



CMI MEDICAL

MEDICAL DEVICES
CERTIFICATION CENTRE

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.

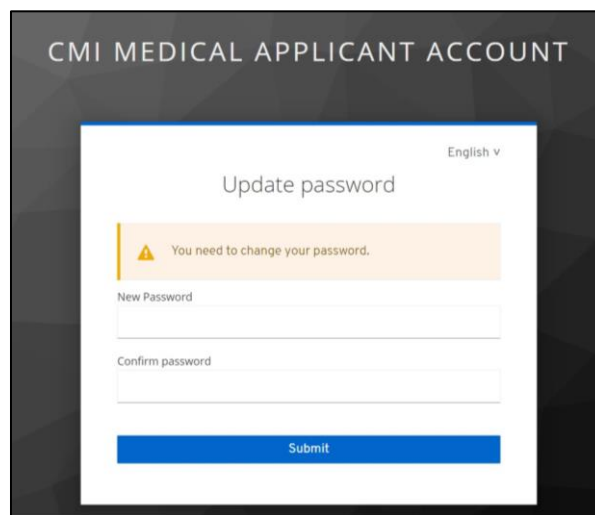
First Chapter

Description of SW MEDECA Interface

First Login

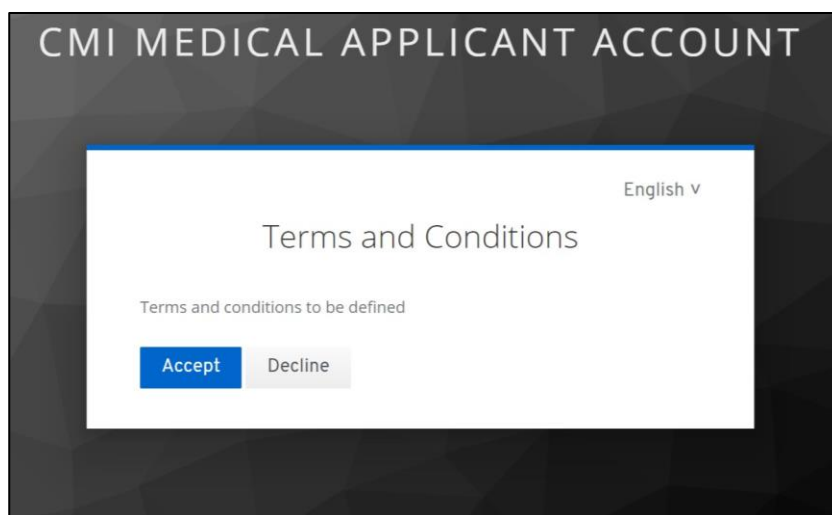
Before you start working with the MEDECA software system, simply referred to as SW MEDECA, you first need to complete and submit the **Initial Application Form for Medical Device Conformity Assessment**. After submitting the form, CMI staff will quickly file your application and create login credentials 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.



The screenshot shows a web interface titled "CMI MEDICAL APPLICANT ACCOUNT" with a sub-header "Update password". In the top right corner, there is a language selector "English v". Below the title, a yellow warning box contains a triangle icon and the text "You need to change your password.". There are two input fields: "New Password" and "Confirm password". At the bottom, there is a blue "Submit" button.

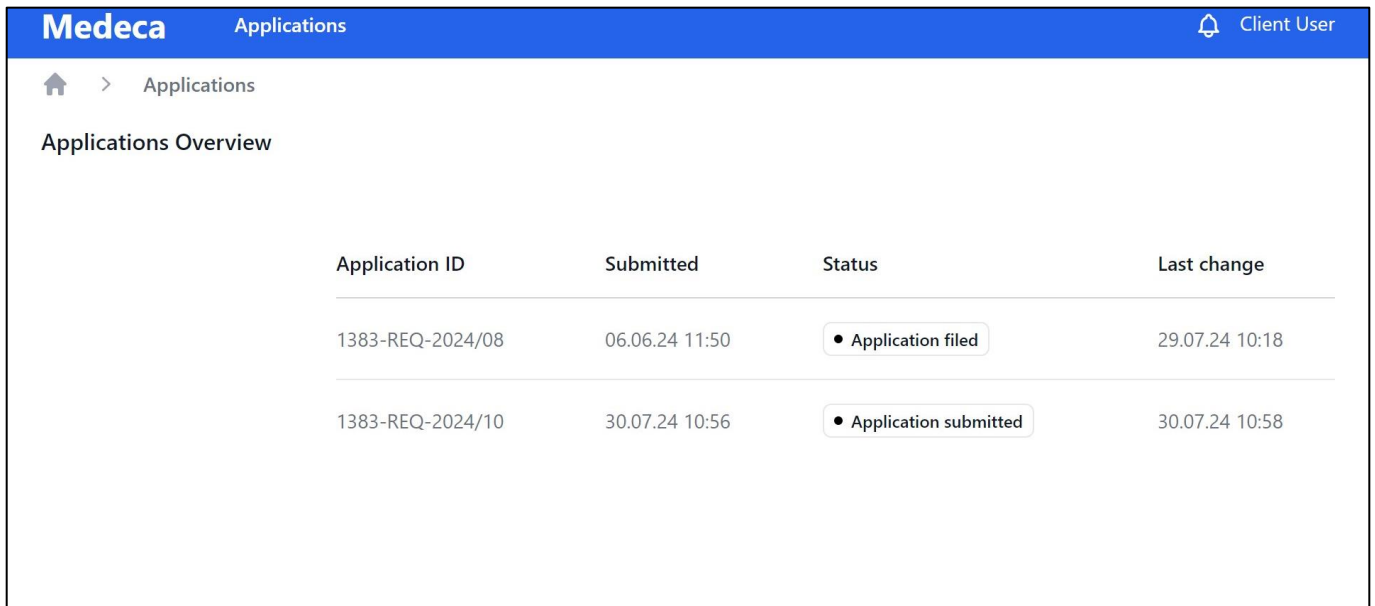
You will then be asked to confirm the **General Terms and Conditions**. Once you have confirmed them, you can easily log in and start using the SW MEDECA environment to the fullest.



The screenshot shows a web interface titled "CMI MEDICAL APPLICANT ACCOUNT" with a sub-header "Terms and Conditions". In the top right corner, there is a language selector "English v". Below the title, the text "Terms and conditions to be defined" is displayed. At the bottom, there are two buttons: a blue "Accept" button and a grey "Decline" button.

Orientation in the User Interface

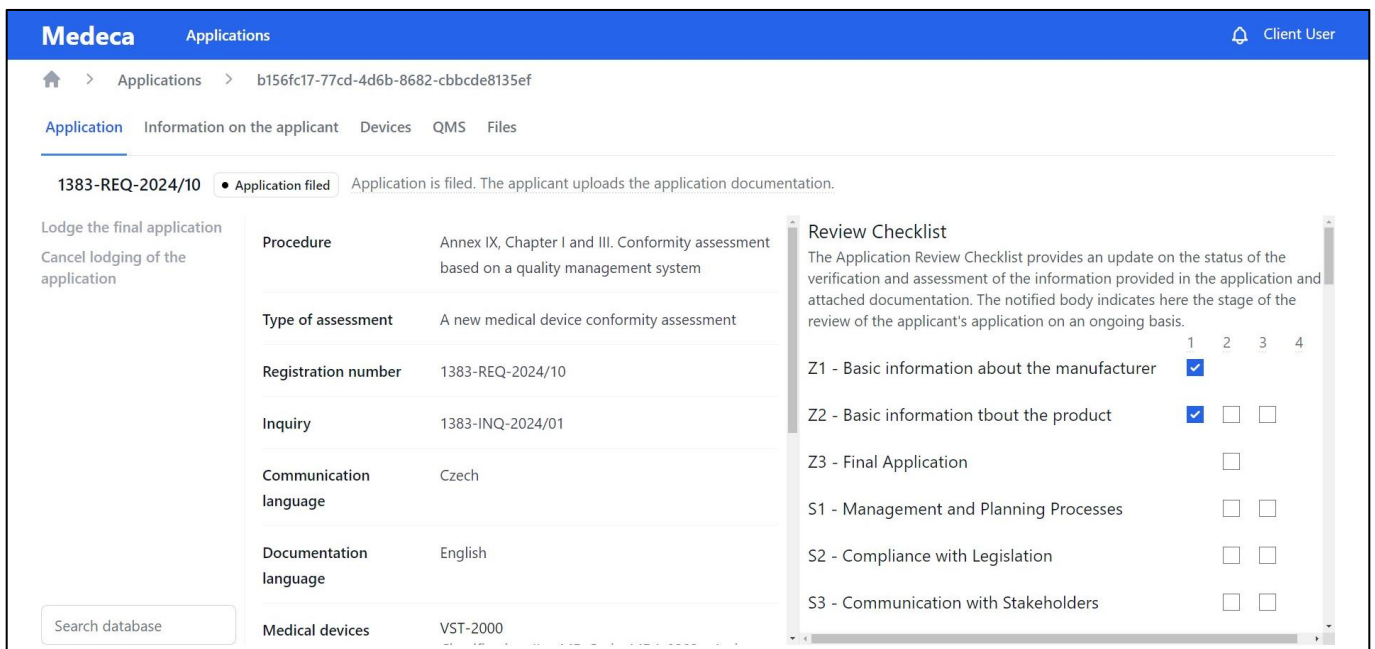
After logging into the system, you will see a tab with an overview of all your submitted applications. On each page of SW MEDECA, there is a navigation bar with the applications tab, and a user menu and notification icon on the right side.



The screenshot shows the 'Medeca Applications' interface. At the top, there is a blue header with the 'Medeca' logo and 'Applications' text, and a user profile 'Client User' on the right. Below the header, there is a navigation bar with a home icon and 'Applications'. The main content area is titled 'Applications Overview' and contains a table with the following data:

Application ID	Submitted	Status	Last change
1383-REQ-2024/08	06.06.24 11:50	● Application filed	29.07.24 10:18
1383-REQ-2024/10	30.07.24 10:56	● Application submitted	30.07.24 10:58

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.



The screenshot shows the 'Medeca Applications' interface for a specific application. The header is blue with 'Medeca Applications' and 'Client User'. The breadcrumb trail is 'Applications > b156fc17-77cd-4d6b-8682-cbbcde8135ef'. There are tabs for 'Application', 'Information on the applicant', 'Devices', 'QMS', and 'Files'. The 'Application' tab is active, showing '1383-REQ-2024/10' with a status of 'Application filed' and a note: 'Application is filed. The applicant uploads the application documentation.'

On the left, there are buttons for 'Lodge the final application' and 'Cancel lodging of the application'. The main content area is divided into two sections:

- Procedure:** Annex IX, Chapter I and III. Conformity assessment based on a quality management system
- Type of assessment:** A new medical device conformity assessment
- Registration number:** 1383-REQ-2024/10
- Inquiry:** 1383-INQ-2024/01
- Communication language:** Czech
- Documentation language:** English
- Medical devices:** VST-2000

On the right, there is a 'Review Checklist' section with a description: 'The Application Review Checklist provides an update on the status of the verification and assessment of the information provided in the application and attached documentation. The notified body indicates here the stage of the review of the applicant's application on an ongoing basis.' The checklist items are:

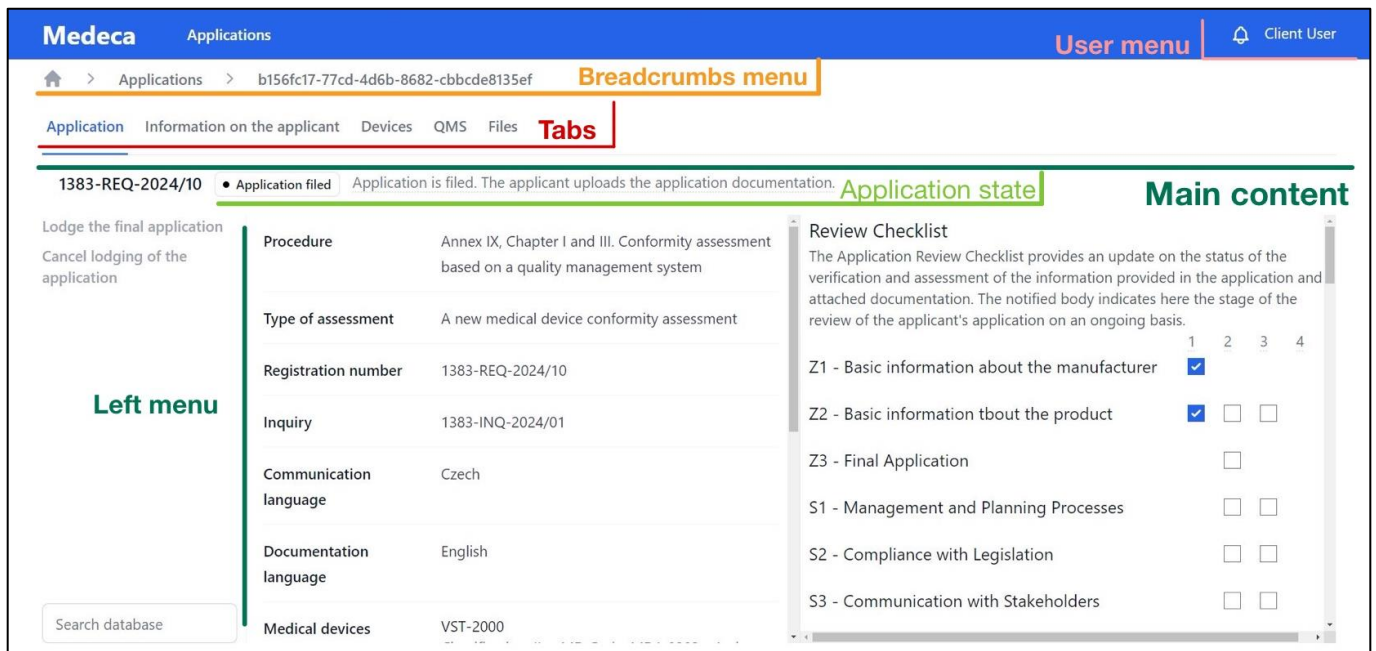
- Z1 - Basic information about the manufacturer (1)
- Z2 - Basic information about the product (2)
- Z3 - Final Application (3)
- S1 - Management and Planning Processes (4)
- S2 - Compliance with Legislation
- S3 - Communication with Stakeholders

At the bottom left, there is a 'Search database' input field.

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.



The screenshot displays the Medeca user interface with the following components:

- Header:** Medeca Applications, User menu, Client User
- Breadcrumbs:** Applications > b156fc17-77cd-4d6b-8682-cbbcd8135ef
- Tabs:** Application, Information on the applicant, Devices, QMS, Files, **Application**
- Application State:** 1383-REQ-2024/10 • Application filed | Application is filed. The applicant uploads the application documentation.
- Left menu:** Lodge the final application, Cancel lodging of the application
- Main content:**

Field	Value
Procedure	Annex IX, Chapter I and III. Conformity assessment based on a quality management system
Type of assessment	A new medical device conformity assessment
Registration number	1383-REQ-2024/10
Inquiry	1383-INQ-2024/01
Communication language	Czech
Documentation language	English
Medical devices	VST-2000

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.



Home > Applications > b156fc17-77ed-4d6b-8682-cbbede8135ef

[Application](#) [Information on the applicant](#) [Devices](#) [QMS](#) [Files](#)

1383-REQ-2024/10

● Application filed

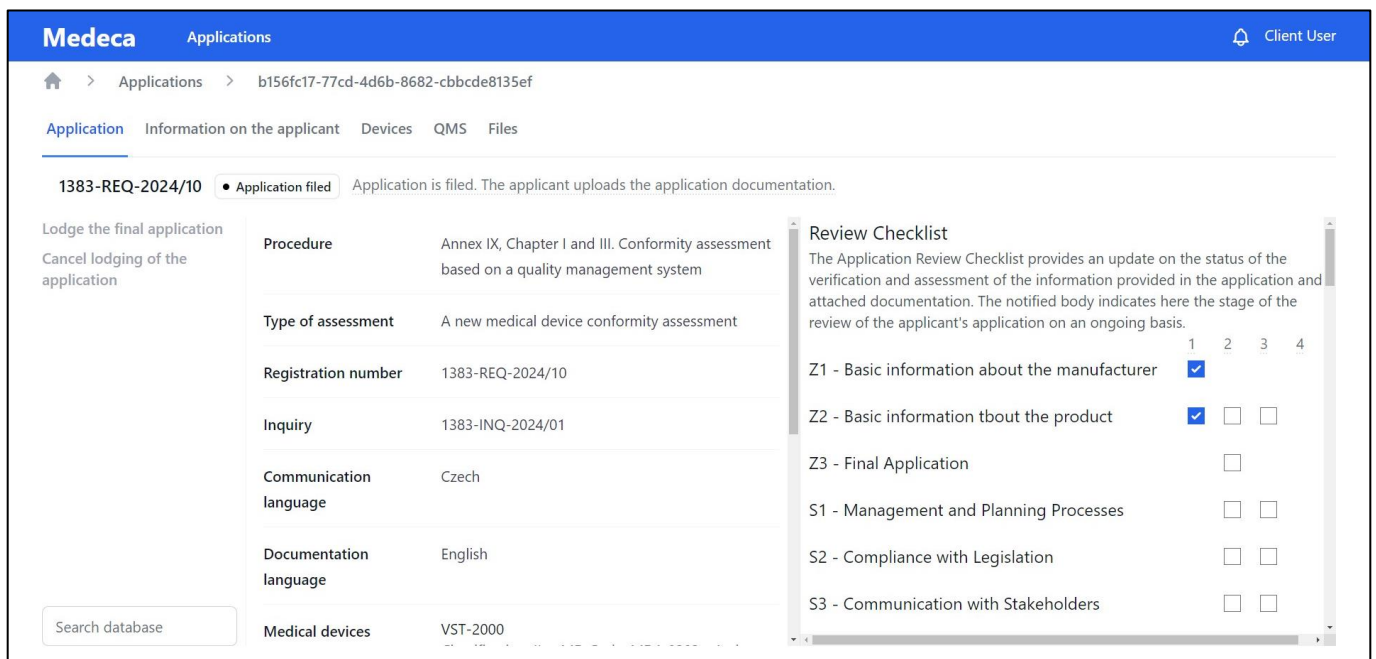
Application is filed. The applicant uploads the application documentation.

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.



Medeca Applications Client User

Home > Applications > b156fc17-77cd-4d6b-8682-cbbcede8135ef

Application Information on the applicant Devices QMS Files

1383-REQ-2024/10 Application filed Application is filed. The applicant uploads the application documentation.

Lodge the final application
Cancel lodging of the application

Procedure	Annex IX, Chapter I and III. Conformity assessment based on a quality management system
Type of assessment	A new medical device conformity assessment
Registration number	1383-REQ-2024/10
Inquiry	1383-INQ-2024/01
Communication language	Czech
Documentation language	English
Medical devices	VST-2000

Search database

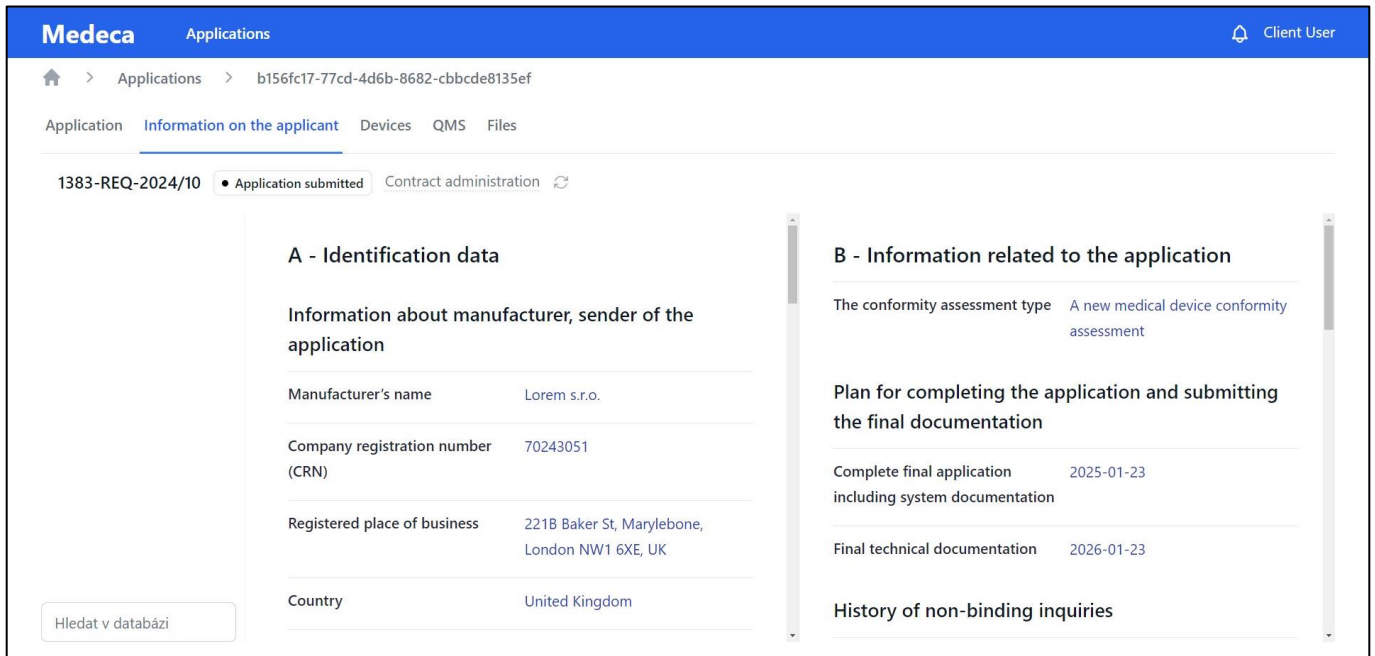
Review Checklist

The Application Review Checklist provides an update on the status of the verification and assessment of the information provided in the application and attached documentation. The notified body indicates here the stage of the review of the applicant's application on an ongoing basis.

	1	2	3	4
Z1 - Basic information about the manufacturer	<input checked="" type="checkbox"/>			
Z2 - Basic information about the product	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Z3 - Final Application		<input type="checkbox"/>		
S1 - Management and Planning Processes		<input type="checkbox"/>	<input type="checkbox"/>	
S2 - Compliance with Legislation		<input type="checkbox"/>	<input type="checkbox"/>	
S3 - Communication with Stakeholders		<input type="checkbox"/>	<input type="checkbox"/>	

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 screenshot shows the Medeca Applications interface. The top navigation bar includes the Medeca logo, the word "Applications", and a user profile icon labeled "Client User". Below the navigation bar, the breadcrumb trail reads "Applications > b156fc17-77cd-4d6b-8682-cbbcd8135ef". The main content area is titled "Application Information on the applicant" and includes sub-tabs for "Devices", "QMS", and "Files". The application ID "1383-REQ-2024/10" is displayed, along with a status indicator "Application submitted" and a "Contract administration" link. The page is divided into two main sections: "A - Identification data" and "B - Information related to the application".

A - Identification data

Information about manufacturer, sender of the application

Manufacturer's name	Lorem s.r.o.
Company registration number (CRN)	70243051
Registered place of business	221B Baker St, Marylebone, London NW1 6XE, UK
Country	United Kingdom

Hledat v databázi

B - Information related to the application

The conformity assessment type	A new medical device conformity assessment
Plan for completing the application and submitting the final documentation	
Complete final application including system documentation	2025-01-23
Final technical documentation	2026-01-23
History of non-binding inquiries	

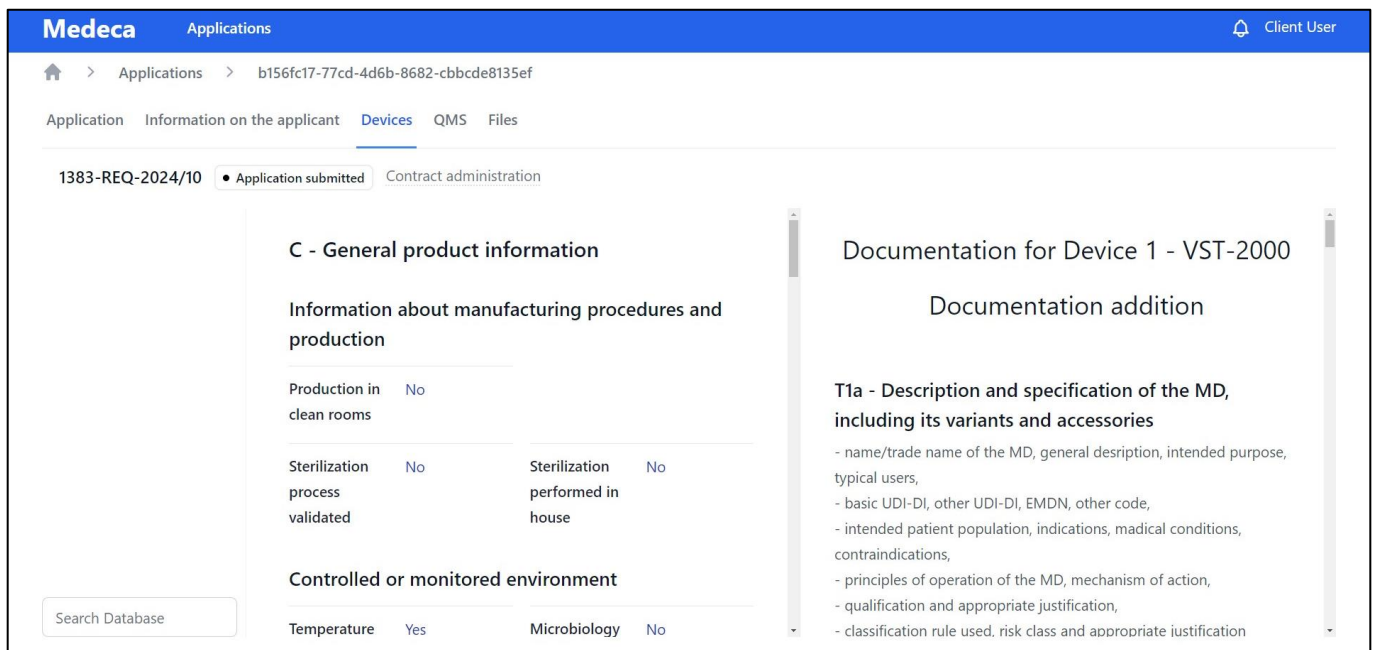
The information you will find here includes:

- **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.



The screenshot shows the Medeca Applications web interface. The top navigation bar includes the Medeca logo, the word 'Applications', and a user profile 'Client User'. Below the navigation bar, there is a breadcrumb trail: 'Home > Applications > b156fc17-77cd-4d6b-8682-cbbcde8135ef'. The main content area is divided into two columns. The left column is titled 'C - General product information' and contains a sub-section 'Information about manufacturing procedures and production'. This section includes a table with the following data:

Production in clean rooms	No
Sterilization process validated	No
Sterilization performed in house	No

Below this table is another sub-section 'Controlled or monitored environment' with a table:

Temperature	Yes	Microbiology	No
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The right column is titled 'Documentation for Device 1 - VST-2000' and contains a sub-section 'Documentation addition'. Below this is a section 'T1a - Description and specification of the MD, including its variants and accessories' with a list of criteria:

- name/trade name of the MD, general description, intended purpose, typical users,
- basic UDI-DI, other UDI-DI, EMDN, other code,
- intended patient population, indications, medical conditions, contraindications,
- principles of operation of the MD, mechanism of action,
- qualification and appropriate justification,
- classification rule used, risk class and appropriate justification

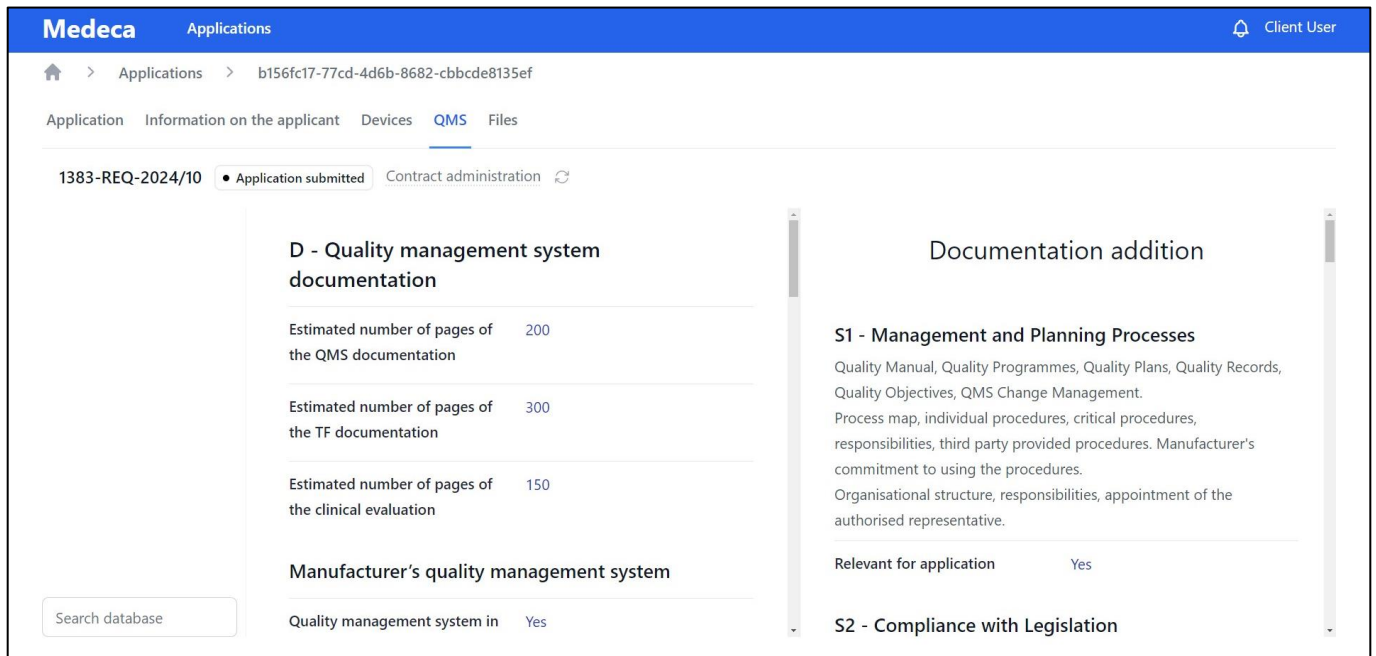
For example, on this tab you will find:

- **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.



The screenshot shows the Medeca Applications interface for a specific application. The breadcrumb trail is: Applications > b156fc17-77cd-4d6b-8682-cbbcede8135ef. The active tab is 'QMS', with other tabs being 'Application', 'Information on the applicant', 'Devices', and 'Files'. The application ID is 1383-REQ-2024/10, and its status is 'Application submitted'. There are also links for 'Contract administration' and a refresh icon.

D - Quality management system documentation

Estimated number of pages of the QMS documentation	200
Estimated number of pages of the TF documentation	300
Estimated number of pages of the clinical evaluation	150

Manufacturer's quality management system

Quality management system in	Yes
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Documentation addition

S1 - Management and Planning Processes
 Quality Manual, Quality Programmes, Quality Plans, Quality Records, Quality Objectives, QMS Change Management.
 Process map, individual procedures, critical procedures, responsibilities, third party provided procedures. Manufacturer's commitment to using the procedures.
 Organisational structure, responsibilities, appointment of the authorised representative.

Relevant for application: Yes

S2 - Compliance with Legislation

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.

The screenshot displays the MEDECA web application interface. At the top left, the logo 'MEDECA' and the word 'Applications' are visible. The top right corner shows a user profile icon and the text 'Client User'. Below the header, a breadcrumb trail reads 'Applications > b156fc17-77cd-4d6b-8682-cbbcd8135ef'. A navigation menu includes 'Application', 'Information on the applicant', 'Devices', 'QMS', and 'Files', with 'Files' being the active tab. The main content area shows the application ID '1383-REQ-2024/10' and a status 'Application filed' with a message: 'Application is filed. The applicant uploads the application documentation.' On the left, there is a section titled 'Upload documentation'. The right side lists several folders with expandable arrows: 'Quality Management System Documentation', 'Test Files - QMS', 'Internal Audit', 'Organisation structure', 'Policies and Procedures', 'Quality Manual', 'UDI', 'Work description and Responsibilities', and 'Technical Documentation for Device 1'.

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

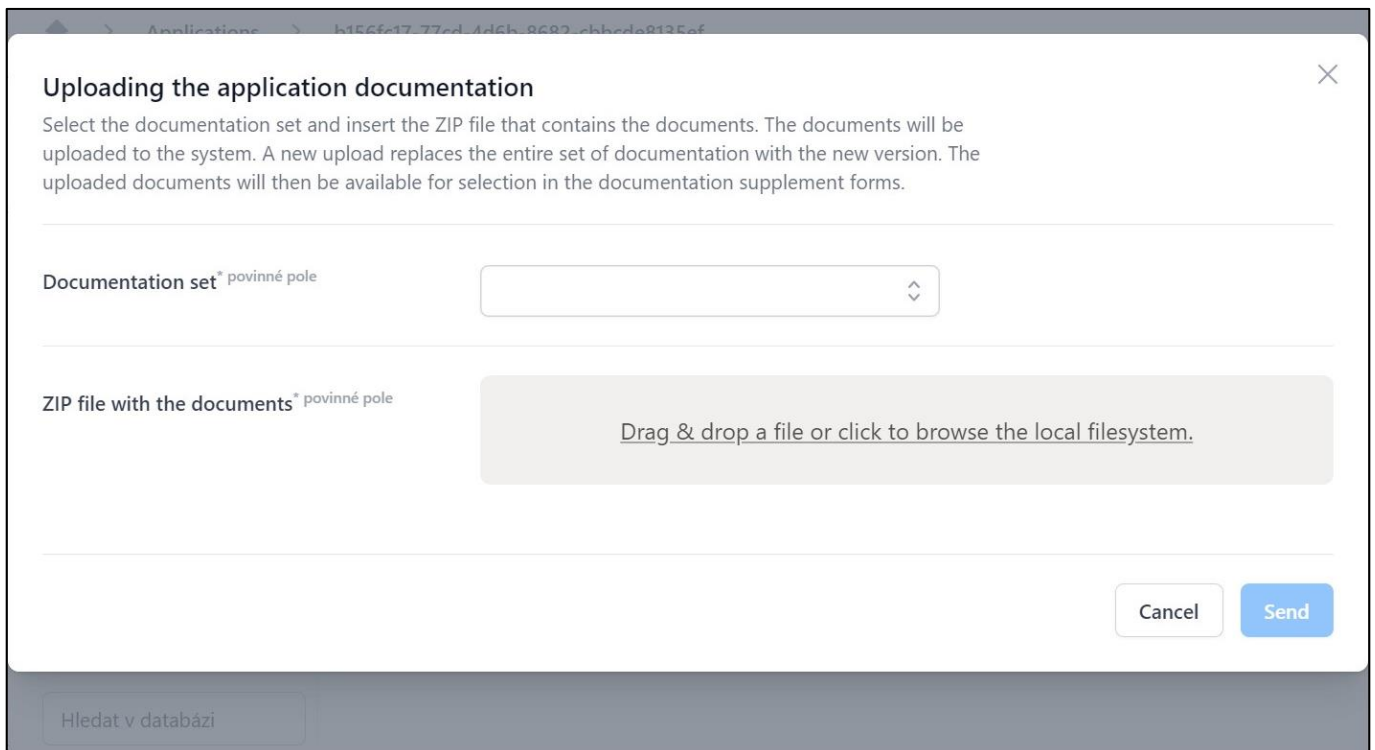
Second Chapter

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.



Uploading the application documentation

Select the documentation set and insert the ZIP file that contains the documents. The documents will be uploaded to the system. A new upload replaces the entire set of documentation with the new version. The uploaded documents will then be available for selection in the documentation supplement forms.

Documentation set* povinné pole

ZIP file with the documents* povinné pole

Drag & drop a file or click to browse the local filesystem.

Cancel Send

Hledat v databázi

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.

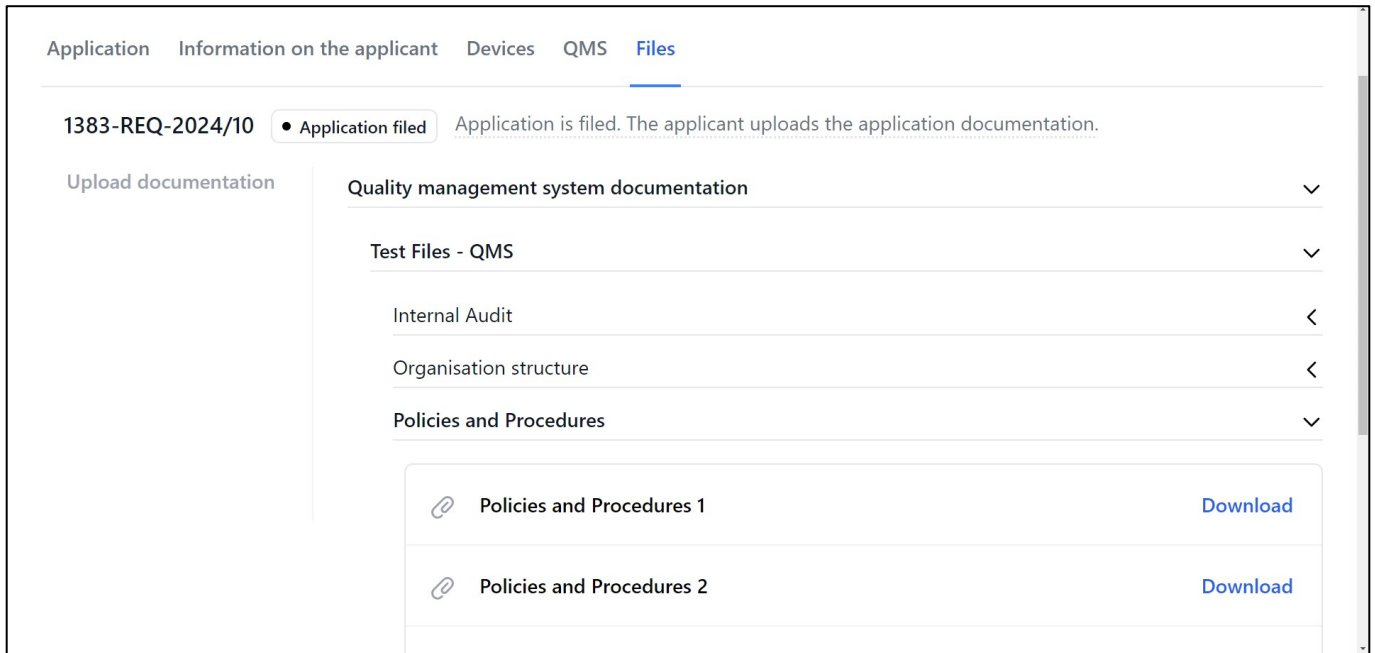
You can then either drag the files into the grey box with your mouse, or click to select them from the directory. The system only allows you to upload compressed files in **ZIP format**.

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.



The screenshot shows a web interface with a navigation bar at the top containing 'Application', 'Information on the applicant', 'Devices', 'QMS', and 'Files' (which is highlighted). Below the navigation bar, the application ID '1383-REQ-2024/10' is displayed next to a status indicator 'Application filed' and a message: 'Application is filed. The applicant uploads the application documentation.' On the left, there is a sidebar with 'Upload documentation'. The main content area shows a tree view of folders: 'Quality management system documentation', 'Test Files - QMS', 'Internal Audit', 'Organisation structure', and 'Policies and Procedures'. The 'Policies and Procedures' folder is expanded, showing two files: 'Policies and Procedures 1' and 'Policies and Procedures 2', each with a 'Download' link.

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.

S7 - Risk Management

Procedures and related documents for risk managemet

Relevant for application

Add files below so that all the requirements listed here are covered (by one or more files). Add a comment to each file indicating where the requirement is fulfilled.

Comment

Add a file from the documentation and a relevant comment

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.

The screenshot shows a user interface for linking files to criteria. It features a window with a title bar containing a close button (1 X). The main area is divided into two sections: 'File from the documentation*' and 'Comment on the file*'. The 'File from the documentation*' section contains a text input field with the value 'Quality Manual 3'. The 'Comment on the file*' section contains a text input field with the value 'Organisational structure and responsibilities - Chapter 6.2, Page 13-15'. Below these input fields, there is a paragraph of text: 'Specify the location of the requirement fulfillment in the document file, e.g. page, chapter, paragraph.' At the bottom of the window, there is a button labeled 'Add a file from the documentation and a relevant comment'.

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 screenshot shows a web interface for logging a final application. At the top, the header includes the MEDECA logo, the word 'Applications', and a 'Client User' profile icon. The main content area is titled 'Log the final application' and contains a confirmation message: 'The applicant confirms that he/she has submitted all documents to determine the application scope and that he/she will pay the relevant fee within 10 days at the latest. By submitting this form, you will switch to the status 'Application Documentation Submitted'.' Below this, there is a section for uploading a 'Signed PDF file of the final application', which includes an upload button and a link to 'Download application PDF file for signing'. There is also a link for 'Fee payment information'. At the bottom right of the form, there are 'Cancel' and 'Send' buttons. The footer of the interface shows a search bar with the text 'Hledat v databázi' and a partially visible 'number' field.

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.

MEDECA Applications Client User

Log the final application

The applicant confirms that he/she has submitted all documents to determine the application scope and that he/she will pay the relevant fee within 10 days at the latest. By submitting this form, you will switch to the status 'Application Documentation Submitted'.

Signed PDF file of the final application*
mandatory field

Signed Application.pdf
Download PDF file to be signed
Payment information

Cancel Send

Hledat v databazi number:

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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