Handbook for clients
WIDAR

How to work with the WIDAR web-based interactive application
(Digital part of the application for conformity assessment under Regulation (EU) 2017/745)

Institute for Testing and Certification, Inc. Czech Republic

1 Introduction

This handbook informs customers of the Institute for Testing and Certification, Inc. (hereinafter referred to as ITC) about the requirements for the structure of technical and clinical documentation submitted with the application for conformity assessment. This handbook also includes a procedure for working with the WIDAR web application, which is an attachment to the conformity assessment application.

2 Requirements for the structure of technical and clinical documentation

The requirements for the scope of the assessment of the technical documentation of the medical device (hereinafter referred to as MD) by the notified body in relation to the classification of MD and the conformity assessment procedure chosen by the manufacturer are described in particular in Annex IX, chap. II and Annex XI, Part A, points 6.1 and 10 of the MDR.

The manufacturer is obliged to draw up and keep up-to-date the technical documentation of the MD, which must enable the conformity of the MD to be assessed in accordance with the requirements of the MDR (see Article 10(4)). In doing so, the documentation must have the elements defined in Annexes II and III of the MDR.

The requirements for the structure of the technical and clinical documentation set by the ITC are linked to the WIDAR web application, which is an annex to the conformity assessment application. The WIDAR application contains a significant number of queries (items to be filled in) resulting from the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR). The queries are categorised according to the risk class of the MD concerned, the conformity assessment procedure and the action (initial certification, request for amendment of the certificate or transfer of the certificate to another notified body) required by the manufacturer.

2.1 Requirements for the structure of the documentation submitted

The technical and clinical documentation should be presented in the following structure (chapters):

1) description of the company and its quality policy;
2) the identification of the manufacturer, the authorised representative (if the manufacturer is not established within the Union) and the identification of the person responsible for regulatory compliance;
3) description and identification of the MD including all its variants and accessories;
4) the intended purpose of the MD, including anticipated indications and contraindications and the intended patient population;
5) previous MD approvals and similar generations;
6) the classification of the MD, including the rule applied and its justification;
7) information on the design, construction and manufacture of the MD;
8) complete description of the labelling of the MD and its packaging, instructions for use, implant card (if applicable);
9) a list (checklist) of the general safety and performance requirements set out in Annex I of the MDR that are applicable to the MD with respect to its intended purpose, including the methods used to demonstrate compliance with these requirements;
10) harmonised standards, common specifications or other solutions used;
11) risk management documentation;
12) Preclinical evaluation - documentation related to the verification and validation of the design of the MD, including the results and critical analysis of all tests/studies

performed on the MD to demonstrate compliance with the general safety and performance requirements (biological evaluation, physical testing, functional suitability tests, animal testing, electrical safety, etc.);

13) clinical evaluation - clinical evaluation report and its updates and clinical evaluation plan in accordance with Article 61(12) and Annex XIV, Part A of the MDR;
14) post marketing surveillance and vigilance system;
15) medicinal substance - where the MD contains a medicinal substance as an integral part, information on this fact, including identification of the source of the substance and details of the tests carried out to assess its safety, quality and usefulness, taking into account the intended purpose of the MD;
16) In the case of MD consisting of substances or combinations of substances that are intended for introduction into the body and are absorbed by the body or locally dispersed in the body, details of the studies performed and their results with respect to those substances;
17) MD containing carcinogens, mutagens, reproductive toxicants or endocrine disruptors - if such substances are part of the MD, a detailed justification for their use must be provided, otherwise a declaration that such substances are not part of the MD must be provided;
18) sterilisation and stability - in the case of sterile MD or MD in a defined microbiological state, description of the environmental conditions for each stage of production; for sterile MD, description of the methods used, including validation reports with regard to packaging, sterilisation and maintenance of sterility;
19) MD with measuring function - in the case of MD with measuring function, a description of the methods used to ensure the specified accuracy;
20) use in combination - if the MD is to be connected to another device(s) for its intended function, a description of this combination/configuration, including evidence of compliance with the general safety and performance requirements for this combination/configuration;
21) draft text of the EU declaration of conformity (see Article 19 and Annex IV of the MDR);
22) quality system documentation - procedures, instructions and forms.

The above list of points defines the minimum content of the technical and clinical documentation to be submitted with the application for conformity assessment. Sections that are not relevant for the type of MD shall be marked N/A.

3 WIDAR application

3.1 TD review procedure via WIDAR

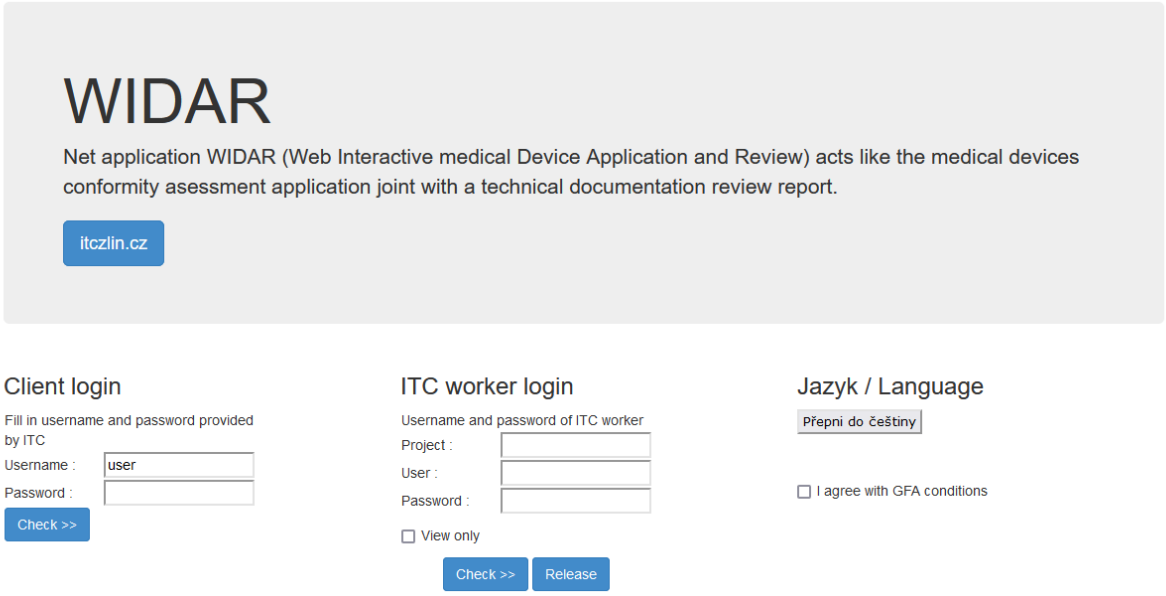
For the purpose of technical documentation (TD) review, a web-based application WIDAR (Web Interactive Medical Device Application and Review) has been developed. The following points summarise the conformity assessment process using this tool:

1) nomination of the project leader and project registration (unique project identification);
2) generating access codes for a specific client;
3) client login to the WIDAR application;
4) filling the database with data (client) and forwarding it to the notified body for review;
5) login of notified body personnel to the WIDAR application;
6) review by notified body staff and closing the first round of TD review;
7) Removal of discrepancies and completion of data by the client, sending for 2nd round of TD review;
8) Round 2 of the TD review concludes with a recommendation for certification in a positive case, if discrepancies persist, a third round of TD review is conducted;
9) if the TD is not compliant even after the 3rd round of TD, the notified body decides to refuse to issue the certificate;
10) The manufacturer has the option to request a 4th round of TD review for an additional fee.

3.2 WIDAR user interface and operating the application

1) Design of the login page for ITC clients;
2) user login to the WIDAR application;
3) WIDAR - Client declaration
4) WIDAR - user interface;
5) WIDAR - input fields and meaning of navigation buttons;
6) WIDAR - input fields and client procedure;
7) WIDAR - filter navigation;
8) list of WIDAR application sections.

3.2.1. Design of the login page for ITC clients



The login window is common for both the client and the ITC employee.

For the client, there is a left section "Client login" and a button "I agree with GFA conditions"

For ITC workers, there is a section "ITC worker login" and a common button "I agree with GFA conditions".

3.2.2. User login to the WIDAR application

An email with a link to log in to the WIDAR application will be sent to the client automatically (from the email account webzadost@itczlin.cz) once the registration requirements have been met, i.e. registration of the company in the EUDAMED database (SRN) and the product (basic UDI-DI for Class III and IIb implantable products (excluding sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)).

The client receives login details (username and password) from the email account webzadost@itczlin.cz.

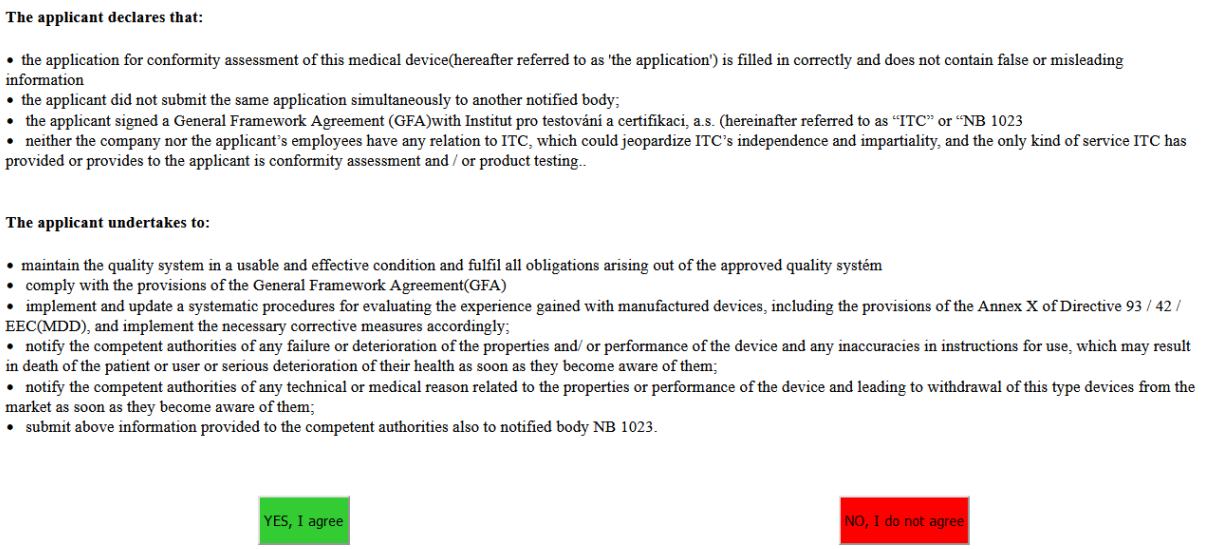
Clicking on the "Switch to English" button under the text Jazyk / Language will display the English version of the login window and all subsequent WIDAR communication will switch to English.

The meaning of the buttons and fields in the WIDAR login window:

itczlin.cz	hyperlink to the ITC website
Section "Client login" "	
Username	username generated and assigned to the client
Password	user password generated and assigned to the client
Check	checks the name, password and acceptance of the GFA terms and conditions
Section "ITC worker login"	
Project	the contract (and project) number recorded in ITC's internal database system
User	username of the ITC employee
Password	ITC user password
Check	checks the name, password and acceptance of the GFA terms and conditions
Release	If another worker has not properly completed their work with this WIDAR project and is blocking access, their session can be terminated and the project released.
View only	for ITC staff to view the current status of the project
Language	Switches between Czech and English
I agree with GFA conditions	This declaration must be confirmed by the client or ITC employee who is logging in by checking the checkbox. Without confirmation, the WIDAR application will not start.

3.2.3. WIDAR - Client declaration

When a client logs in to a project in WIDAR for the first time, a declaration window will appear (regardless of the fact that they have already submitted a similar signed declaration to ITC in the form of a "paper" application). The client must agree to the declaration or else they will be denied access.



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:

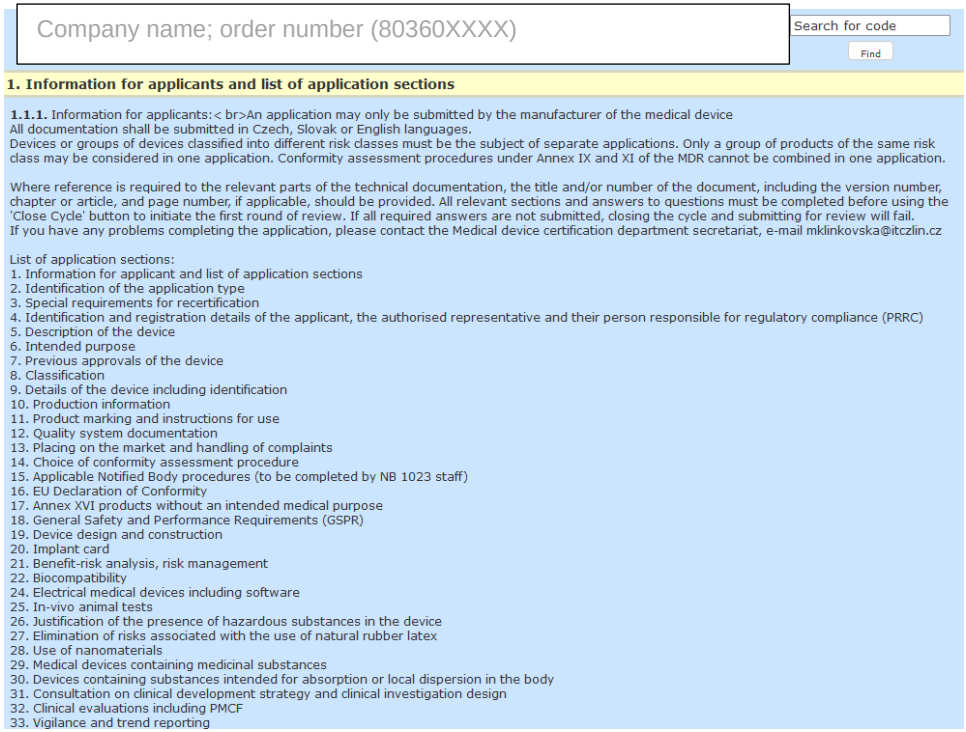
- maintain the quality system in a usable and effective condition and fulfil all obligations arising out of the approved quality systém
- comply with the provisions of the General Framework Agreement(GFA)
- implement and update a systematic procedures for evaluating the experience gained with manufactured 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.

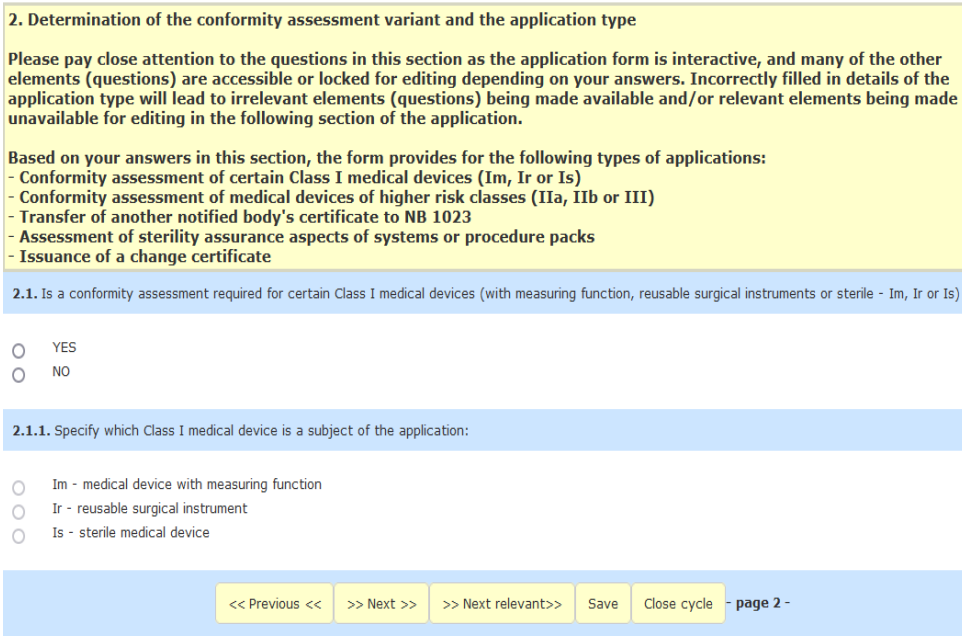
YES, I agree

NO, I do not agree

Subsequent logins by the same client to the same project do not repeat the consent requirement.

3.2.4. WIDAR - user interface





The client is shown a series of

- blue coloured fields (texts with information and data entry requests)
- grey fields that are inaccessible
- white fields, where the client adds information either by text, or by checking in checklists, or by selecting the position of switches (radiobuttons)

At the bottom of each page there is a **navigation bar** with buttons and a page number:

- << Previous <<
- >> Next >>
- >> Next relevant >>
- Save
- Close cycle

- In the upper right corner of each page there is a navigation element "Search for code" and a button "Find"

3.2.5. WIDAR - Input fields and meaning of navigation buttons

Displaying fields:

- blue coloured fields are informative and permanently inaccessible for the client - these fields are called **QUESTIONS** (number > 2800)
- the grey fields are currently inaccessible, but access to them may change depending on the answers to some questions in the form of checkboxes and/or YES/NO switches etc.
- the white fields are currently accessible, but access to them may change depending on the answers to some questions in the form of a checkbox and/or YES/NO switches, etc.

For example, if the switch "MD Active - MD non-active" is set by clicking on "MD – non-active", all fields related to active medical devices will be greyed out and inaccessible for input.

Navigation bar with buttons

Button:	**Meaning:**
<< Previous <<	Go back one page in the text (to the previous page)
>> Next >>	Go to the next page
>> Next relevant >>	Getting to the next page that is accessible (not greyed out)
Save	Save a WIDAR instance in progress
Close cycle	Once all relevant fields are filled in, they are saved and all data are locked for changes and information is sent to ITC staff that they can initiate a review of the technical documentation.

Note: However, if the client omits to fill in some mandatory fields, the cycle closure will fail and WIDAR will provide a list of field codes for the fields that are not filled in. Only after they have been completed the cycle can be closed.

3.2.6. WIDAR - input field and client procedure

A WIDAR request contains a sequence of elements (questions to be answered).

The elements may vary in nature according to the form of the question to be answered:

a) Text field in which the answer to the question is entered in text form. We recommend that all text is entered using the computer keyboard. Copying and pasting text from other applications or files (e.g. from Excel spreadsheets or Adobe acrobat (.pdf) files, and especially from specialised programs and applications) may not be successful. If you still intend to paste large amounts of text from files such as MS Word, MS Excel, etc., 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.

b) A switch that contains two or more rings, only one of which can be selected at a time by clicking.

c) The list (checkbox) contains two or more checkboxes, at least one of which must be selected by clicking to check. Multiple checkboxes of the list can be checked (for example all of them), if no checkbox is checked, WIDAR will report an error when trying to close the cycle and identify this element as unfilled.

d) The drop-down menu will expand when clicked and offer two or more answers from which one can be selected. If no option is selected, WIDAR will report an error when attempting to close the cycle and identify this element as unfilled.

e) The toggle switch with the text field works the same as switch b), but offers the possibility to add additional text to the field next to each ring (position) of the switch, e.g. a justification for this choice.

f) A list with a text field works the same way as list c), but offers the possibility to add additional text, e.g. a justification for this choice, in the field next to each checkbox (list item).

The text on the blue background is fixed, and represents questions or instructions to the applicant, to which the applicant responds by typing the requested information (including a reference to the part of the attached technical documentation that addresses the issue) in a grey unframed box, the size of which varies according to the length of the inserted text.

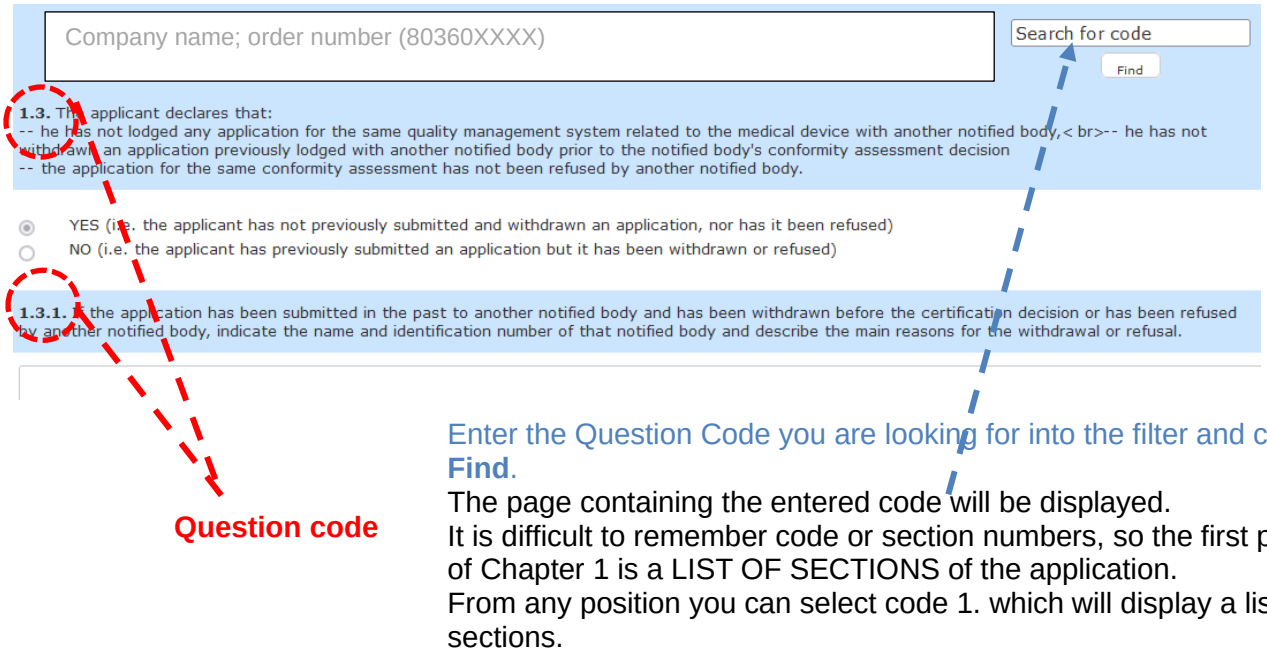
The grey box framed in pink is for comments and evaluation of the element by the notified body staff (NB 1023). More than one member of the documentation assessment team may enter comments in the same field. For internal use, each comment will be marked with the abbreviation of the name of the author of the comment/finding and the exact times of insertion are also stored in the database.

These pink framed fields are not visible to the applicant when initially completing the application. Only after the NB 1023 staff have recorded their comments and observations on all relevant aspects (they have carried out the first round of review of the technical and clinical documentation) will the application show the applicant the text of the comments on which he/she is obliged to comment appropriately in the next round.

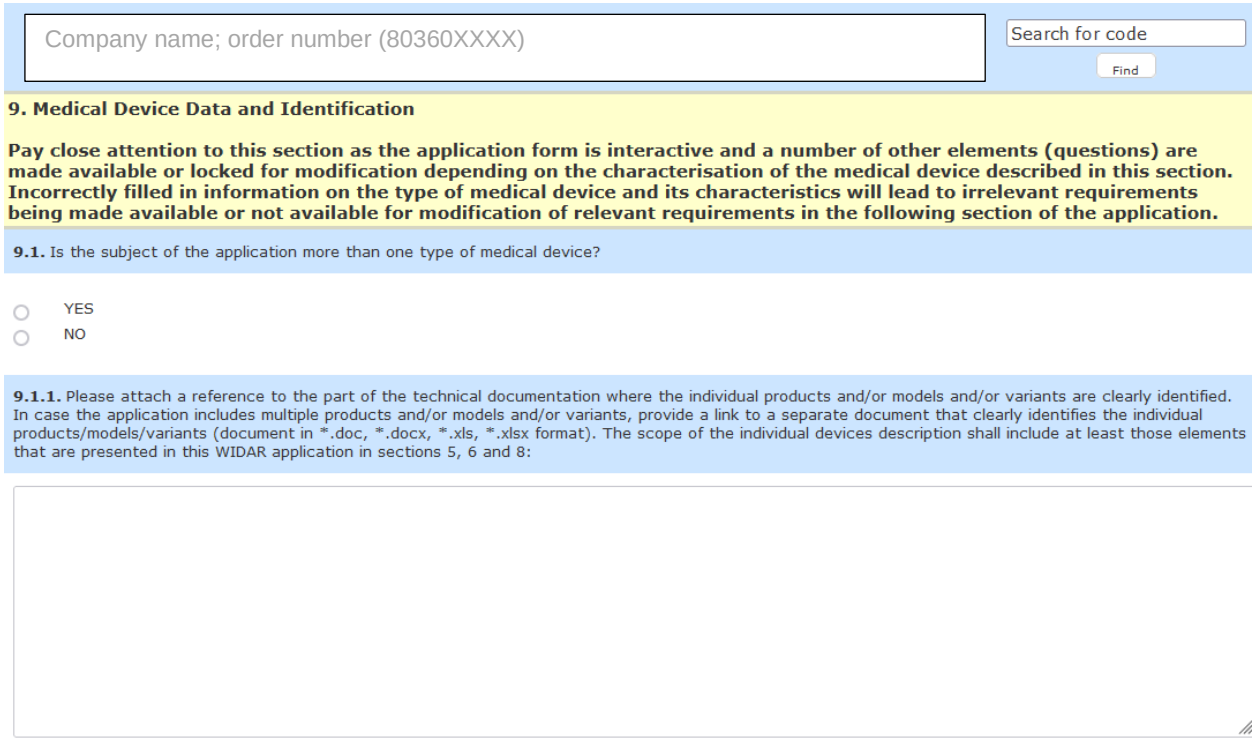
Space is provided after each section for a summary evaluation of the section, including identification of nonconformities and observations.

The application is configured so that only the relevant sections or parts of sections are displayed to the manufacturer after the medical device data is entered (i.e. for non-sterile products, section 18 Sterilization is not displayed etc.).

3.2.7. WIDAR - filter navigation



Enter the Question Code you are looking for into the filter and click **Find**.
The page containing the entered code will be displayed.
It is difficult to remember code or section numbers, so the first page of Chapter 1 is a LIST OF SECTIONS of the application.
From any position you can select code 1. which will display a list of sections.



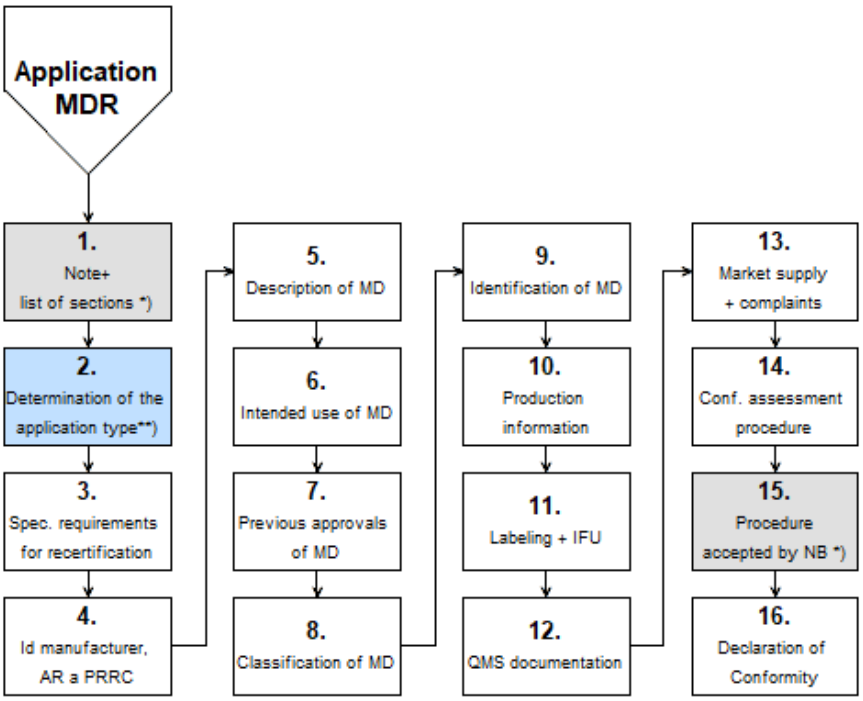
You can access the list of application sections from any location (here section 9.) by entering the code 1. and clicking the **Find** button.
The list contains a total of 45 sections (see list below)

3.2.8. List of WIDAR application sections

1) Information for applicants and list of application sections
2) Identification of the application type
3) Special requirements for recertification
4) Identification and registration details of the applicant, the authorised representative and their person responsible for regulatory compliance (PRRC)
5) Description of the device
6) Intended purpose
7) Previous approvals of the device
8) Classification
9) Details of the device, including identification
10) Production information
11) Product marking and instructions for use
12) Quality system documentation
13) Placing on the market and handling of complaints
14) Choice of conformity assessment procedure
15) Applicable Notified Body procedures (to be completed by NB 1023 staff)
16) EU Declaration of Conformity
17) Annex XVI products without an intended medical purpose
18) General Safety and Performance Requirements (GSPR)
19) Device design and construction
20) Implant card
21) Benefit-risk analysis, risk management
22) Functional capability (performance) testing and simulated use tests
23) Biocompatibility
24) Electrical medical devices including software
25) *In vivo* animal tests
26) Justification for the presence of hazardous substances in the device
27) Elimination of risks associated with the use of natural rubber latex
28) Use of nanomaterials
29) Medical devices containing medicinal substances
30) Devices containing substances intended for absorption or local dispersion in the body
31) Consultation on clinical development strategy and clinical investigation design
32) Clinical evaluations including PMCF
33) Vigilance and trend reporting
34) Post-market surveillance plan (PMS plan)
35) Periodic safety update report (PSUR)
36) Summary of safety and clinical performance data (SSCP)
37) Devices supplied in a sterile state
38) Stability and shelf life
39) Devices intended for sterilisation by the end user
40) Accuracy and metrological traceability of devices with a measurement function
41) Reusable surgical instruments
42) Medical device systems and procedure packs
43) Application for transfer from another notified body to NB 1023 ITC
44) Overview of changes and scientific knowledge related to the device
45) Summary of findings

3.2.9. Graphical distribution of the questions in the WIDAR application according to the chosen procedure

Common parts for all procedures (section code 1-16)

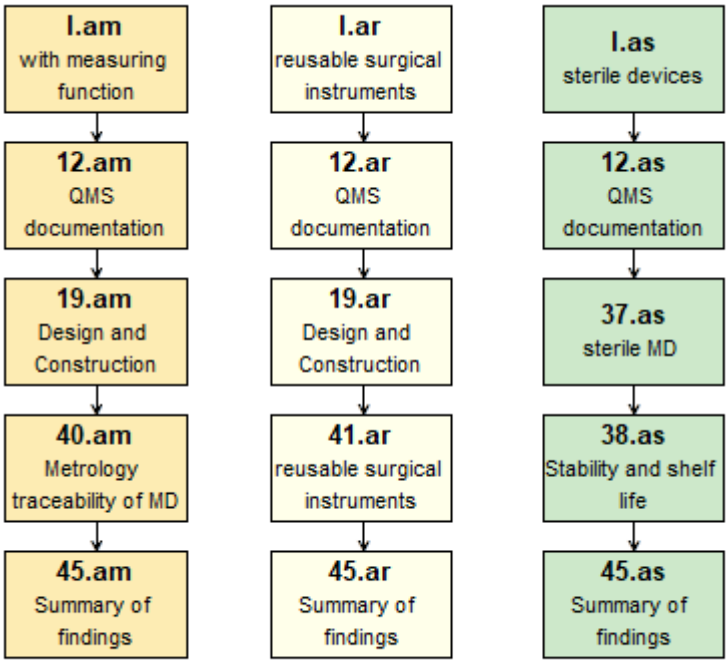


Notes:

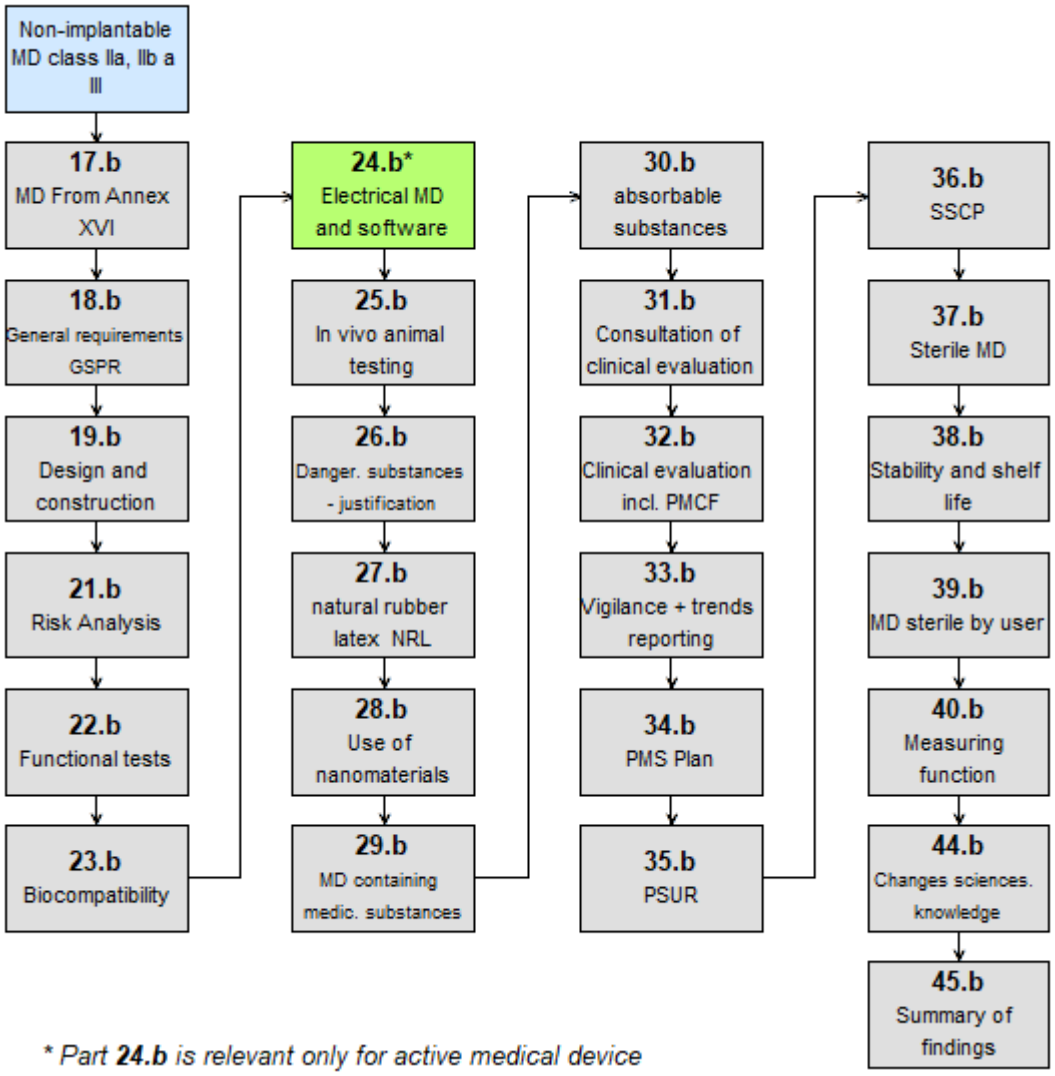
**) The sections highlighted in gray do not contain any inputs (questions), but only information for the manufacturer.*

***) Depending on the selected request type, some common sections are not displayed or are replaced by a specifically modified section, which is displayed in the section corresponding to the selected type.*

Parts for Class I (Im, Is and Ir)

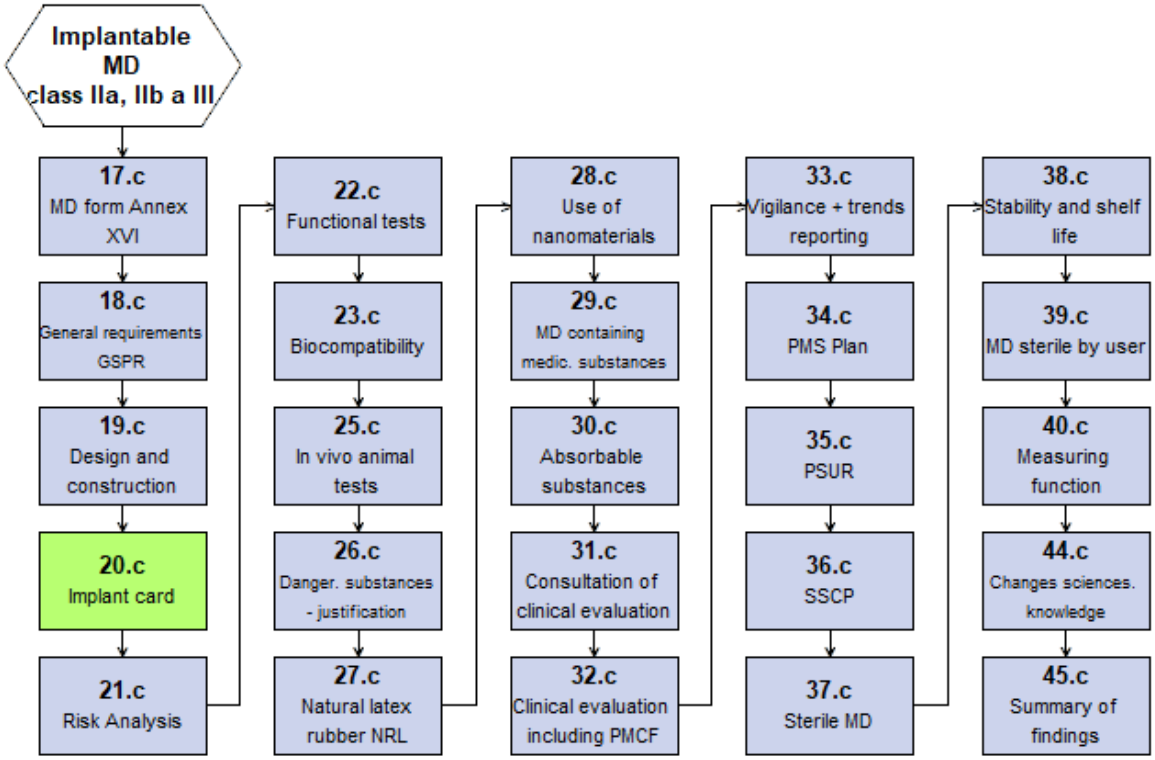


Parts intended for non-implantable MD of Class IIa, IIb and III (section code No 17b - 45b)

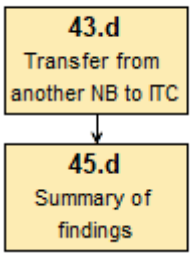


** Part **24.b** is relevant only for active medical device*

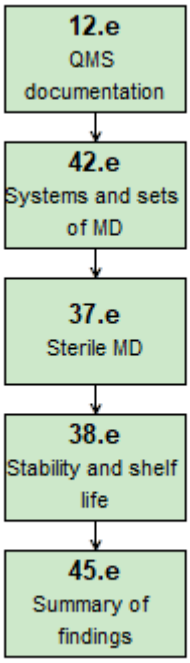
Parts intended for implantable devices of class IIa, IIb and III (section code No 17c - 45c)



Parts intended for the transfer of the certificate (section code No 43d - 45d)



Parts for sterilization of the systems and procedure packs (section code No 12e - 45e)



Sections to be used for the Application for change of Certificate (Section Code No 4f - 45f)