

WIDAR off-line application

User manual for NB 1023 clients

1. Introduction

The WIDAR off-line application (WIDARoff) fully replaces the previous version of WIDAR working on-line with the SQL database, as the stability of the on-line application depended on the quality of the connection and other aspects. Even short-term instabilities of the Internet connection on the client or Internet provider side caused problems with the display of stored data. For this reason, it was decided to replace the WIDAR system with an off-line version (WIDARoff), in which the client's work is done on the client's computer, where any backups with intermediate results are also stored, and the ITC technical documentation assessors (notified body NB 1023) work in the same way.

During the compilation of the client-side responses and the ITC assessment, all data entered and edited are processed on the computer of the relevant client or ITC assessor and do not require a connection to the ITC server or Internet access at this stage. Only after the completion of a given task (so-called **cycle** on client-side or **round** on ITC-side) is access to Internet services required in order to upload the data as a single file to the database. If the connection or network fails at this point, the file can be resent repeatedly until receipt of a complete intact file is acknowledged. In the event of severe internet connection problems (e.g. blackout at the provider), the file can also be transferred on a compatible data carrier.

Since WIDARoff works with the same SQL database as the previous on-line version of WIDAR, it can be used for new projects as well as for projects that have already been developed in the on-line version of WIDAR, both on the client side and by ITC staff. In these cases, existing SQL database data is displayed in the new environment without any corruption or data loss.

WIDARoff has been designed for environments running WINDOWS 10 and above. The uneditable view is designed for the Microsoft Edge web browser. Since Microsoft intends to discontinue support for WINDOWS 10 as of fall 2025, upgrading to WINDOWS 11 is desirable.

This manual describes the procedure for use of WIDARoff by client staff; the ITC staff procedure is covered in another manual for internal ITC use.

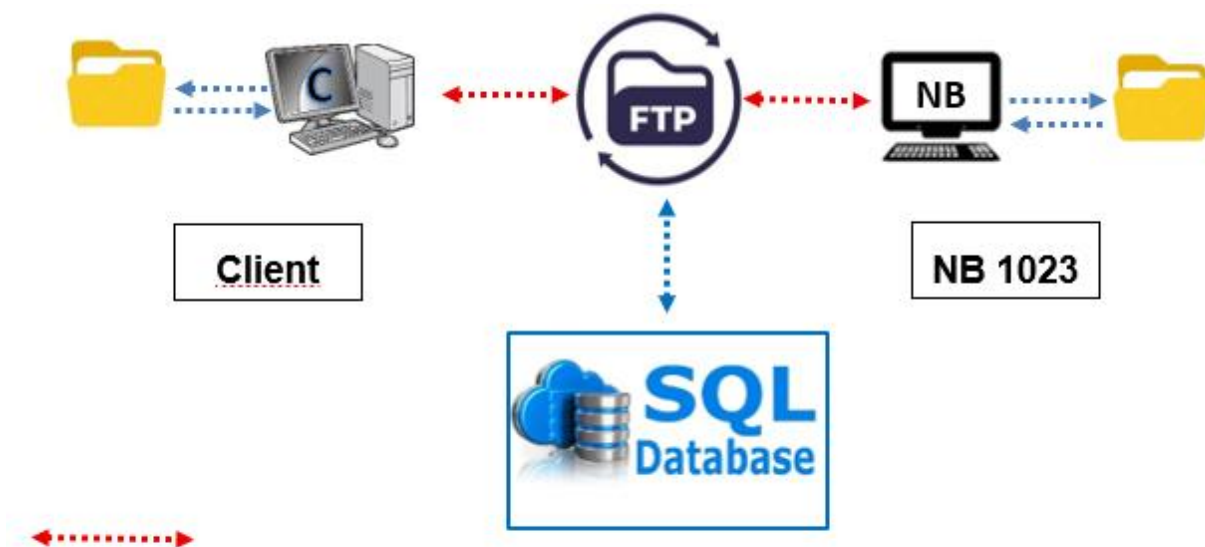
The abbreviation NB is used in this document to distinguish actions performed by ITC staff (NB 1023 Notified Body), while client actions are denoted by the abbreviation C.

2. Block diagram of client-database communication

When completing elements (WIDAR questions), the client does not send its data directly to the database located on the ITC server, but primarily stores it on its computer in a work folder of its choice. Once all the required information has been completed and checked for completeness, the data from this folder is transferred to the ITC FTP server in the form of a unique file marked *.wid, where it can be accessed by ITC assessors.

At the command of the ITC assessor, the data is copied from the FTP server to the SQL database.

The ITC assessors download the data from the FTP server to a selected work folder on their computers where they store the results of the desk review, which they upload to the FTP server and the database after the review is completed. This edited file is then forwarded to the client who saves it to their work folder and appends their responses to the NB 1023 findings and the process repeats, see diagram below. The red arrow indicates the stage where data transfer via the internet or intranet is necessary.

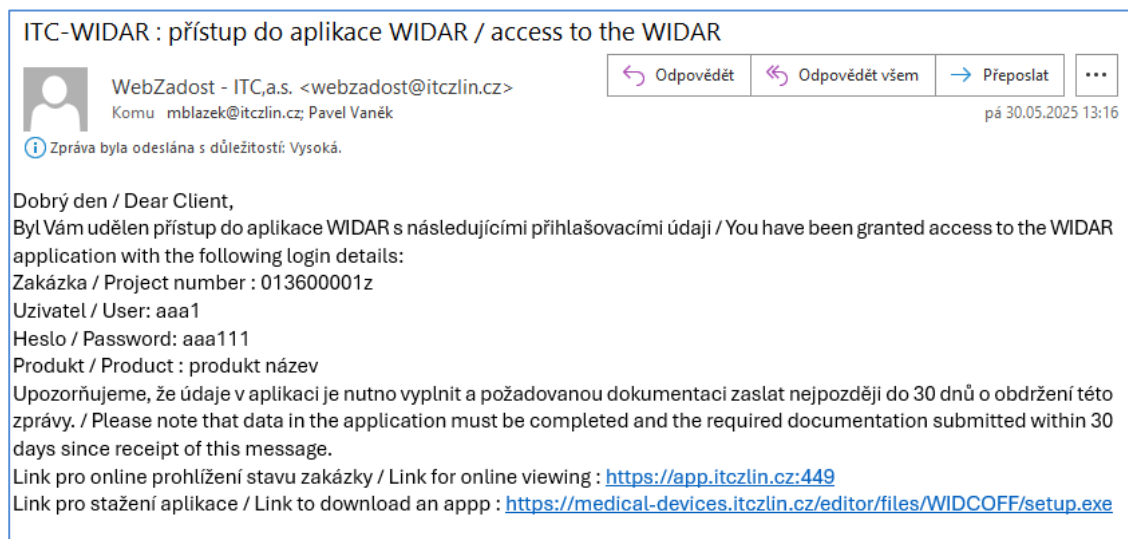


The red arrow indicates the stage where data transfer via the internet or intranet is necessary.

3. First cycle - client work with WIDAR-C-OFF

The responsible NB 1023 officer will generate a new project in WIDARoff. This means that he/she allocates a data space in the SQL database for this project and creates the first *.wid format data file on the ITC FTP server, which is notified to the client by the following e-mail sent from the e-mail address webzadost@itczlin.cz.

Text of the e-mail to the client:



Neither the FTP server address nor the *.wid file address is important to the NB user or the client, as data transfers are handled automatically by the application.

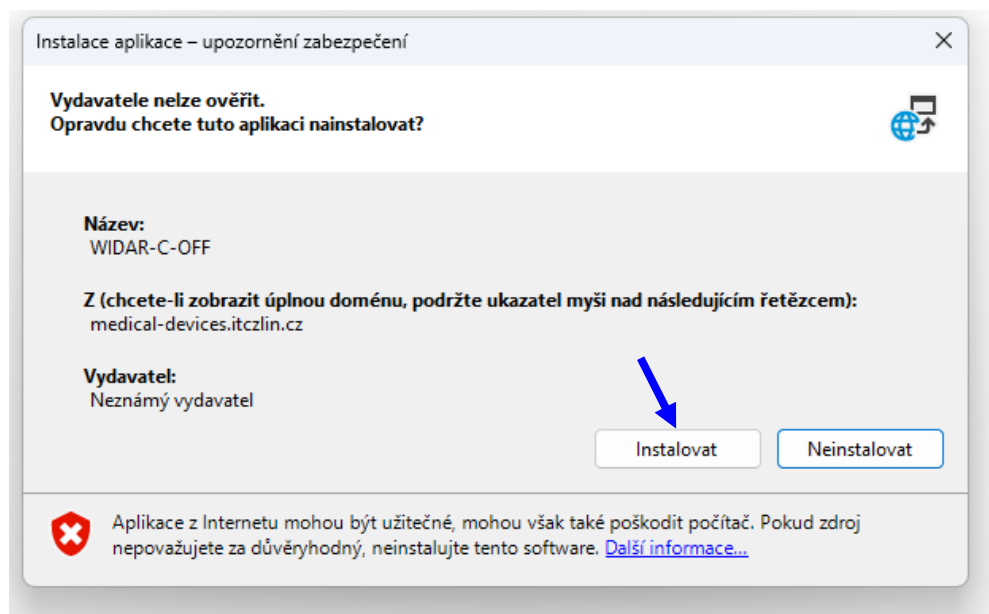
The project number consists of 9 digits followed immediately by a letter of the lowercase Latin alphabet in case one application (project) includes several separate medical devices with their own technical documentation.

It is advisable to note down the project number, the user name and the password, as these access data will be requested several times during the project.

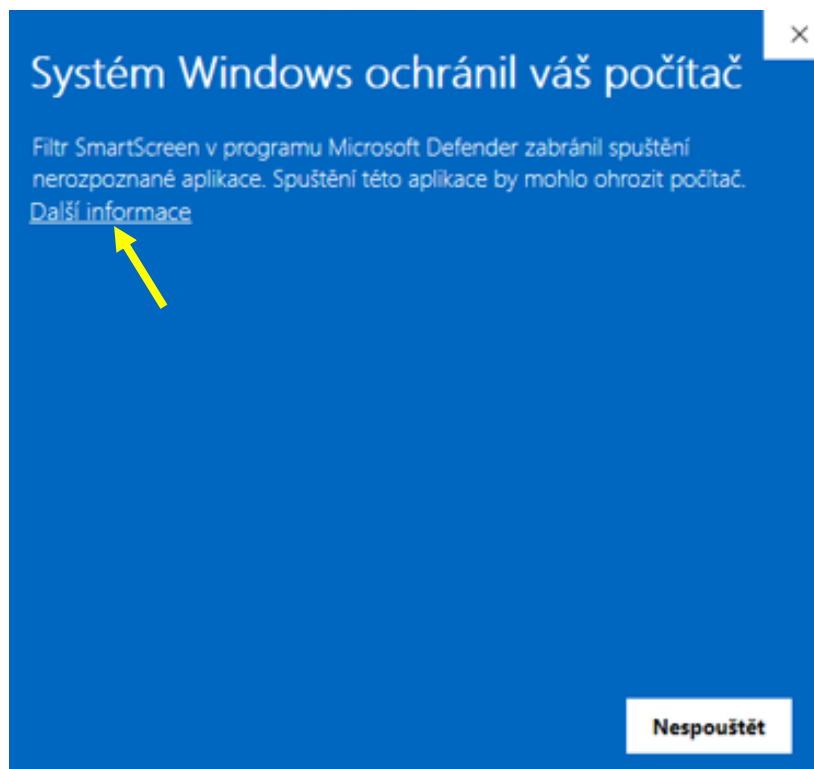
3.1. Download the WIDAR-C-OFF application

Upon receipt of the e-mail, the client will use the hyperlink "Link to download an app" included in the e-mail shown above, marked "ITC-WIDAR: access to the WIDAR".

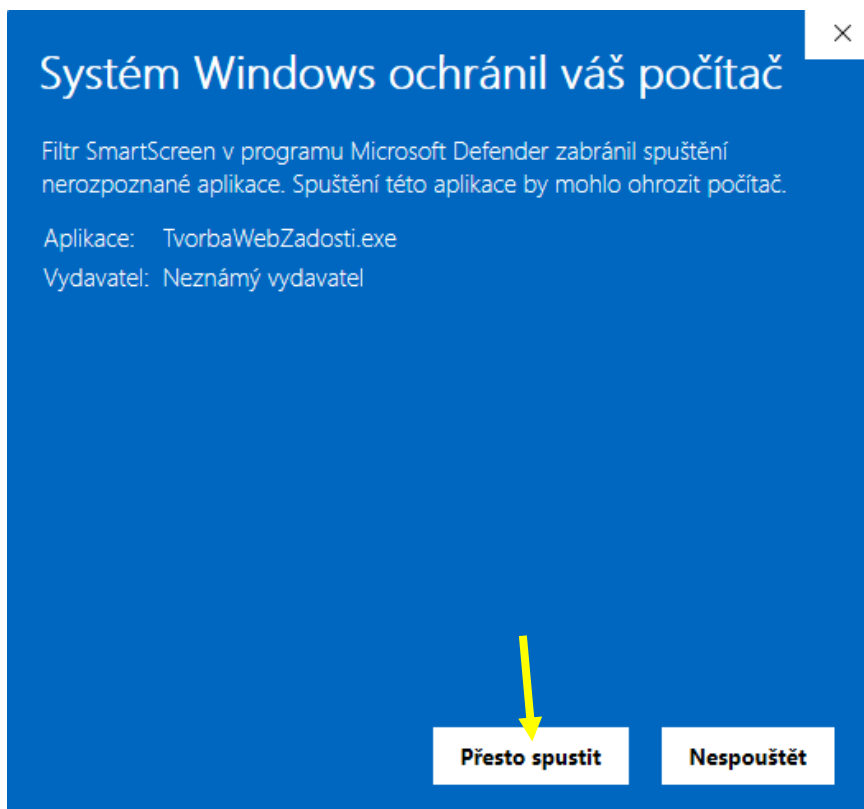
The client clicks on the link to download the WIDAR-C-OFF application and, depending on the version of their operating system, information about a possible threat to the computer will appear when running an application whose publisher is not recognised by the operating system:



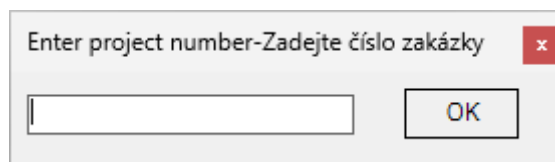
After clicking on "Install", another system warning appears.



Now you have to click on the "More information" link and then click on the "Run anyway" button to agree to run the application.

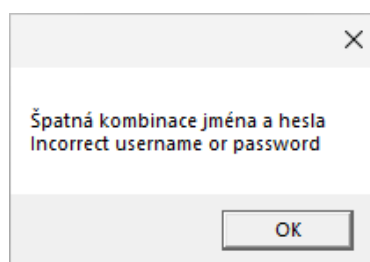


Once the application has been started, a dialog box appears asking the client to enter the job/project number. The client then uses the project number received in the e-mail:



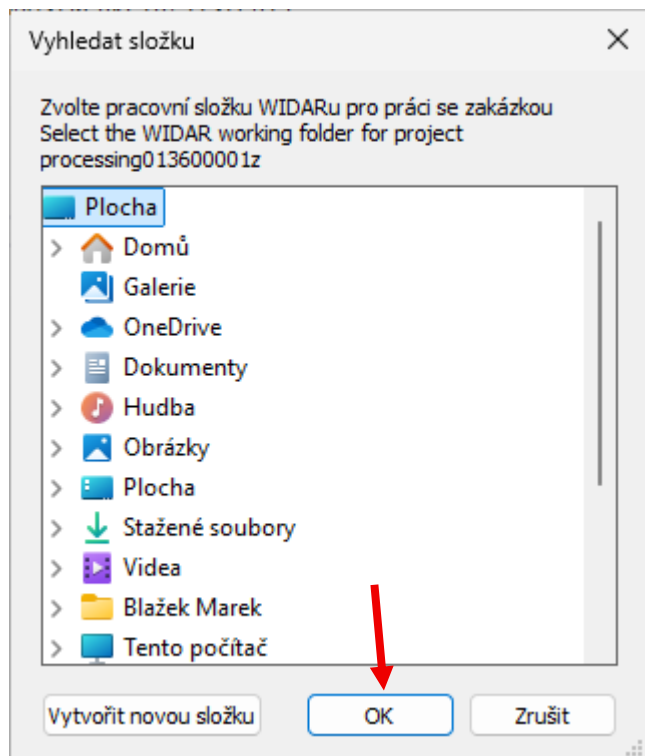
The number must be entered in the format as communicated to the client by e-mail, i.e. the project number followed by the part designation immediately, i.e. without a space or slash, e.g. 013600001z. If the wrong number is entered, the client is informed and the application is terminated.

If the correct project number has been entered, the client is then asked to enter the access codes (User/Pass - Name/Password), which the client also obtained from the e-mail. In case of incorrect input, the client is informed about the use of incorrect access codes:



After a successful login, an explorer window appears asking the client to select the working folder on the client's computer where he wants to save his data processed by the just downloaded application WIDAR-C-OFF.

In this working folder, the program will store all the files that the client has been saving in the project, as well as the final file to be sent to the NB database. Files sent from NB 1023 after each round of review will also be saved in this working folder.



If the client does not select any folder and just clicks OK, the created files will be saved to the Desktop of the client's computer. However, this option is impractical, as dozens of files are commonly stored in the work folder and the desktop becomes cluttered. It is good practice to use the project number for the name of the working folder, but this is not a requirement at all.

The file names that WIDARoff creates automatically have a fixed structure, consisting of the project number, the project part designation (if it exists), the date and time in the extended display format YYYY-MM-DD-hh-mm, followed by the so-called job id (a system variable for programming purposes), a json abbreviation characterizing the file type, followed by the source (author) code of the file. The file name is terminated by a period followed by the extension "wid" referring to the WIDARoff program:

013600001-z-RRRR-MM-DD-hh-mm-idzakázky-json-XXXX.wid

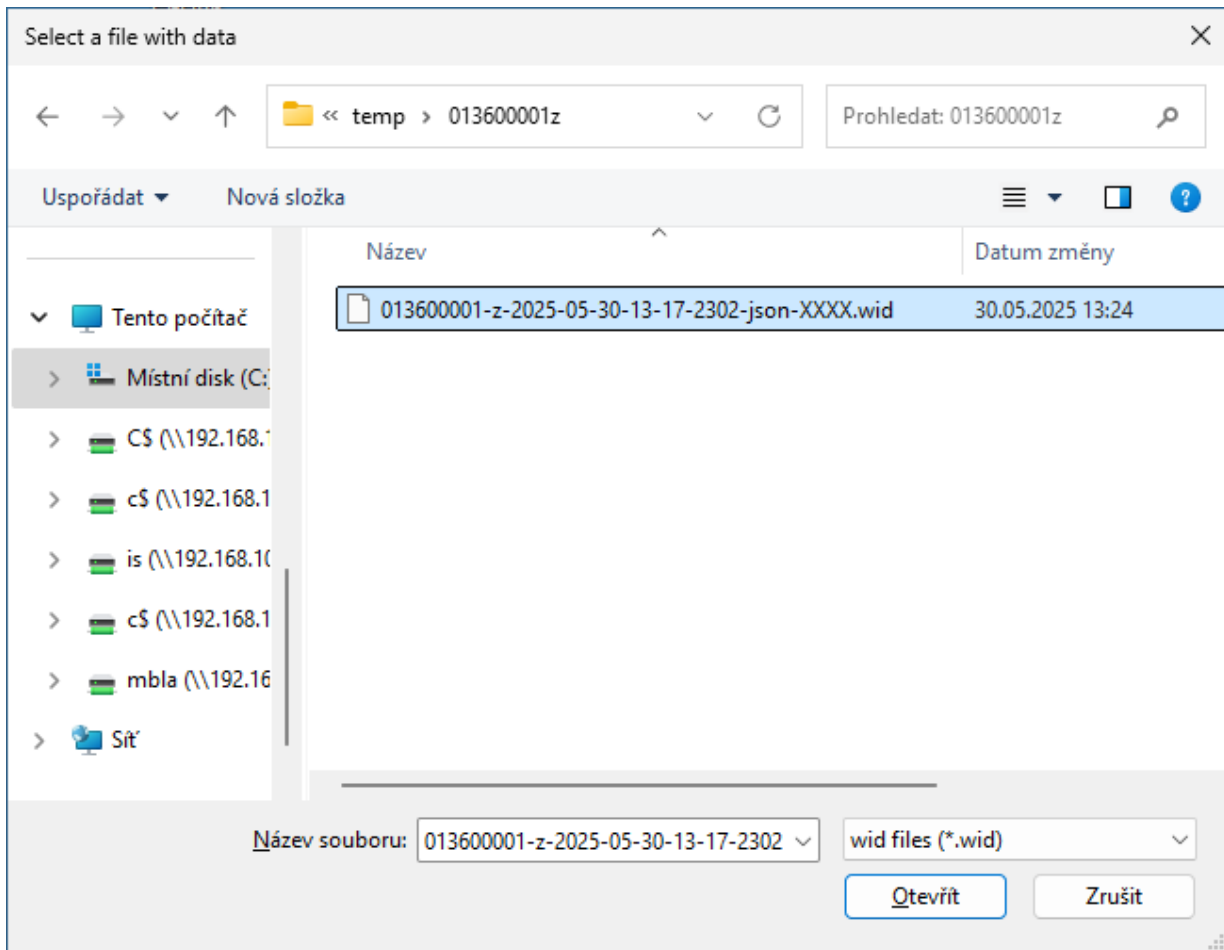
The file source code takes the values XXXX (a file generated and sent from the NB 1023 via FTP server) or C (a file created by the client).

If the WIDAR-C-OFF application is updated over time, the client will be informed of this fact by e-mail sent from the e-mail address webzadost@itczlin.cz, and the e-mail will include a link to an address from which the new version of the application can be downloaded, analogous to the first download described above.

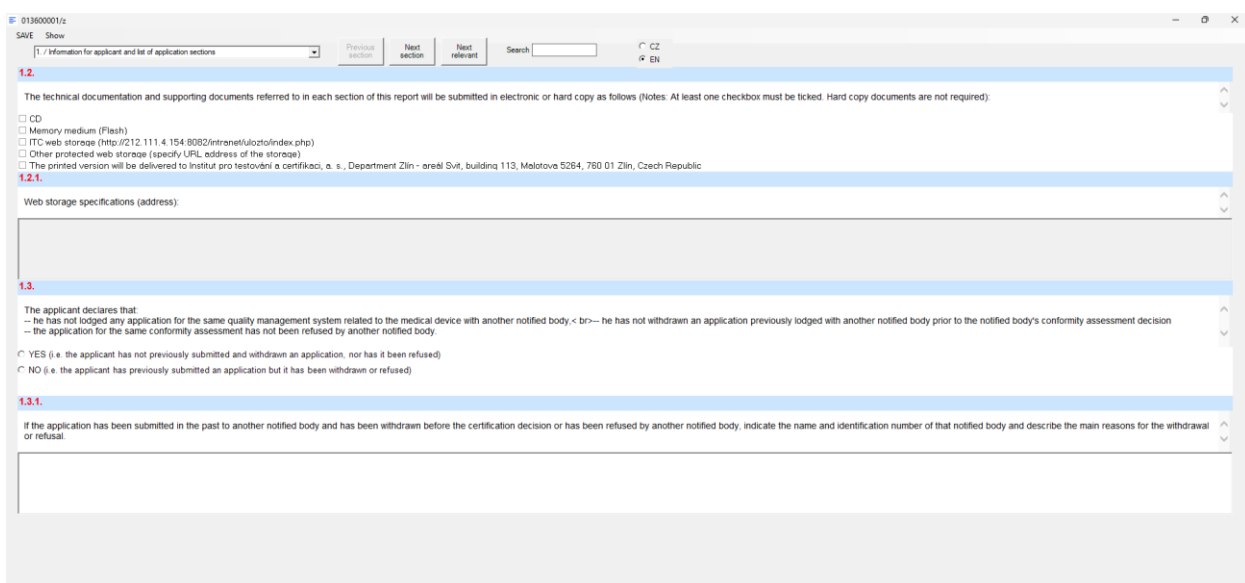
3.2. Linking the WIDAR-C-OFF application to the data file

Next, WIDAR-C-OFF will use the explorer to ask which of the files in the selected working folder the client intends to work with. In almost all cases, the client chooses the most recent file.

Only in exceptional cases (for example, if the client discovers that it has previously made an error in filling in data while working with WIDAR-C-OFF) can the client return to one of the older, previously saved files where the error has not yet occurred.

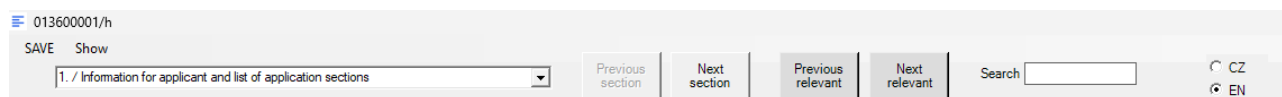


Selecting the file by double-clicking or clicking on the "Open" button will launch WIDAR-C-OFF and display the workspace for entering information related to the technical and clinical documentation of the project. The workspace consists of a navigation bar located at the top, followed by a series of elements (questions) that the client is required to answer. The answers to some questions will make the following questions (irrelevant for the medical device in question) inaccessible.



3.3. Description of the WIDAR-C-OFF environment

The navigation bar contains in the upper left part the project number (or even its part) and two buttons "SAVE" and "Show", followed by a drop-down menu for direct selection of the project section for viewing and/or processing - filling and editing data. Movement between sections can be controlled by the "Previous Section", "Next Section", "Previous Relevant" and "Next Relevant" buttons.

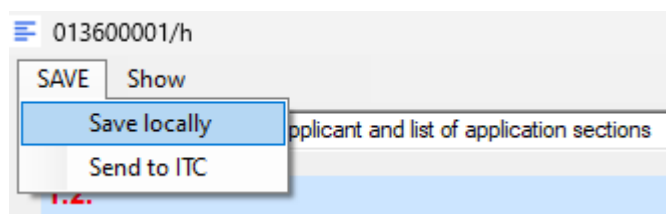


When the "Next Relevant" button is used, elements irrelevant to the medical device are ignored and the next relevant element is displayed. Similarly, irrelevant elements are not displayed when using the "Previous Relevant" button.

The field after the "Search" label allows free search of sections and their elements with direct access to the element.

The last element of the control panel is a switch (radiobutton) CZ/EN, which allows to select the language version of the menu and question text in all elements. The default setting is English (EN); by clicking on CZ you can switch to Czech at any time.

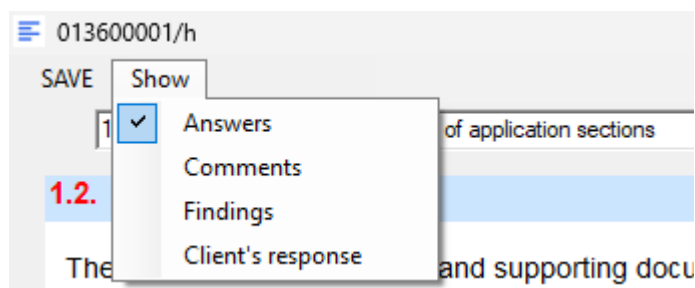
The "SAVE" menu offers the following two options when clicked:



- Save locally - allows the client to save the work in progress file (even repeatedly) to the working folder of their computer without needs for an internet connection. Each subsequent local save will create a new *.wid file in the selected working folder.
- Send to ITC - after completing the answers to all required (and therefore relevant) WIDAR questions, the file developed within a given cycle is transferred to ITC via this route. Here, however, the existence of an internet connection is a prerequisite.

3.4. Display options

If the "Show" menu is selected, a checklist with 4 options for selecting the display of the WIDAR-C-OFF workspace opens:



By checking one or more options (up to 4), the client selects which data panels he wants to display. The layout of the window (i.e. which panels will be displayed and which will not) is controlled by selecting the options on the "Show" tab. There are 4 options:

- ✓ *Answers* displays the client's data that they have entered into the WIDAR, and answers intended for NB 1023 staff (distinguished in red).

- ✓ *Comments* are for NB staff statements on the answers and relevant parts of the technical documentation in that section. Comments can be edited and formatted in terms of font type, size and font. The comment is used by the staff member to characterize the part of the technical documentation related to the selected section, describing the level, strengths and weaknesses of the section.
- ✓ *The finding* related to the section has 3 states and a text part containing the structure (hierarchical) of the findings and a detailed description of the findings with reference to the violated articles of the MDR, common specifications CS, MDCG guidelines, provisions of harmonised standards or other technical specifications. The first time the section is opened, the finding is in the status 'Finding not entered'. The NB 1023 assessor shall change the status of the finding to "YES" or "NO" by clicking on "Finding not entered". A description of the finding is provided in the text, and its removal, if applicable, in subsequent rounds. This means that the text part may contain a description of the finding even if the status of the finding is 'NO'. This may occur, for example, in a second round where the status of the finding was 'YES' after the first round and the client has corrected the deficiencies in the second cycle, so that the assessor is indicating by setting it to 'NO' that this part has been satisfactorily fixed. The text portion of the finding then documents the finding and its fixing in subsequent cycles.

Finding not provided

Finding NO

Finding YES

- ✓ *The client's response* comes into consideration in the second and subsequent cycles; here the client describes how the nonconformity was resolved or the reasons for the nonconformity.

In the first cycle, by default, only the answers are displayed, in which the client inserts his information and links to the corresponding parts of the technical documentation (name of the technical documentation file, chapter, page, or paragraph addressing the response), but it is possible to set the display of other parts of the 4 offered by checking the "Display" menu.

Since the workspace on the display is divided between panels corresponding to the checked parts in the "Display" menu, it is advisable to check only those parts that make sense to display, so as not to reduce the area of the panels that the client is working with. In the case of Cycle 1, this is only the "Answers" section, since "Comments" and "Findings" contain the results of the NB 1023 Notified Entity staff's assessment of the element (client responses), and "Client Response" is the response to the NB's comments, so in Cycle 1 all 3 remaining panels are always blank. Their use, on the other hand, is necessary in the second and higher cycle or round.

Below the navigation bar, the elements are shown, identified by the section number and the serial number of the element in that section. The sequence numbers may not form an unbroken line.

The client can see a series of:

- blue coloured fields (labels with information and data entry requirements); these fields are informational and permanently inaccessible to the client - they are called QUESTIONS
- grey fields, which are inaccessible but access to them can vary depending on the answers to certain previous questions in the form of checkboxes and/or YES/NO switches etc.
- white fields, in which the client is obliged to fill in information either by text or by ticking checklists or by selecting the position of radio buttons; access to them may also vary depending on the answers to certain previous questions in the form of checkboxes and/or YES/NO switches, etc.
- As this is the first cycle, there are no light red coloured fields containing NB comments and findings. These will not be displayed to the client before the first round of NB 1023 comments.

013600001/c

SAVE Show

8. / Classification

Previous section Next section Previous relevant Next relevant

Search

CZ EN

8.1.

Have you followed the MDCG 2021-24 Guidance on classification of medical devices when classifying the medical device under consideration?

☒ YES

☐ NO

8.2.

Provide justification for not using MDCG 2021-24, describing deviations if applicable.

8.3.

Is this product an accessory of a medical device?

☐ YES

☒ NO

8.5.

Determined risk class of the device:

☐ Im

☐ Ir

☐ Is

☐ IIa

☒ IIb

☐ III

8.6.

Provide a brief justification for the classification and the rule(s) used, including the relevant indent, in accordance with Annex VIII of the MDR Regulation. Please provide a reference to the relevant part

02-TF-JPLM Stanovení rizikové třídy
Z hlediska základních pojmů přílohy č. VIII Nařízení evropského parlamentu a rady (EU) 2017/745 se jedná o zdravotnický prostředek s přechodnou dobou použití (1.1), invazivní a aktivní (2.1), aktivní
Z přílohy č. VIII Nařízení evropského parlamentu a rady (EU) 2017/745 v aktuálním znění, je pro klasifikaci jako aktivní ZP použito pravidlo 9 (kapitola 6.1). Všechny aktivní terapeutické prostředky určité takové, že s přihlédnutím k povaze, hustotě a místu aplikace energie mohou energii do lidského těla nebo z těla předávat nebo vyměňovat potenciálně nebezpečným způsobem; v takovém případě

8.7.

3.5. WIDARoff application elements

Application elements can take the following six formats:

- A text field in which the answer to the question is entered in text form. It is recommended to enter the text using the computer keyboard. Copying and pasting text from other applications or files is possible, but transferring from specialized programs and applications may not always be successful. If the client still intends to paste large amounts of text from external files and copying is causing problems, it is recommended to use the "Paste as plain text" function using the Ctrl-Shift-V keyboard shortcut or by right-clicking and selecting this function from the menu. Client-side text cannot be formatted, only one standard font is used.
- A switch that contains two or more rings (buttons), only one of which can be selected at a time by clicking.
- A list (checkbox) containing two or more checkboxes, at least one of which must be selected/checked by clicking. Multiple checkboxes of the list can be checked (for example all of them). If the client does not check any checkbox, WIDARoff will report an error when trying to close the cycle and identify this element as unfilled.
- The drop-down menu will expand when clicked and offer two or more responses from which one can be selected by clicking. If no option is selected, WIDARoff will report an error when attempting to close the cycle and identify this element as unfilled.

- e) The switch with a text completion field works in the same way as switch (b), but offers the possibility to add additional text in the field next to the activated ring (switch button), e.g. the reason for the choice.
- f) A list with a text field works the same as list c), but offers the possibility to add additional text in the field next to each checkbox (list item), e.g. the justification for this choice.

3.6. Completing the WIDAR responses and closing cycle 1

The client fills in the answers in order from the lowest section and element numbers to the highest. The answer must always be completed by referring to the section of the technical documentation where the necessary evidence for the claim presented in the answer is given (Identification and version of the technical documentation file, section, page, paragraph, etc.) so that both parties (client and NB 1023) clearly address the same aspect.

All parts of the documentation must be available digitally in a text-searchable format (not scanned graphics) and in the language agreed with the NB client (Czech CZ, Slovak SK and English EN options are available).

The client navigates through the sections using the navigation bar and the "Previous Section", "Next Section", "Previous Relevant" and "Next Relevant" buttons, and can also use the "Search" filter to enter the section number or item number.

For long texts, WIDARoff displays each section as a single long window, which can be navigated using the scroll bar at the right edge of the window. Scrolling with the mouse wheel also works, but may not be reliable - it depends on the type of mouse and its control software (driver), and especially on the position of the cursor.

Within a section, individual elements are displayed, which can also be controlled in the case of long texts inserted into the element window by scrollbars, which are located on the right edge of each element, to the left of the section scrollbar.

The client can save the results of their work in progress at any time using the "SAVE" button and the "Save locally" submenu, see the figure in section 3.3 of this manual. This will save the current data in the working folder selected by the client (see chapter 3.1.) in the specific *.wid format.

The format and name structure of this file is similar to that shown in chapter 3.1 for the NB generated file, but differs in the current time and code reserved for client (C code used instead of XXXX).

Each use of the "Save locally" function results in another new *.wid file being saved to the working folder that the client has chosen for this project. The name of the file differs from the previous ones only by the date and time of saving encoded in the name. In the standard alphabetical ordering of file names in a folder, this file is the last one. If the client intends to continue filling in the WIDAR after an arbitrarily long interruption, it launches the WIDAR-C-OFF application (if not already running), opens the appropriate folder and opens the last file in it by double-clicking or clicking the "Open" button.

Once all relevant answers have been filled in, the client activates the "SAVE" button and the submenu "Send to ITC". The first time the client's data is sent to ITC, the "Client consent" confirmation window is activated with the contents of the declaration in this window. The client expresses his/her consent by clicking "YES"; if he/she clicks "NO", no further process will take place. The language of the declaration depends on the choice of CZ or EN in the switch on the navigation bar.

Client consent

The applicant declares that:

- the application for conformity assessment of this medical device(hereafter referred to as 'the application') is filled in correctly and does not contain false or misleading information
- the applicant did not submit the same application simultaneously to another notified body;
- the applicant signed a General Framework Agreement (GFA)with Institut pro testování a certifikaci, a.s. (hereinafter referred to as "ITC" or "NB 1023
- neither the company nor the applicant's employees have any relation to ITC, which could jeopardize ITC's independence and impartiality, and the only kind of service ITC has provided or provides to the applicant is conformity assessment and / or product testing..

The applicant undertakes to:

- maintain the quality system in a usable and effective condition and fulfil all obligations arising out of the approved quality systém
- comply with the provisions of the General Framework Agreement(GFA)
- implement and update a systematic procedures for evaluating the experience gained with manufactured devices, including the provisions of the Annex X of Directive 93 / 42 / EEC(MDD), and implement the necessary corrective measures accordingly;
- notify the competent authorities of any failure or deterioration of the properties and/ or performance of the device and any inaccuracies in instructions for use, which may result in death of the patient or user or serious deterioration of their health as soon as they become aware of them;
- notify the competent authorities of any technical or medical reason related to the properties or performance of the device and leading to withdrawal of this type devices from the market as soon as they become aware of them;
- submit above information provided to the competent authorities also to notified body NB 1023.

Ano
Ne

Before sending to the ITC, the client must again confirm his identity by entering the assigned name and password.

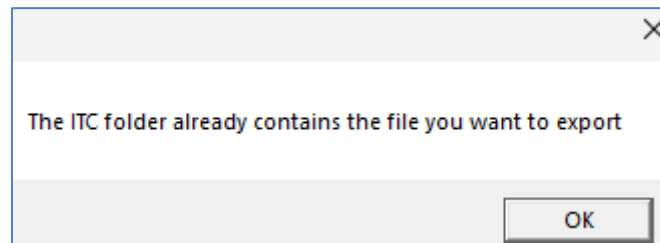
WIDAR-C-OFF then checks that all relevant questions have been completed. If this is not the case, the client receives the information "All answers have not been completed, upload is not possible. Please fill in the marked items". This message is followed by a list of item numbers that should have been completed but were not:

Not any items have been filled, the sending is impossible. Please fill in the indicated items (2.1. > 2.2. > 2.3. > 2.4. > 2.5. > 2.5.1. > 7.4. > 7.6. > 7.10. > 8.2. > 9.15. > 9.20. > 9.21. > 9.22. > 9.22.1. > 9.23.1. > 9.23.2. > 9.35. > 9.36. > 9.38. > 10.1.1. > 10.10. > 10.11

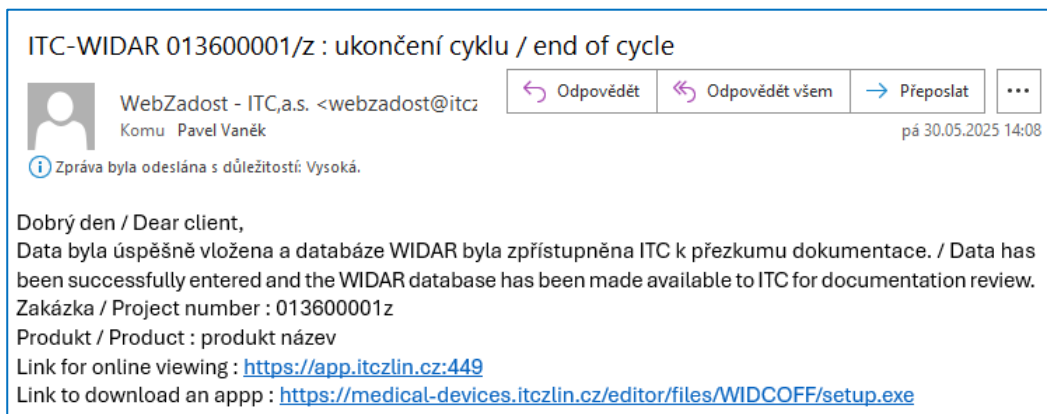
The client shall complete the answers to the indicated questions and try to submit again. If the WIDAR-C-OFF has already been completed correctly, the file is sent to the ITC FTP server designated for this purpose.

The client can exit and close the WIDAR-C-OFF form in the standard way, i.e. by clicking on the cross in the top right edge of the window, but the system requires confirmation to prevent the client from inadvertently exiting or leaving the application without saving the data.

If the client subsequently attempts to upload the same file to the FTP server again, the new upload will not occur and the client will be informed that this data file has already been uploaded to ITC:



From the client's viewpoint, this is a cycle closure, but still subject to approval by one of the NB staff assigned to review this project. Only after this approval will the client receive a confirmation e-mail:



This completes the 1st cycle and the entered data (responses) are reviewed by the NB 1023 reviewers in the 1st round of review and the database is now filled with their comments and records of non-conformities.

4. Client activities in the second cycle

The client activities described in this chapter are applied by analogy in the third or fourth cycle.

Once the client's responses and documentation are reviewed by NB 1023 staff, the project manager proceeds to close the round. Following this, the client will receive an automated e-mail notification from the webzadost@itczlin.cz e-mail address that Round 1 of the documentation review has been completed and the WIDAR has been made available for responses.

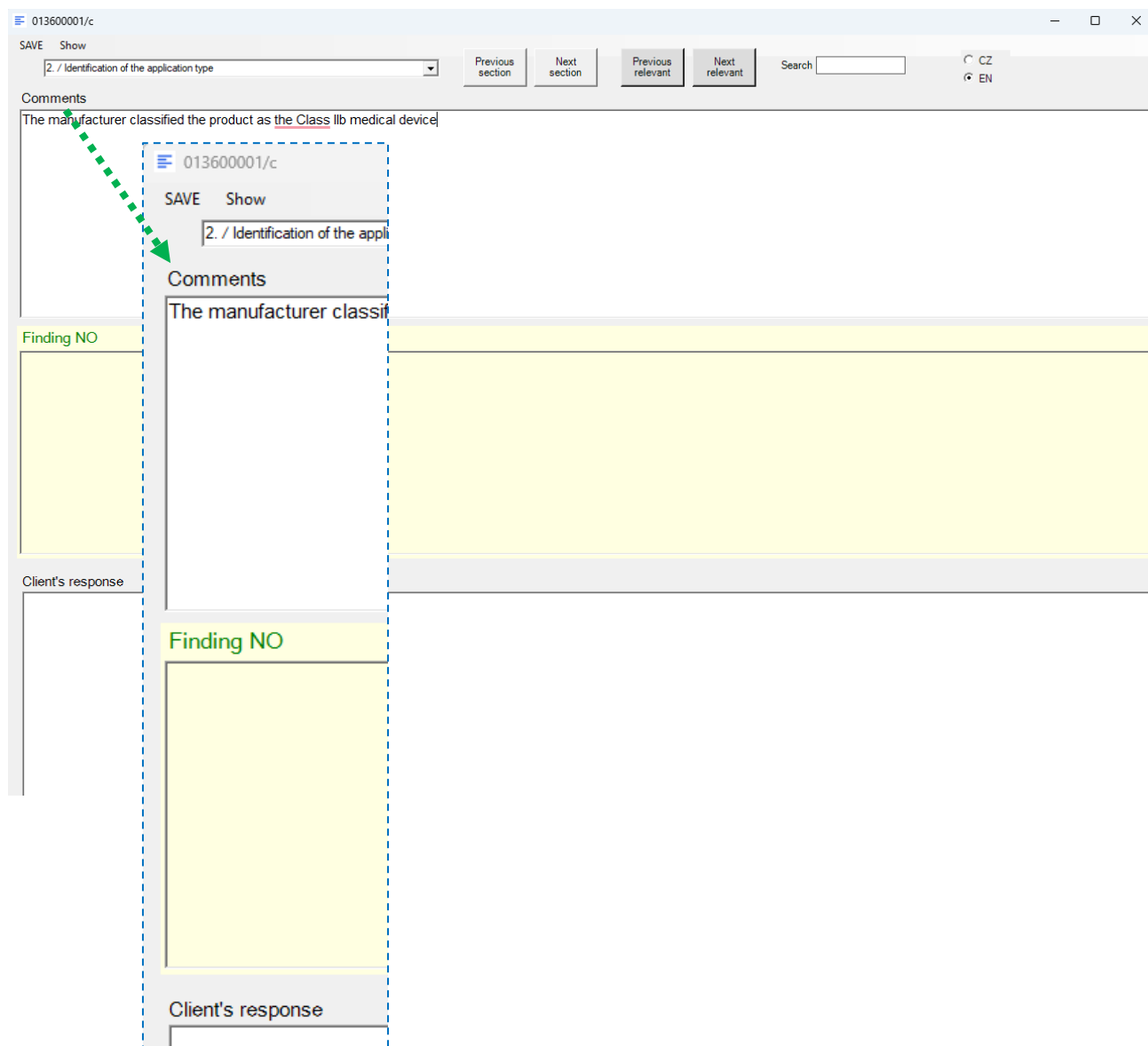


The client launches the 'WIDAR-C-OFF' application that he/she installed in the first cycle and fills in the project number and part of project letter, if applicable, and uses the access data (username and password) to access the actual WIDAR data. He chooses a working folder on his computer (it is advisable and recommended to use the same folder as in the first cycle, but a different folder can be specified as well).

In this folder, the application downloads the *.wid file generated after the first run (with the code XXXX, since its origin is NB). Now the client double-clicks or clicks the "Open" button to display the data after round 1 on the desktop.

The default workspace view settings in the second and each subsequent cycle differ from the first cycle, as there are already NB comments and findings from the first (next) round.

By default, when opened, you will not see the panel with your "Answers", but the "Comments", "Findings" and "Client's Response" panels.



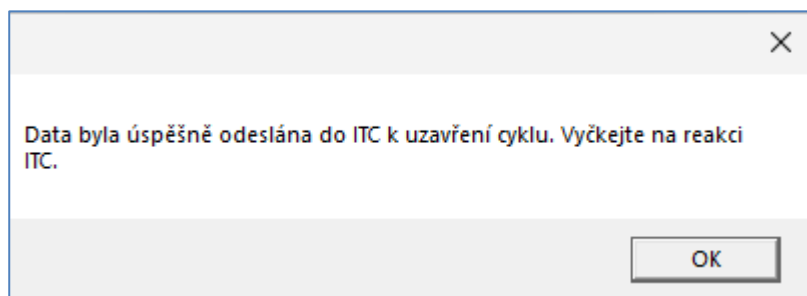
However, he can view the panel with his answers by using the "Show" menu and checking the "Answers" item in the list provided, as shown in section 3.4 of this manual.

The client navigates through each section using the "Previous Section" "Next Section," "Previous Relevant," "Next Relevant," or free search by item number ("Search"). He enters his comments and corrective actions on the findings in the "Client's Response" panel where "Finding YES" is indicated.

The "Previous Relevant" and "Next Relevant" buttons will not display blank items (without inserted text or other input) or items where "Finding NO" is indicated at this stage. In this context, it is worth noting that the 'Findings' panel may contain text even if the panel header states "Finding NOT". This situation occurs when a "Finding YES" from an earlier round has been removed in an earlier cycle and the NB 1023 review has accepted and confirmed the removal by switching to the "Finding NO" status.

During the review, the client can save his/her data to the selected directory using the "SAVE >> Save Locally" menu. When the client has entered responses to all Findings, he/she closes the cycle via the "SAVE - Send to ITC" menu.

This copies the file from the client's computer to the appropriate folder on the ITC FTP server, and the client is notified of the successful transfer.



Once the ITC staff member has ensured that the results of the second cycle have been downloaded to the SQL database, the client will receive an e-mail notification in the same way as after the completion of the first cycle.

5. Project completion procedure

In subsequent rounds, the NB 1023 and the client proceed in a manner analogous to that described in Chapter 4 of this manual until ITC decides to close the review with a final verdict of acceptance or rejection of the submitted technical documentation.

At the conclusion of the final round, when the client's response is no longer expected, the project manager closes the entire project. This avoids the possibility of adding further information on both the client and NB 1023 side.

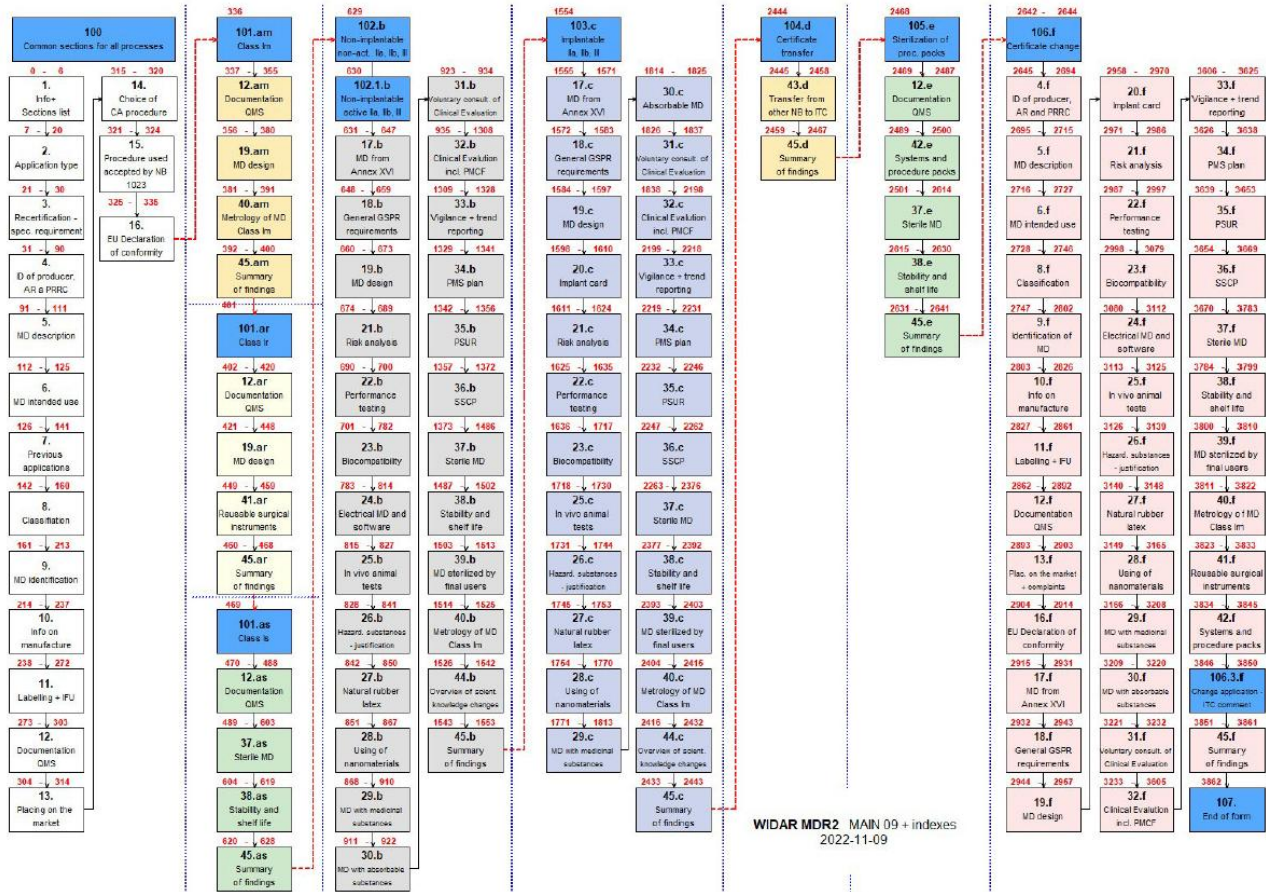
The client is then informed by e-mail that the project has been closed and the database locked against any changes by the client and NB 1023.

6. Annexes

Annex 1: List of all sections in WIDAR including indices of elements included in them (red numbers above each section symbol)

Annex 2: Structure of WIDAR flow

Annex 1: Structure of WIDAR for MDR - Section consistency and number of elements in them



Annex 2: Structure of WIDAR for MDR - overview diagram

