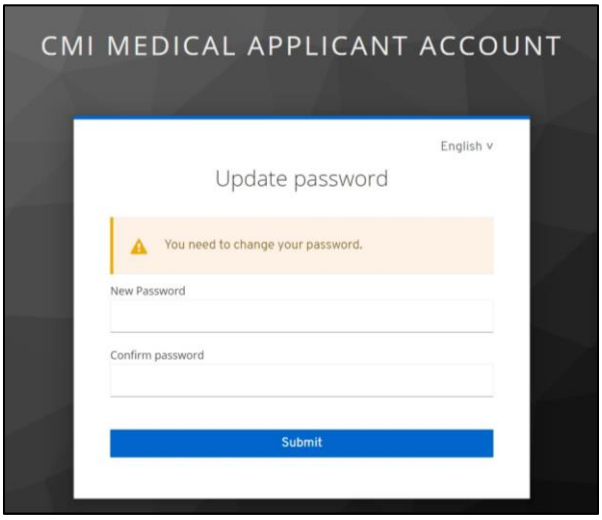
First Chapter

Description of SW MEDECA Interface

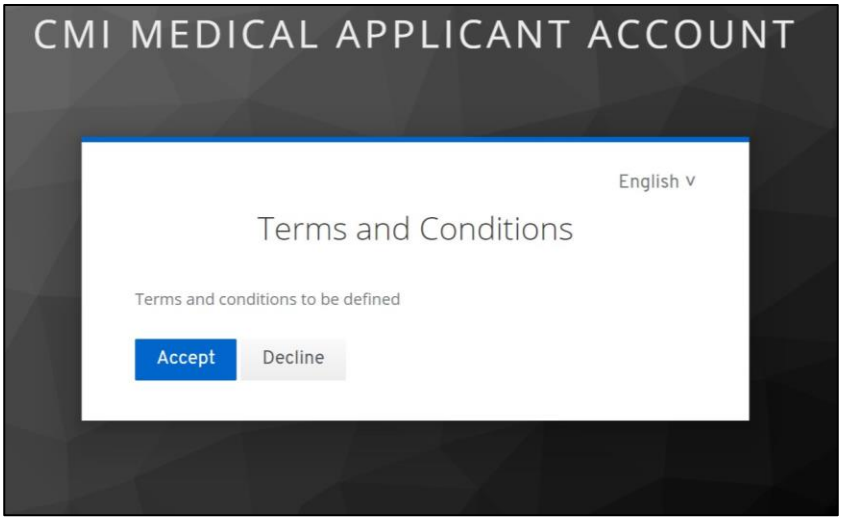
First Login

Before you start working with the MEDECA software system, simply referred to as SW MEDECA, you first need to complete and submit the **Initial Application Form for Medical Device Conformity Assessment**. After submitting the form, CMI staff will quickly file your application and create login credentials for you. These will then be sent to the **Administrative Contact Person (ACP)** email address you provided on the initial form.

In the email, you will find a link to set your **own password** to access the system. We recommend setting your password to be strong enough to ensure maximum security of your data.

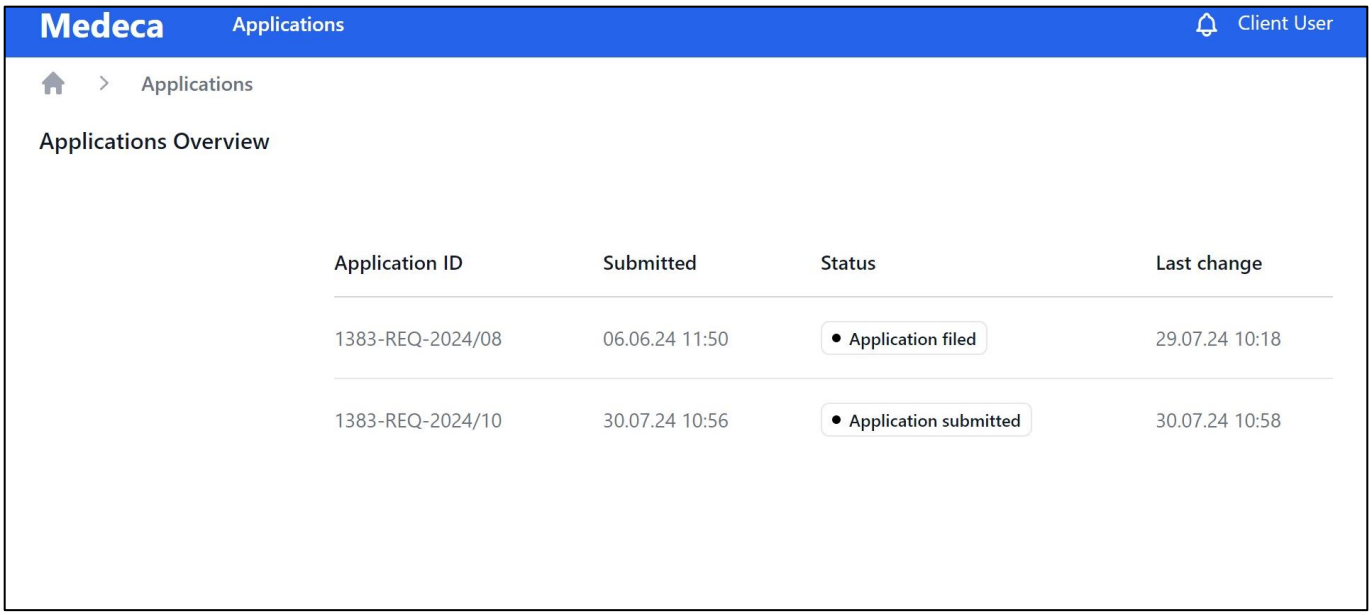


You will then be asked to confirm the **General Terms and Conditions**. Once you have confirmed them, you can easily log in and start using the SW MEDECA environment to the fullest.

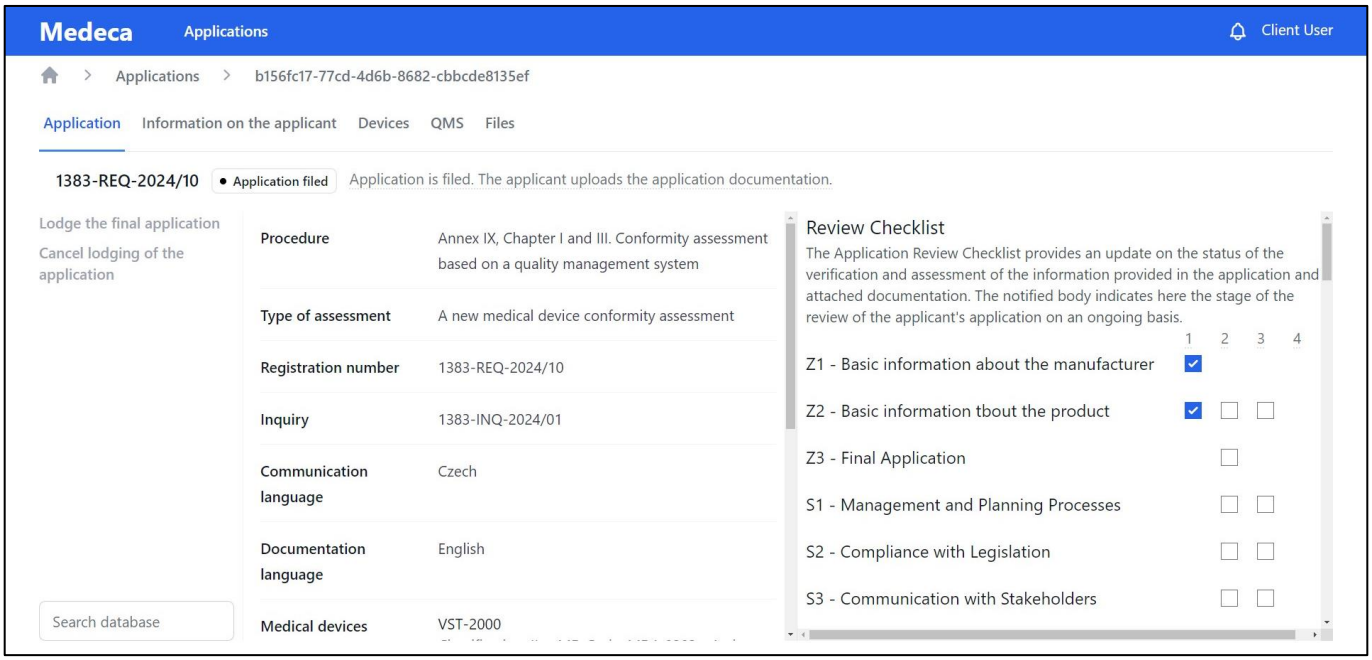


Orientation in the User Interface

After logging into the system, you will see a tab with an overview of all your submitted applications. On each page of SW MEDECA, there is a navigation bar with the applications tab, and a user menu and notification icon on the right side.



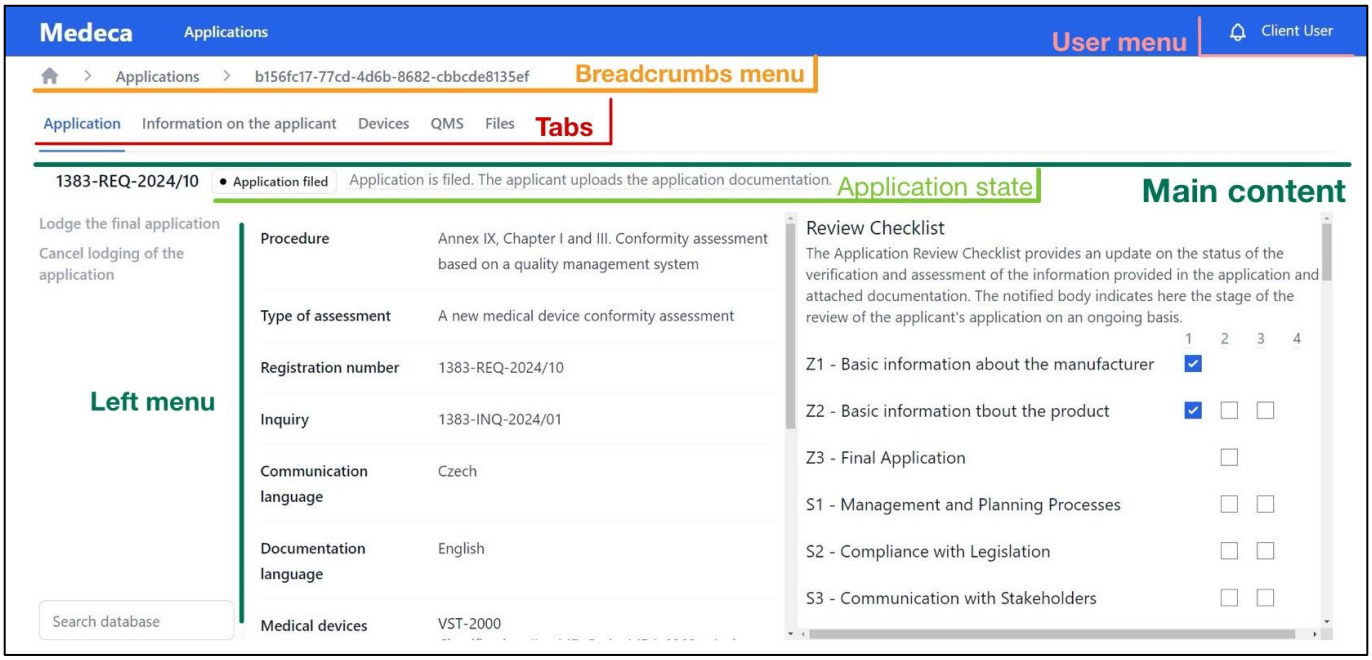
Selecting a specific application will open a page with detailed information about that application. On this page, you will find important information and tabs to help you with navigation and using the system.



Orientation in the User Interface

The SW MEDECA has a unified interface structure that makes it easy to navigate. Each page is divided into the following sections:

- **Navigation elements:** at the top of the page you will find a **breadcrumb menu** and **application tabs** to help you navigate easily.
- **User menu:** here you can change the interface language, access brief system documentation, and **log out** and there is also the notification icon.
- **Left menu:** The left menu shows the **action commands** you can use on the current page.
- **Main content:** this shows the main content of the page, which can sometimes be split into two columns. At the top of the main content, you will also find the **registration number** and the **current status** of the application with a brief description.

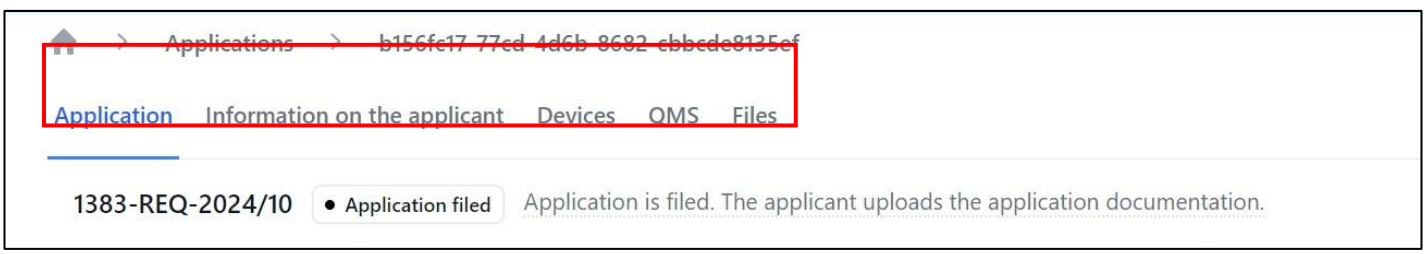


Application Detail

In the application detail, you have all the necessary information clearly available to you, and this is where virtually all the application work in SW MEDECA takes place. The information is divided into blocks that you can easily view using the **tabs** at the top of the page.

The following tabs can be found here:

- **Application**: Basic information about the application.
- **Information on the applicant**: basic information about the applicant.
- **Devices**: General information about the products, technical documentation, if applicable, and **criteria for conformity assessment**.
- **QMS**: General information on quality management system documentation and **criteria for conformity assessment**.
- **Files:** list of files related to the application.

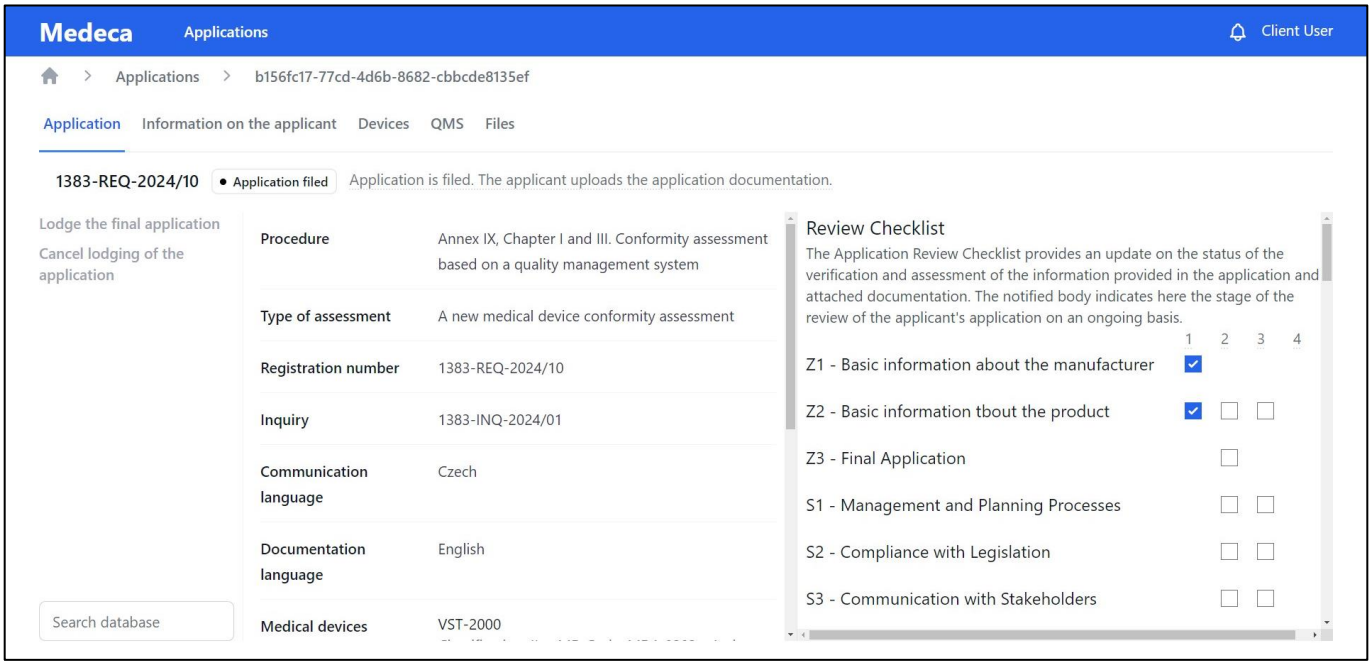


Application Detail – Application Tab

The Application tab serves as the initial page of the application details and contains mainly basic information such as:

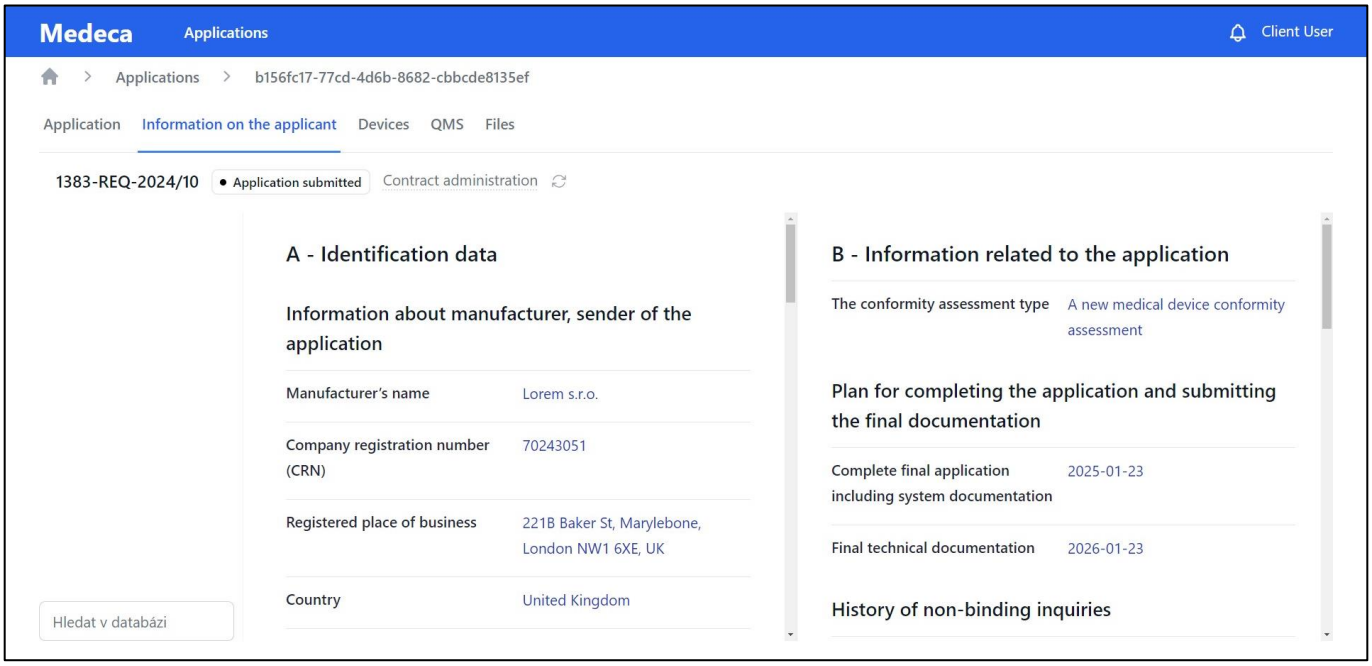
- **Type and Procedure of conformity assessment**
- **Registration number and number of relevant inquiry**
- **Language of communication and documentation**
- **Basic information on devices**
- **Date of the final application submission**

On the right side of the page is the Review Checklist. We update this checklist regularly to give you an indicative overview of the current status of your application.



Application Detail - Applicant Information Tab

On this tab you will find identification details and detailed information regarding your application. It is mainly used to summarize and check the basic information you have filled in the entry form.



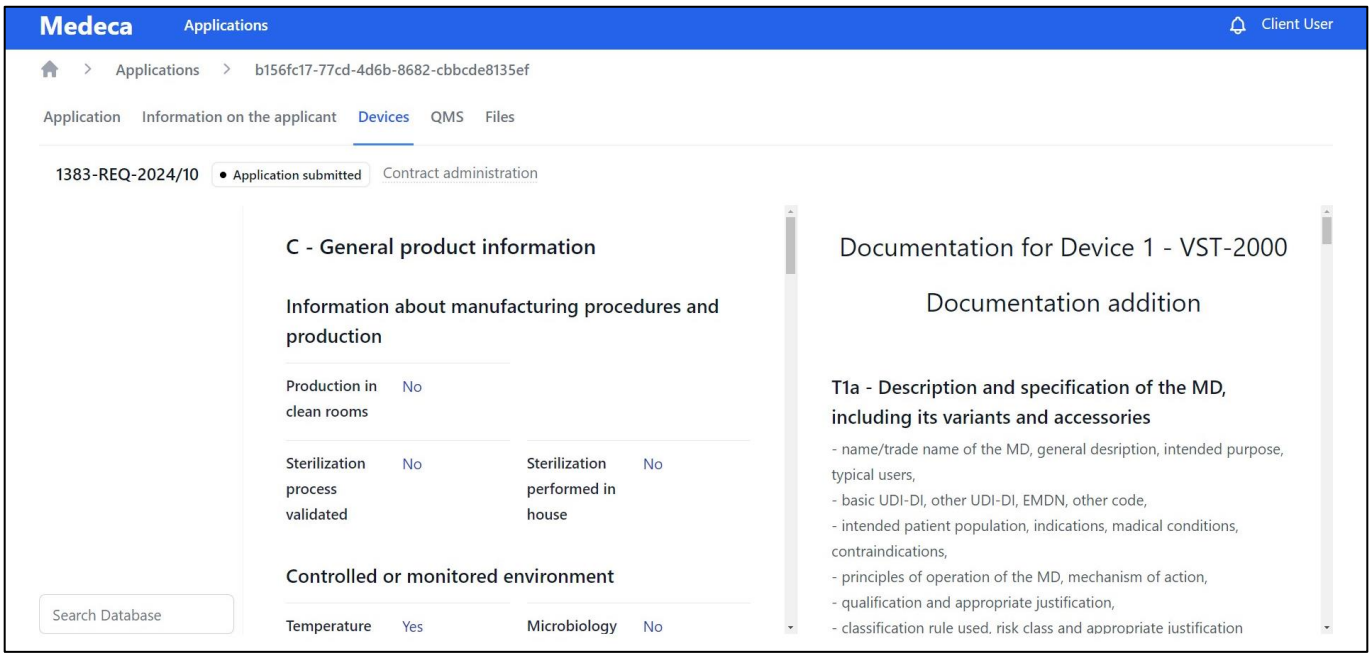
The information you will find here includes:

- **Your company name and address**
- **CRN, and SRN** (Single Registration Number)
- **Invoice information**
- **Contact details** for the **ACP, PRRC** or other contact persons
- **Information related to the application:** for example, documentation submission schedule, list of critical suppliers, standards for maintaining the quality management system, etc.

This information will help you manage your application efficiently and ensure that all the necessary details are filled in correctly and completely. If you discover an error in any of the information or if it has been changed, please contact us to arrange for a correction.

Application Detail – Devices Tab

Under the Devices tab, you will find general information about your products and production processes, which has been taken from the initial application form. The right-hand column lists the criteria for conformity assessment to which you will link relevant documents. Details on uploading and linking documents can be found in chapter two.



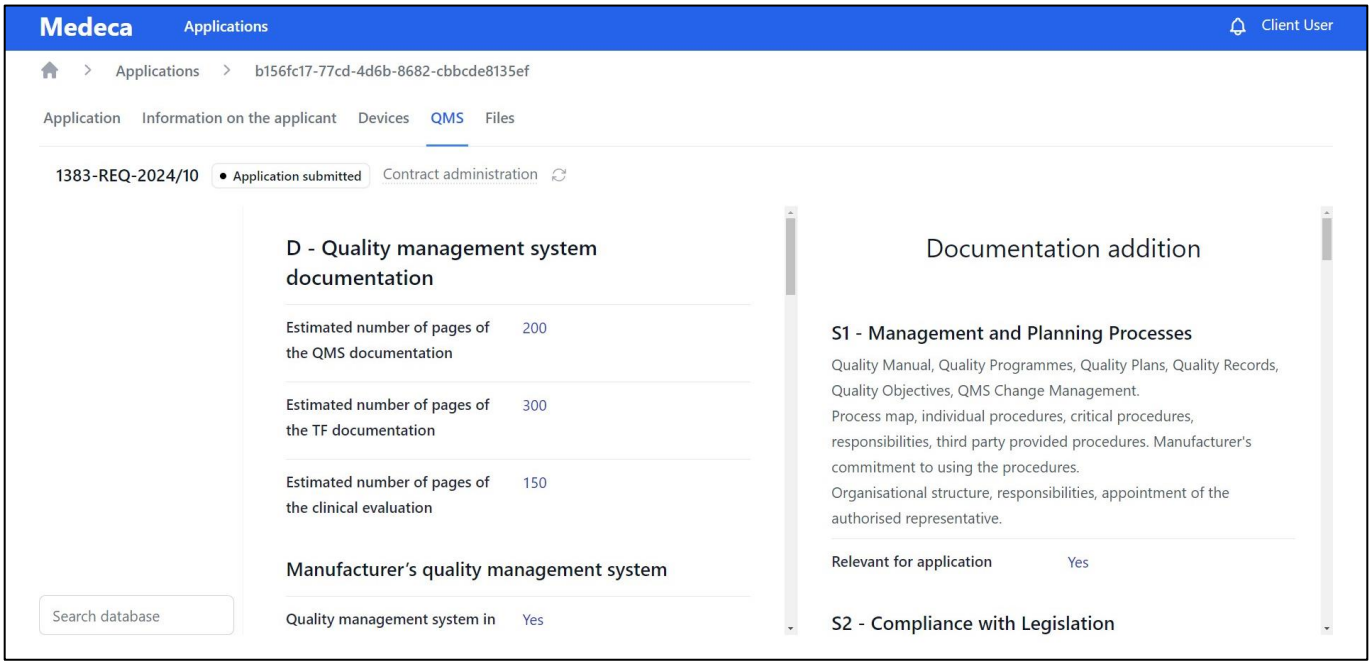
For example, on this tab you will find:

- **Information on manufacturing processes and production**
- **Information about the controlled or monitored environment**
- **Manufacturing process technologies used**
- **Generic device group (EMDN)**
- **Basic UDI-DI**
- **Intended purpose and description of the device**
- **List of models and variants**

Application Detail – QMS Tab

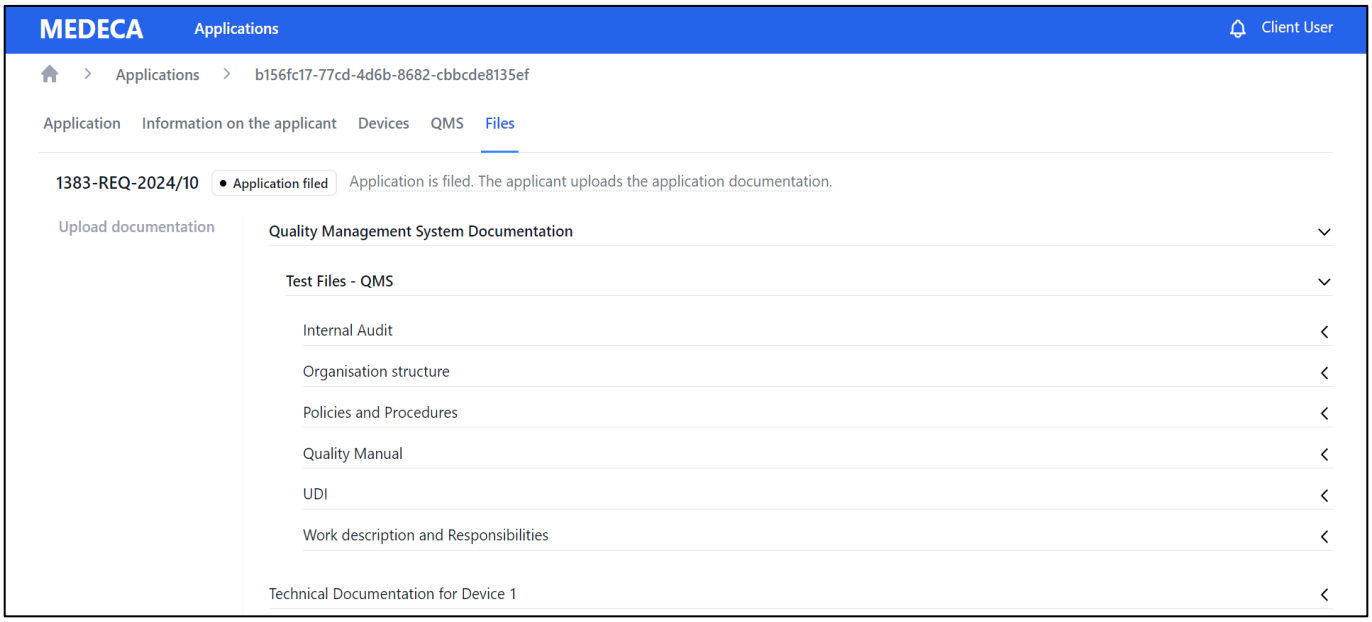
The QMS tab is dedicated to your implemented quality management system. In the left column you will find general information such as the estimated number of pages of your documentation and the standards according to which your system is structured.

In the right column are the criteria for conformity assessment, which are discussed in detail in chapter two.



Application Detail – Files Tab

On this tab, on the left side, you will find the action command to upload documentation files. On the right side of the page, you will find an overview of all uploaded files, which are clearly divided into the respective folders.



For each application, there is always **one "Quality Management System Documentation"** folder and a **number of "Device Technical Documentation"** folders corresponding to **the number of devices** to which your application concerns

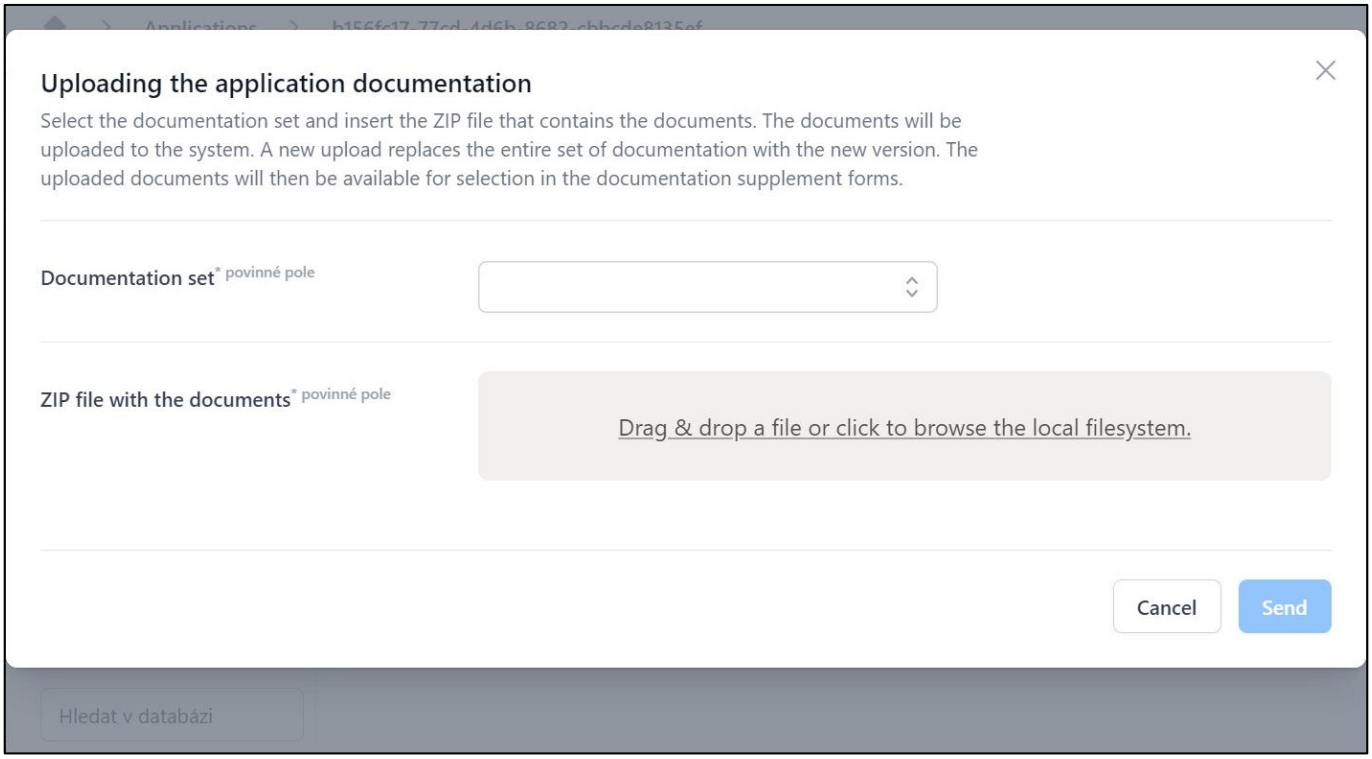
Second Chapter

Description of Basic Processes

Uploading Files

Uploading your documentation correctly is essential for the entire conformity assessment process. To ensure smooth progress, the documentation must be clear and easily accessible. In MEDECA SW, we have designed an environment that simplifies this process.

Uploading documentation is done on the "**Files**" tab. After selecting the "**Upload documentation**" command from the left bar, the file upload window opens.



Select the documentation set to which you want to upload your files — either the Quality Management System documentation or the Technical Documentation for each of your devices.

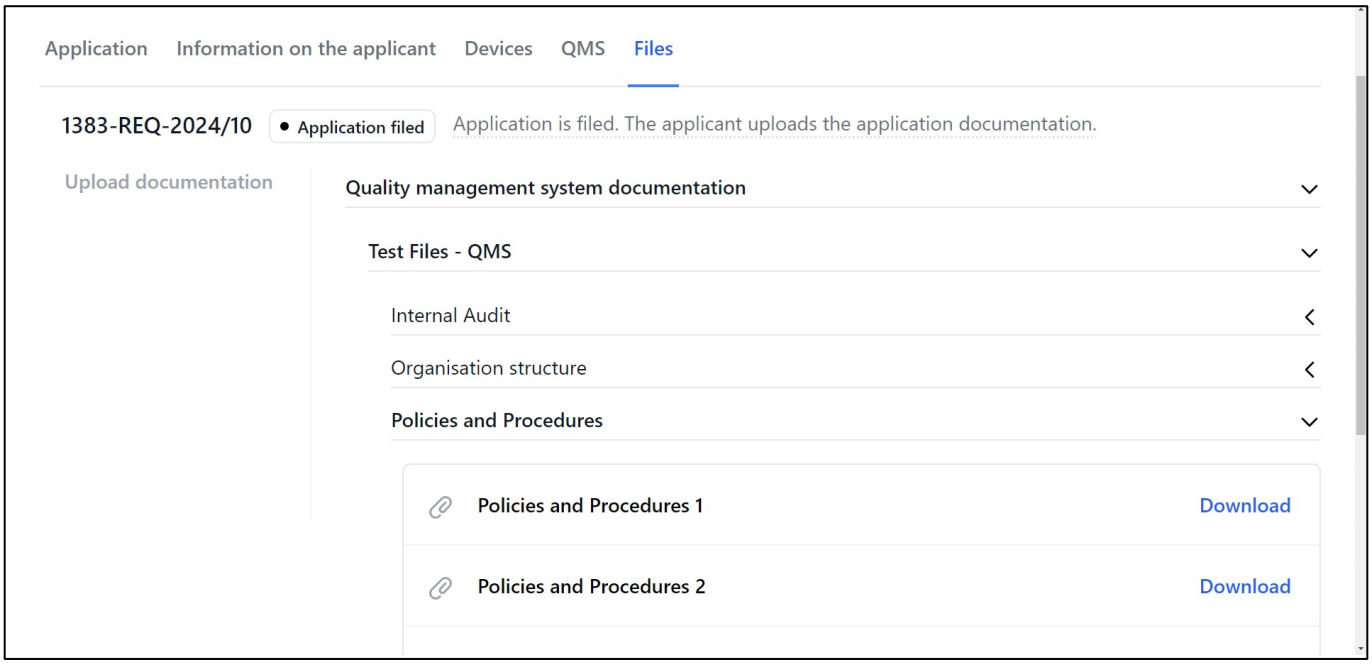
You can then either drag the files into the grey box with your mouse, or click to select them from the directory. The system only allows you to upload compressed files in **ZIP format**.

Depending on the size of the documentation, the upload may take several minutes. Please be patient and keep the window open until the upload process is complete.

Uploading Files

You can view the uploaded files in the "**Files**" tab. Clicking on the documentation set you have uploaded the files to will display the structure of your documentation.

Initially, all folders are closed, but you can easily open them to view each individual uploaded file.



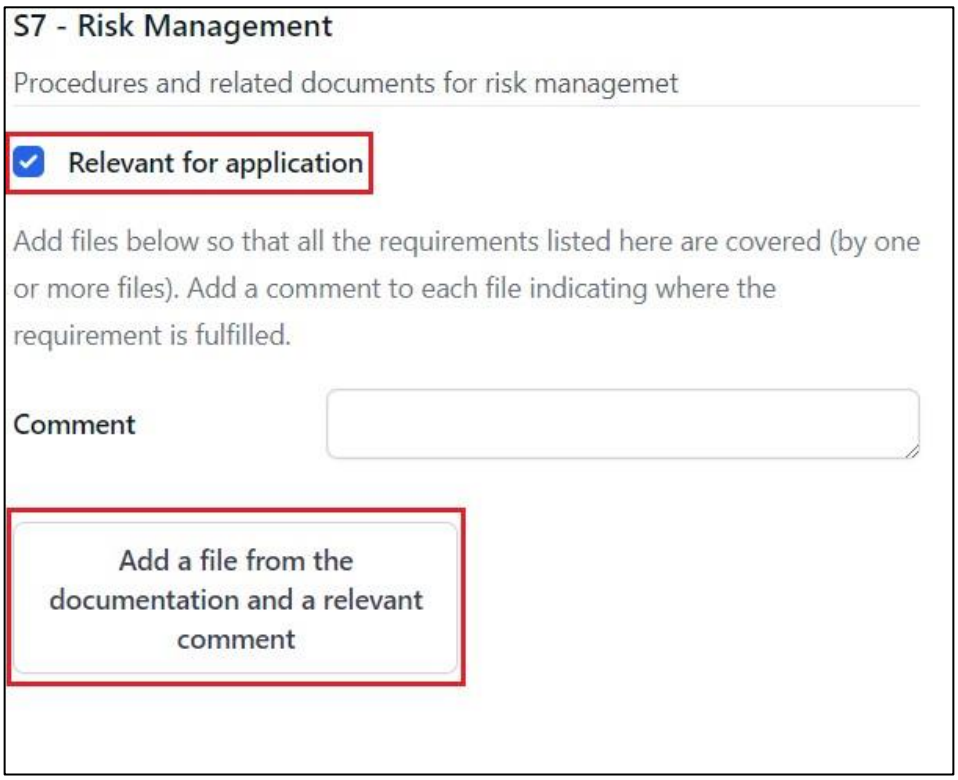
Once your documentation is uploaded, you can move on to the next step, which is to link the files to criteria for conformity assessment.

Linking Files to the Criteria

Once the files are uploaded, they must be linked to the criteria. These criteria can be found on the Devices and QMS tabs and provide a clear checklist of the requirements set by the MDR for assessing compliance.

To edit the criteria, click the "Edit" button in the right column under the **QMS** or **Devices** tabs. For each criteria, you must first decide whether it is relevant to your application. This is done by checking the box "**Relevant to the application**." If you find that a criterion is not relevant to your application, please justify your decision in a comment.

After checking the box, you will see a button to add the file and an option to add comments with relevant information.

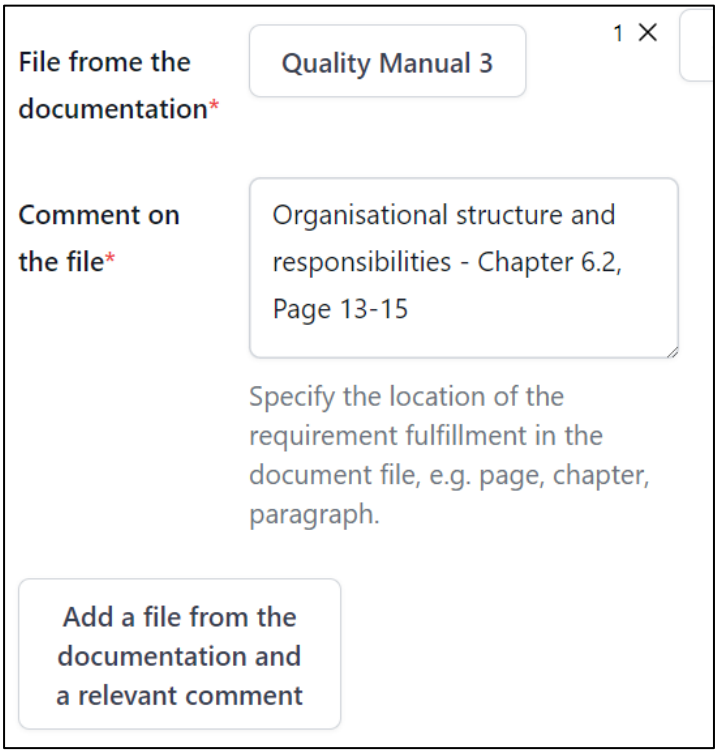


Linking Files to the Criteria

Select a file from the menu, either by choosing it from the drop-down list or typing it in. Then, specify exactly where the evidence fulfilling the criteria requirements can be found within the document. State for example:

- **The page number**, where the requirements are located.
- **The chapter**, that contains relevant information.
- **The paragraph number**, if relevant.

This will ensure that reviewers can quickly find the information they need and check that the criteria are met without time delays.



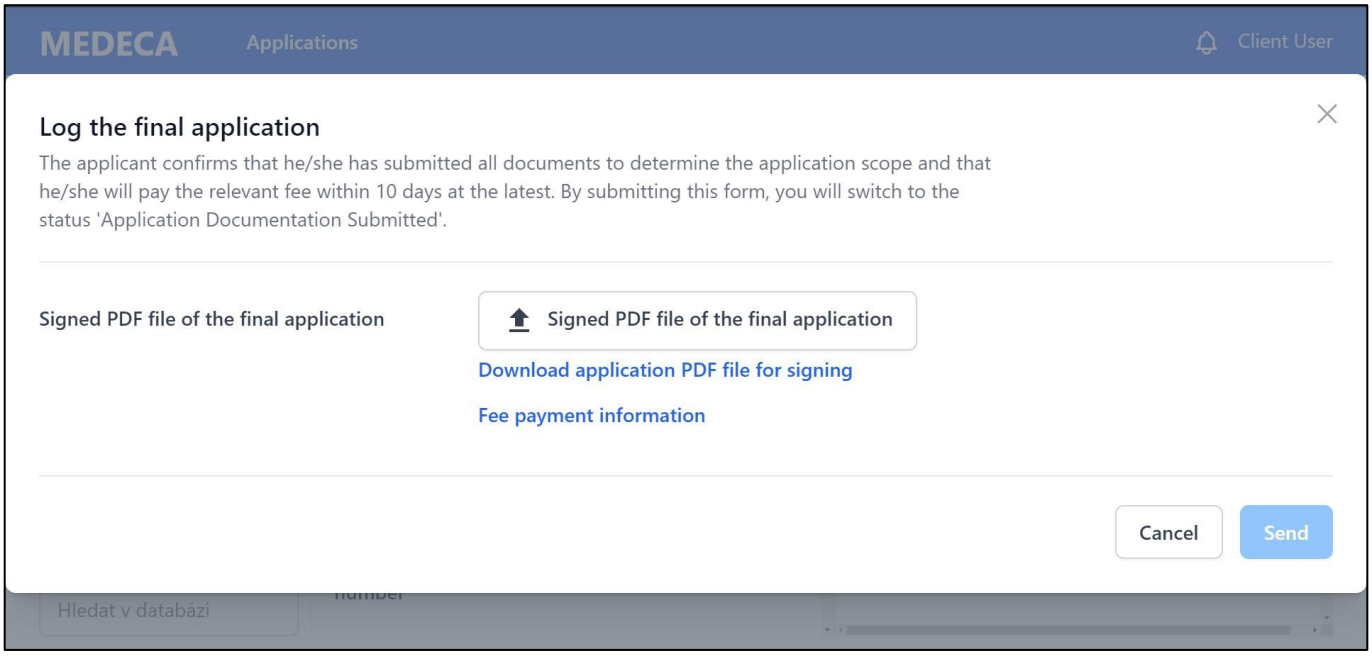
You can easily add more files by clicking the „**Add File**“ button. Follow the same steps: select the file, assign it to the appropriate criterion, and provide a detailed description of where in the document the requirements are addressed.

Lastly, be sure to **save** your progress regularly to ensure your updates are recorded properly.

Lodging the Application

Once all your files have been successfully uploaded and **linked to all relevant assessment criteria**, you can proceed to the **submission of your application for conformity assessment**.

After selecting the "**Lodge the Final Application**" command on the **Application** tab, the application submission window will appear. Use the links to download the **application form** for signing and to view **pricing information** on the CMI website.



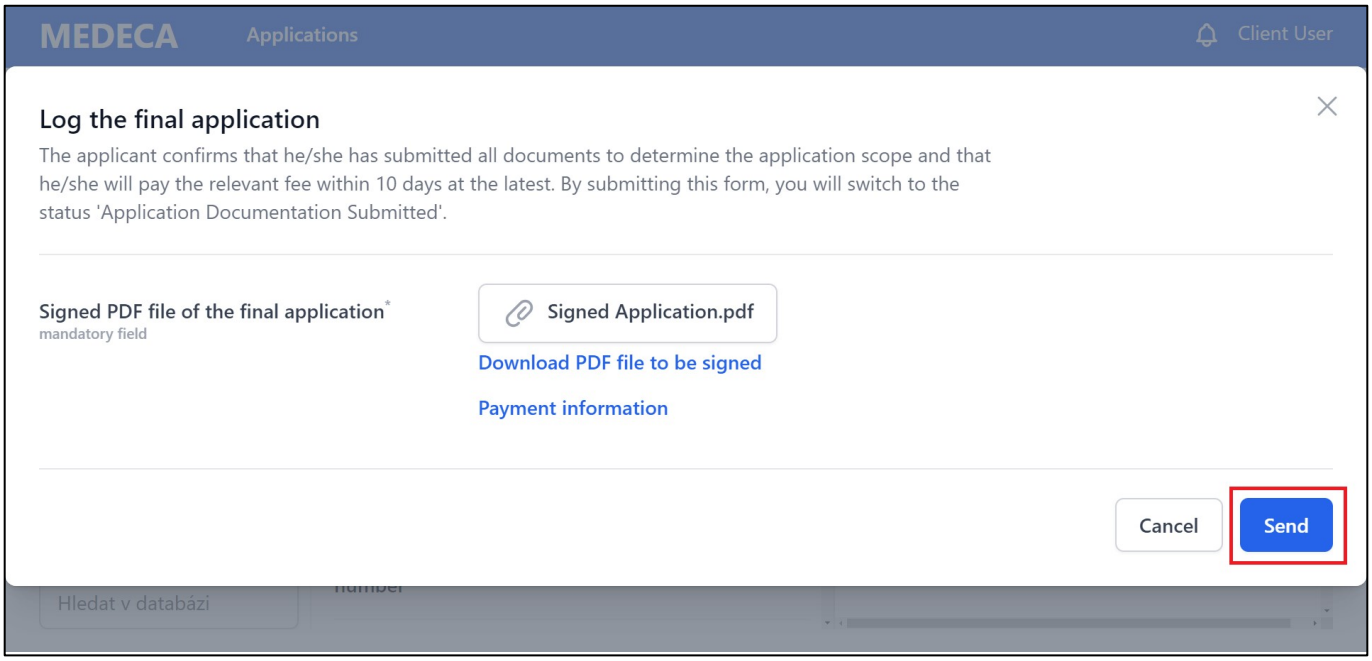
The application lists all relevant information available in SW MEDECA, such as the information written from the initial form, the files associated with the criteria and your comments.

Lodging the Application

The application must be signed by an authorised person of the manufacturer in section F (end of document). The application cannot be accepted without a signature and you will be asked to correct it.

F - Signiture of the Applicant	
Signature of the authorised representative of the applicant who submitted the application for conformity assessment:	

Use the „**Lodge the final application**" button to upload the signed application. Confirm the action with the „**Send**" button.



With this, your application is officially lodged.

CMI MEDICAL
MEDICAL DEVICES CERTIFICATION CENTRE

Contact us

Do you require assistance or wish to verify if your medical device qualifies for assessment by CMI?
Do not hesitate to reach out to us:

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