Name of the document:

Procedure for submitting a request for a medical device conformity assessment

Supplementary information (Purpose and content of the document), Abstract:

The document describes the procedure for a manufacturer of medical devices to prepare and submit a non-binding inquiry and request for conformity assessment according to Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR)

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Attention: Making copies of a document and providing the document to the persons (not from CMI) is not permitted without the consent of the employee who approved the document.

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	Certification of reference materials
X	Medical devices certification
	Invoicing
	Financial control (internal audit)
	Financial accounting, domestic and foreign business trips
	CMI information system (including file service and archiving)
	Inspection body
	Gauge calibration and testing
	Property
	Metrological control of pre-packaged goods
	Interlaboratory comparison
	Wages, human resources, personal data
	Follow-up document to PJ CMI
	Gauge verification
	Conformity assessment of terminal telecommunications equipment (authorized person 256)
	Conformity assessment of measuring instruments (authorized person 250)
	Assessment of the eligibility of entities for authorization
	Documents taken over and in progress by the Ministry of Industry and Trade
	Registration for repairs and installation of meters
	Meter type approval and related agenda
	Agreements (lease agreements, metrological performance agreements, collective agreements)
	Frequency spectrum management
	Damage commission, damages
	Technical development
	Creation and preservation of state standards
	Creation of metrological regulations, guidelines, standards
	Bookkeeping
	Software validation
	Debt collection
	SMD performance
	Staff training and certification of staff in metrology
	Expert opinions, professional assessments

Table of contents

Explanation of abbreviations and terminology

Applicant	Those interested in the conformity assessment before signing the implementation contract on the medical device conformity assessment
CMI	Czech Metrology Institute
CMI Medical	Medical Devices Certification Centre
EUDAMED	European database on medical devices
FSCA	Field Safety Corrective Actions
Manufacturer	Those interested in the conformity assessment after signing the implementation contract on the medical device conformity assessment
MD	Medical device
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council
NB	Notified body
PMCF	Post-Market Clinical Follow-up
PSUR	Periodic Safety Update Report
GSPR	General Safety and Performance Requirements)
SRN	Single Registration Number
UDI	Unique Device Identification
UDI-DI	Device Identifier

1. Introduction

This document describes how a manufacturer (or its authorized representative) of medical devices, or an applicant, should prepare and submit a non-binding inquiry and subsequently an application for a conformity assessment of the quality management system or assessment of the technical documentation of its medical device under Regulation (EU) 2017/745 of the European Parliament and of the Council to the Czech Metrology Institute (CMI). This fulfils the requirements of Annex VII (4.2.a) of the MDR on the publication of a description of the application procedure by which manufacturers can obtain certification.

This document follows the methodical instruction "Medical Devices Certification Procedure" No. 880-MP-C001, issued by the Czech Metrology Institute.

CMI provides general information about its activities as a notified body, the scope of CMI's designation and other information related to medical devices conformity assessment, including contacts to relevant CMI employees on its website in the section CMI Medical – Medical Device Certification Centre (https://www.cmi.gov.cz/mdr).

This methodical procedure is also published on the website of the Czech Metrology Institute in the section CMI Medical – Medical Devices Certification Centre, as binding instructions for all applicants interested in conformity assessment at CMI. Together with this procedure, the currently valid price list of services of CMI Medical is published, in which applicants can find the fees charged for specific conformity assessment activities in accordance with Annex VII (4.2.b) of the MDR.

2. Communication with applicants and request for non-binding information

Applicants should direct all questions regarding the conformity assessment of medical devices to the CMI Medical Contract Administration and Support Department, which is responsible for all pre-contract communications between applicants and CMI. Applicants may send their questions either to the e-mail address medical@cmi.gov.cz or directly to the individual staff members of the CMI Medical Contract Administration and Support Department, whose contacts are listed on the CMI website in the CMI Medical - Medical Devices Certification Centre section (https://www.cmi.gov.cz/mdr)

The assigned Contract Administrator will contact the inquiring entity, generally within 5 working days of receiving the message.

According to the MDR, Annex VII, point 1.2.3(d) CMI as a notified body shall not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment. Therefore, questions of this type cannot be answered.

3. Obligation to register manufacturers and authorised representatives

Before submitting an application to the Czech Metrology Institute, the applicant must be registered in the electronic system for the registration of economic operators (part of the European Database on Medical Devices - EUDAMED). The registration shall be carried out in accordance with the MDR, Article 30. A single registration number (SRN) is assigned to the manufacturer or authorised representative.

4. Acceptable documentation languages and communication languages

CMI fully accepts documentation sent by the applicant in Czech, Slovak or English. Documentation sent in other languages will also be accepted, but in this case, the documentation will be translated by a professional translation agency and the cost of the translation will be charged to the applicant. The standard conformity assessment time will be increased by the time needed to translate the documents.

The communication languages between the applicant and the CMI are Czech and English, with regard to the linguistic affinity with Czech, communication in Slovak is also possible.

5. Procedure for submitting a non-binding inquiry

5.1. Preparation and submission of a non-binding inquiry

In case of interest in medical device conformity assessment at CMI, the applicant must first submit a non-binding inquiry via the relevant electronic form, which can be found on the CMI website in the CMI Medical - Medical Device Certification Centre section (https://www.cmi.gov.cz/mdr), or at this link:

https://www.cmi.cz/mdr/poptavky/forms/app/form/medeca_poptavka

Detailed information on completing the non-binding inquiry form is available on the CMI Medical website as well as on the form itself in the form of help.

Once all the information in the Non-Binding Inquiry Form has been duly and truthfully filled in, a PDF document of the Non-Binding Inquiry Form will be automatically generated for the applicant. This generated file will be signed electronically or manually by the responsible person of the applicant and sent together with the necessary attachments to the CMI by email to medical@cmi.gov.cz (in case of manual signature, the applicant will send a scanned copy of the inquiry).

Necessary attachments to the non-binding inquiry are:

- instructions for use for each medical device,
- a description of each medical device,
- the applicant's quality management system certificates (if any),
- the quality management system certificates of the applicant's critical suppliers (if any),
- the applicant's organisational structure,
- the applicant's manufacturing process map,
- certificates according to Directive 93/42/EEC (MDD) or Regulation 2017/745 (MDR) for each medical device (if any).

5.2. Non-binding inquiry review

The CMI shall formally and factually review the non-binding inquiry.

5.2.1. Formal review of the non-binding inquiry

The formal review of the non-binding inquiry includes a check on the completeness of the non-binding inquiry, including the submission of the necessary attachments.

If necessary, or if, for example, inconsistencies are found between the information in the inquiry and the attached documents, the Contract Administrator may request the applicant to complete and clarify this information.

In the event that there is no agreement between the Contract Administrator and the applicant, or the applicant is not responding to the request to complete the information within the specified time limit, the Contract Administrator shall close the business case and inform the applicant of this fact.

5.2.2. Factual review of the non-binding inquiry

The objective of the substantive review of the non-binding inquiry is to verify the possibility of the CMI's assessment of the product and to form the basis for the rough planning of the project, i.e. in particular to verify cursorily whether the inquiry provides the appropriate qualification, classification and other necessary data about the device.

In case at any time during the review of the non-binding inquiry, any of the above information needs to be completed, clarified, or additional information needs to be provided for the purpose of preliminary

verification of the qualification and classification of the medical devices, assignment of MDR codes, etc., the Contract Administrator will request the applicant to complete the non-binding inquiry using the applicant's contact information provided.

The result of the preliminary verification of product qualification and classification is independent of the subsequent conformity assessment process and is not a binding decision of the competent authority.

The result of the above review is, in particular, a conclusion as to whether the CMI is able to carry out a conformity assessment of the medical device in question, taking into account the scope of its appointment and the resources available (in particular human resources). The conclusion as a whole or in parts may be subject to the validity of the claims made by the applicant, especially if the Project Leader has doubts about them.

In the event of a negative outcome of the review of the inquiry (i.e. the CMI is unable to carry out the requested conformity assessment or the applicant has not completed the necessary information within the specified time limit despite repeated requests from the CMI), the Contract Administrator shall close the business case and inform the applicant of the inability to carry out the requested conformity assessment, together with information on the preliminary verification of the qualification and classification of the product or the inability to complete the review of the non-binding inquiry due to failure to provide all necessary information, as appropriate.

5.2.3. Procedure in case of disagreement between the applicant and the CMI

In the event of disagreement of CMI with the qualification or classification indicated by the applicant in the inquiry, the Contract Administrator shall send this information to the applicant, including a justification. At the same time, he/she shall ask the applicant whether he/she will accept the CMI's opinion (and therefore change the classification in the CMI's opinion), which would result in mutual agreement, or not, and the justification thereof.

In the event of a continuing dispute over qualification or classification, the Contract Administrator shall request the applicant to ask the competent authority of the Member State in which the manufacturer or the authorised representative has a registered place of business for an opinion on qualification or classification in accordance with Article 51(2) of the MDR, in order to allow the non-binding inquiry review process to continue.

The decision of the competent authority of the Member State may not be challenged by the CMI.

5.2.4. Outline of project planning

In the event of a positive outcome of the inquiry review (i.e. the CMI is likely to be able to carry out a conformity assessment of the medical device), a project planning outline will be carried out.

5.3. Sending a non-binding quotation to the applicant

The Contract Administrator will then prepare a non-binding quotation for conformity assessment services for the applicant. This non-binding offer shall include, in particular, a preliminary estimated price for the conformity assessment.

This preliminary estimated price may differ from the price specified when signing the implementation contract for conformity assessment, as it is based only on the information supplied with the non-binding inquiry, and therefore without detailed knowledge of the medical device or the complete manufacturer's documentation. At the same time, this price is based on the assumption that the conformity assessment process is carried out in a standard way, the applicant provides the necessary cooperation and has prepared documentation of adequate quality without any nonconformities, and therefore no further additional iterations will be necessary.

The quotation also includes a preliminary estimated price for the surveillance activities. This will be calculated by the Contract Administrator as the product of an estimate of the number of hours spent on

the performance of the subject activities during the surveillance period and the hourly rates specified in the currently valid published CMI price list.

The Contract Administrator will then sign and send this non-binding quotation to the applicant together with information on the further procedure and a request to accept the quotation sent within 90 days.

The applicant accepts the non-binding quotation by sending an e-mail to the Contract Administrator, informing them of the acceptance of the non-binding quotation.

The non-binding offer is valid for 90 days. If the applicant does not accept the offer within this period, the Contract Administrator may extend the deadline for a further 14 days or terminate the business case according to the procedure in Section 5.2.2 of this document.

6. Procedure for submitting an application for conformity assessment and its review

6.1. Requirements for each type of conformity assessment procedures

This chapter lists the requirements for each conformity assessment procedure that an applicant may submit an application to the CMI. These procedures are as follows:

- Conformity assessment of quality management system and conformity assessment of technical documentation according to MDR, Annex IX,
- Conformity assessment based on product conformity verification – production quality assurance according to MDR Annex XI, Part A

Two types of applications can be submitted to the CMI for these conformity assessment procedures, namely:

- Application for conformity assessment of a quality management system according to Regulation (EU) 2017/745 MDR,
- Application for conformity assessment of quality management system and assessment of technical documentation according to Regulation (EU) 2017/745 MDR.

6.1.1. Conformity assessment of quality management system according to MDR, Annex IX, chapter I and III

This procedure applies to devices listed in MDR, Article 52, points 4, 6 and 7, i.e. Class IIb non-implantable devices, Class IIa devices and Class I devices with a measuring function, placed on the market in a sterile condition and reusable surgical instruments.

All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records (MDR, Annex IX (2.2)).

The manufacturer must already have a quality management system in place in accordance with the MDR when submitting the application. The CMI assesses the conformity of the quality management system with the requirements of the MDR, Annex IX, Chapter I, Section 2.2. even if the manufacturer has a certified quality management system according to EN ISO 13485. If the manufacturer uses this standard and provides a valid certificate, this conformity of the system with the standard is taken into account, but the conformity of the quality management system must still be assessed in accordance with the MDR. MDCG 2020-14 is taken into account when planning the audit and assessment of the quality management system.

The documentation to be submitted for the assessment of the quality management system shall fulfil all the requirements in accordance with the MDR.

In addition, the applicant must ensure access to the technical documentation. This shall be assessed for Class IIa and non-implantable Class IIb devices for at least one device for each generic device group.

The applicant shall submit an Application for Conformity Assessment of the Quality Management System to the CMI. In the Initial Application Form for Medical Device Conformity Assessment, in the Introduction section, the applicant shall select the option: *'Annex IX, Chapter I and III. Conformity assessment based on the quality management system'*.

6.1.2. Conformity assessment of quality management system and conformity assessment of technical documentation according to MDR, Annex IX, chapter I, II and III

This procedure applies to Class IIb implantable devices within the scope of the CMI designation.

The quality management system shall comply with the requirements set out in section 6.1.1 of this procedure.

The technical documentation shall fulfil all the requirements of the MDR and in particular, comply with the General Safety and Performance Requirements (GSPR) of Annex I of the MDR and be prepared in accordance with Annexes II and III of the MDR.

The applicant shall submit an Application for Conformity Assessment of Technical Documentation to the CMI together with the Application for Conformity Assessment of the Quality Management System. In the Initial Application Form for Medical Device Conformity Assessment, in the Introduction section, the applicant shall select the option: *'Annex IX, Chapter I, II and III. Conformity assessment based on a quality management system and on assessment of technical documentation'*.

6.1.3. Conformity assessment based on product conformity verification – production quality assurance according to MDR Annex XI, Part A

Conformity assessment based on a product conformity verification - production quality assurance procedure applies, within the scope of the CMI designation, only to risk class I devices placed on the market in a sterile condition (class Is), with a measuring function (class Im) or for reusable surgical instruments (class Ir) and to class IIa medical devices (for this risk class the procedure according to MDR, Annex XI, Part A, point 10 will be applied).

For devices of risk class Is, Im and Ir, the applicant shall submit an Application for Conformity Assessment of the Quality Management System to the CMI. In the Initial Application Form for Medical Device Conformity Assessment, in the Introduction section, the applicant shall select the option: *'Annex XI, Part A. Conformity assessment based on product conformity verification & production quality assurance'*.

For risk class IIa devices, the applicant shall submit an Application for Conformity Assessment of Quality Management System to the CMI. In the Initial Application Form for Medical Device Conformity Assessment, in the Introduction section, the applicant shall select the option: *'Annex XI, Part A, Section 10. Conformity assessment based on product conformity verification & production quality assurance and assessment of technical documentation'*. The technical documentation shall be assessed for devices selected on a representative basis.

6.2. Completing the Initial Application Form for Medical Devices Conformity Assessment on the website

The applicant may submit a formal application for conformity assessment to the CMI after accepting the non-binding quotation.

The applicant may not submit the same application for conformity assessment for the same medical device at the same time to another notified body (see MDR, Article 53, paragraph 1). Where the CMI finds that the applicant has done so and the date of submission to the CMI is later (i.e. a more recent application has been submitted to the CMI) than the date of submission to another notified body, the CMI shall reject such application. The Contract Administrator in MEDECA software shall close the business case and inform the applicant of this fact.

The applicant shall start the application process by completing the appropriate Initial Application Form, which can be found on the CMI website in the CMI Medical - Medical Device Certification Centre section (https://www.cmi.cz/mdr), or at this link:

https://www.cmi.cz/mdr/poptavky/forms/app

According to the requirements of the MDR, the applicant shall submit one or more applications to the Czech Metrology Institute, depending on the chosen conformity assessment procedure and classification of their medical device (for conformity assessment according to Annex IX of the MDR for Class III and Class IIb implantable medical devices according to Article 52(4) of the MDR, the applicant must submit an Application for Conformity Assessment of the Technical Documentation for the medical device in addition to the Application for Conformity Assessment of the Quality Management System).

The required type of application or combination thereof shall be selected directly by the applicant in the Initial Application Form by selecting the relevant conformity assessment procedure as described in Chapter 6.1.

Once the applicant has duly and truthfully completed the Initial Application Form, he/she shall submit the Initial Application Form. The submission of the form by the applicant will provide the Contract Administrator, CMI Medical Director, CMI Medical Department Heads, and Preclinical and Clinical Trial Managers with information in the MEDECA software system (SW MEDECA). The Contract Administrator in the SW MEDECA will assign a registration number to the application (which will be used for subsequent communication between CMI and the applicant) and the previously sent non-binding inquiry. Subsequently, the Contract Administrator will create a user in SW MEDECA, i.e. generate login data for the applicant to the SW MEDECA client area, which will be sent to the e-mail address provided, together with instructions on the further procedure and a link to the SW MEDECA.

6.2.1. Login of the applicant to the MEDECA software system

After receiving the login details, the applicant will make the first login to the SW MEDECA. Here, he/she becomes familiar with the General Terms and Conditions of CMI for the certification of medical devices and then confirms his/her agreement to their wording, thereby expressly committing himself/herself to comply with these conditions. CMI reserves the right to make changes to these terms and conditions, but must always inform the applicant.

In the SW MEDECA, the applicant has access to the user manual or can ask the Contract Administrator about activities in the SW MEDECA.

6.2.2. The Initial Application Form Review

The Contract Administrator will carry out a formal review of the initial application form to verify, in particular, its completeness. In addition, the Contract Administrator will check that the applicant is registered in EUDAMED and has been allocated an SRN identification number.

In the event that any of the obligations described above are not fulfilled, or in the event that significant inconsistencies are found between the information in the application and the request form, or in the

event of other suggestions, the Contract Administrator may request completion and clarification of this information from the applicant via the SW MEDECA.

In the event that there is no agreement between the Contract Administrator and the applicant, or if the applicant does not respond to the request to complete the information within the time limit, the Contract Administrator shall close the business case and inform the applicant of this fact via the SW MEDECA.

6.3. Completing the application

Once all of the above obligations are met, the applicant is allowed to upload the documentation into the SW MEDECA. On the Files tab, the applicant uploads the following:

- a ZIP file containing the documentation related to the quality management system under 'Quality management system documentation',
- a ZIP file containing technical documentation on medical devices under 'Technical documentation for device X' (the number of ZIP files must be equal to the number of sets of technical documentation specified in the application).

As far as the technical documentation is concerned, the applicant is required to submit the following:

- a draft EU Declaration of Conformity,
- the instructions for use of the medical device.

As for the other documents, the applicant has the option of either submitting them immediately at this step or taking advantage of the extended deadline for their submission. In this case, the applicant is obliged to submit the complete technical documentation within 30 days of the CMI's call, but no later than one year after the signing of the general contract for the medical device conformity assessment between the applicant and the CMI, unless the CMI and the applicant agree on another individual schedule.

The next step of the application is to match the relevant evidence to the requirements of the application:

1) The applicant in the SW MEDECA on the QMS card
    - for the relevant requirement, the applicant ticks the box "Relevant for the application" and assigns the corresponding documents from the list to the requirement (here the manufacturer uses the documents from the ZIP file uploaded in the point above in the section "Quality management system documentation", and fills in the comments with the exact reference of the fulfilment of the requirement in the assigned files),
    - For a non-relevant requirement, the applicant fills in the justification in the comment.
2) Applicant in SW MEDECA on the Devices tab
    - for the relevant requirement, the applicant ticks the box "Relevant for the application" and assigns the corresponding documents from the list to the requirement (here the manufacturer has the documents from the ZIP file uploaded in the point above in the section "Technical documentation for device X", and fills in the comments with the exact reference of the fulfilment of the requirement in the assigned files),
    - for a non-relevant requirement, the applicant fills in the justification in the comment.

Subsequently, the applicant generates the final application form in the SW MEDECA and sends it signed to the CMI via the SW MEDECA.

By sending the signed final application form, the application for conformity assessment of medical devices is officially lodged.

All CMI Medical Heads of Department and Pre-Clinical and Clinical Trial Managers are informed of the lodged application via the SW MEDECA.

At this point, the applicant is also asked to pay the request review fee, which is in the amount of the current published price list on the CMI website in the CMI Medical section (https://www.cmi.gov.cz/mdr). Payment of the fee is a condition for initiating the review of the submitted request.

6.3.1. The Application review

The finalisation of the application, its submission and payment of the fee by the applicant is followed by a formal and factual review of the application by the CMI.

6.3.1.1. Formal review of the application

The formal review of the application includes, in particular, checking that the application review fee has been paid in accordance with the currently valid CMI price list, that the application has been signed by an authorised person of the applicant or an authorised representative, and then checking that the application is complete, i.e. that all criteria that are marked as relevant are accompanied by relevant documents, and that all criteria that are marked as irrelevant are justified. The Contract Administrator may also review the relevance of the documents in the technical file.

If any non-conformities are found, the Contract Administrator may request the applicant to complete and clarify this information through the SW MEDECA. In case of any non-conformities in the documents or in the evidence assigned, the Contract Administrator shall request a correction of the application in the SW MEDECA, which means that the manufacturer is allowed to re-upload the application documentation and assign the evidence as described in Section **Chyba! Nenalezen zdroj odkazů.** of this procedure. In the case of non-conformities directly in the application, the Contract Administrator will request an amendment to the application in SW MEDECA, then the applicant will be able to change the data filled in the Initial Application Form in SW MEDECA as described in Chapter 6.2 of this procedure.

In the event that there is no agreement between the Contract Administrator and the applicant, or if the applicant does not respond to the request to complete the information within the time limit, the Contract Administrator shall close the business case and enter a reason or comment in the SW MEDECA. In addition, the Contract Administrator informs the applicant of the closure of the business case.

6.3.1.2. Review of the scope of the application to verify the ability to implement the contract

The purpose of the scope review is to preliminarily verify the ability of the CMI to perform a conformity assessment of the devices and whether the submitted application meets the relevant MDR criteria, i.e. in particular to verify, using the submitted quality management system documentation, whether the application provides the required information on the manufacturer's quality management system.

Should any information need to be added from the applicant during the application review process, the Contract Administrator will request the applicant to complete the necessary information via the SW MEDECA. The applicant will be required to clarify or provide this information within a specified period (normally 15 days). If the applicant fails to do so even after repeated calls, the CMI will reject the application, notify the applicant of this fact and publish information on the rejection in the EUDAMED electronic system.

Similarly, the Contract Administrator will publish information on any withdrawal of the application by the applicant in the EUDAMED electronic system.

As a result of the above review, the CMI shall conclude whether it is able to carry out a conformity assessment of the medical device in question, given the scope of its appointment and the resources available (in particular human resources).

In the event of a negative result of the application review (i.e. the CMI is not able to carry out the conformity assessment or the applicant has not completed the necessary information within the deadline despite the CMI's request), the Contract Administrator will inform the applicant about the impossibility

to carry out the requested conformity assessment, possibly together with information about the preliminary verification of the qualification and classification of the device or the impossibility to complete the application review due to the failure to provide all the necessary information.

In the case of a positive result of the application review (i.e. the CMI is able to carry out a conformity assessment of a given MD), the rough planning of the project proceeds.

The Contract Administrator shall inform the applicant of the result of the application review, normally within thirty days of the receipt of the application.

6.3.1.3. The rough planning of the project and preliminary suggestion of the project team

As part of the rough planning of the project, a preliminary suggestion of the project team that could assess compliance on a given contract is made. The project team consists of the Medical Device Conformity Assessment Team, the Final Review Committee and the Decision Making Committee.

In the event that CMI finds that it does not have the required human resources, it shall reject the request for objective reasons on the part of the notified body and the Contract Administrator shall inform the applicant of this fact.

6.4. Conclusion of the general contract

In case of a successful review of the application and fulfilment of all requirements by the applicant, the Contract Administrator will prepare a draft of the general contract for medical device conformity assessment. This contract includes a specification of all medical devices to be assessed, together with the selected conformity assessment procedures according to the MDR. The contract shall also include a preliminary estimated price for the conformity assessment service, which is taken from the non-binding quotation on the basis of the preliminary estimated calculation carried out.

This preliminary estimated price may differ from the price specified when signing the implementation contract for conformity assessment, as it is based only on the information supplied with the non-binding inquiry, and therefore without detailed knowledge of the medical device or the complete manufacturer's documentation. At the same time, this price is based on the assumption that the conformity assessment process is carried out in a standard way, the applicant provides the necessary cooperation and has prepared documentation of adequate quality without any nonconformities, and therefore no further additional iterations will be necessary.

The Contract Administrator will then send a draft contract on behalf of the CMI to the applicant for approval and signature, together with information on the further procedure.

The contract is sent in electronic form and signed with certified electronic signatures. If this procedure is not possible, the contract is signed manually.

If there are changes to the standard contract wording as a result of negotiations with the applicant, the Contract Administrator will ensure that the relevant amendments and additions to the standard contract are reviewed by the CMI Legal Department. If no agreement is reached on the wording of the contract and the contract is not concluded, the relationship between CMI and the applicant shall terminate and the provisions of the General Terms and Conditions shall apply. In such a case, the Contract Administrator will simultaneously submit information to EUDAMED.

If the applicant agrees to the draft of the general contract for the medical device conformity assessment, he/she shall sign it. Upon receipt of the signed contract, the Contract Administrator will forward it to the Director of CMI Medical for signature, store it in SW MEDECA for the contract and forward it to the CMI Legal Department for publication on the Register of Contracts.

When signing the general contract, CMI issues an advance invoice to the applicant for 50% of the preliminary estimated price.

The general contract must be signed directly between the applicant and CMI.

6.5. Submission of complete technical documentation

After the signing of the general contract for the medical device conformity assessment, the deadline for the submission of the complete technical documentation by the applicant begins. If the applicant has not submitted it immediately when lodging the application, he/she is obliged to submit it no later than 30 days after the call from the CMI, but no later than one year after the signature of the general contract for the medical device conformity assessment between the applicant and the CMI, unless a different timetable is agreed in the general contract.

The applicant provides the technical documentation according to the procedure described in Section 6.3 of this document.

In the event of non-compliance with these conditions, a sanction will be applied according to the general contract for the medical device conformity assessment, in which case the CMI may terminate the general contract for the medical device conformity assessment. In such a situation, the Contract Administrator will inform the applicant of this fact and submit the relevant information to the EUDAMED database.

When the complete technical documentation is delivered, CMI will issue a tax document, an invoice for 30 % of the preliminary estimated price, to the applicant.

6.5.1. The review of the complete documentation of the application

The formal review of the complete documentation of the application includes, in particular, checking that the application is complete, i.e. that all criteria that are marked as relevant are accompanied by relevant documents, and that all criteria that are marked as irrelevant are justified.

If any non-conformities are found, the Contract Administrator may request the applicant to complete and clarify this information through the SW MEDECA. In case of any non-conformities in the documents or in the evidence assigned, the Contract Administrator shall request a correction of the application in the SW MEDECA, which means that the manufacturer is allowed to re-upload the application documentation and assign the evidence as described in Section 6.3 of this procedure. In the case of non-conformities directly in the application, the Contract Administrator will request an amendment to the application in SW MEDECA, then the applicant will be able to change the data filled in the Initial Application Form in SW MEDECA as described in Chapter 6.2 of this procedure.

In the event that there is no agreement between the Contract Administrator and the applicant, or if the applicant does not respond to the request to complete the information within the time limit, the Contract Administrator shall close the business case and enter a reason or comment in the SW MEDECA. In addition, the Contract Administrator informs the applicant of the closure of the business case.

If the documentation is found to be complete, the submitted documentation will be confirmed to the applicant, and the process of submitting the documentation for assessment will be considered to be complete.

7. Preparing for the conformity assessment process

7.1. Nomination of the project team

The project team consists of the medical device conformity assessment team, the final review committee and the decision making committee.

The design of the team is based on the preliminary personnel proposal that was made during the application review and is recorded in MEDECA software.

7.2. Review of the impartiality and independence of personnel in relation to the project

The review of the impartiality and independence of the proposed project team for a particular project is carried out by the Contract Administrator.

The review of impartiality and independence in relation to the project shall be carried out separately for each nominee and shall consist of a review of information from public sources and any other information obtained.

7.3. Nomination of the project team

Following a review of the impartiality and independence of the personnel on a given project, the nomination of these personnel is made by the Director of CMI Medical.

In the event that CMI does not have the necessary human resources for a given contract, the Procurement Administrator will reject the application for objective reasons on the part of the notified body

7.4. The application review

The Project Leader is responsible for ensuring a detailed review of the application. He/she keeps the Contract Administrator informed of his/her activities.

In the event that at any time during the detailed review of the submitted documentation any of the information provided needs to be supplemented or clarified or additional information needs to be provided, the Project Leader will inform the Contract Administrator who will request clarification or supplementation from the applicant.

In particular, the Project Manager, in collaboration with the designated Conformity Assessment Team and other CMI Medical personnel, will undertake the following steps as part of the detailed review of the documentation:

- Checking the qualification of the product as a medical device
- Checking the classification of the medical device
- Checking the correct assignment of MDR codes/aspects to the medical device
- Verification that the conformity assessment procedure chosen by the applicant is applicable
- Detailed examination of the quality management system documentation
- Detailed examination of the technical documentation
- Prepare a detailed internal project plan

8. Determination of the Specified Estimated Price and conclusion of the Implementation Contract

8.1. Determination of the Specified Estimated Price for the conformity assessment process

The Contract Administrator will calculate the cost of the medical device conformity assessment process and establish a specified estimated price for conformity assessment services.

In particular, the following aspects shall be taken into account when calculating the time volume of the contract:

- the required conformity assessment process,
- the size, organisational structure and number of employees of the manufacturer,
- the number of production sites,
- the number of suppliers and subcontractors of the manufacturer,
- the quantity and classification of the medical devices to be assessed,
- the extent of documentation,
- and other specific aspects of the contract.

In determining the number of audit days, the CMI may rely on the document of the International Accreditation Forum. This document emphasises the specific parameters of the given project, including the size and number of employees of the manufacturer, so that the interests of small and medium-sized enterprises (as defined in the European Commission Recommendation 2003/361/EC) are also respected as far as possible when determining the price. The duration of the audit is normally determined using one auditor. In the event that more than one auditor is involved, the total duration of the audit is reduced accordingly. One audit day corresponds to 8 man-hours of auditor work.

8.2. Conclusion of the Implementation Contract for medical device conformity assessment

Based on the specified estimated price for the conformity assessment process, the Contract Administrator in cooperation with the CMI Legal Department will prepare a draft of the implementation contract for the medical device conformity assessment. The draft contract shall also include the specified estimated price for the conformity assessment and an estimated completion date for the conformity assessment. The General Terms and Conditions shall be an integral part of the contract.

If there is a need to provide additional necessary documents during the certification tasks, or if the documents already submitted are incomplete or incorrect, or if there is a need to clarify any questions, settle disagreements or anything else to supplement or provide cooperation from the applicant, the estimated deadline specified in the Implementation Contract for the medical device conformity assessment shall be adjusted by the time before the applicant provides the requested cooperation.

The specified estimated price for the conformity assessment process is valid if the process is carried out in a standard way, the manufacturer provides proper cooperation and has prepared documentation of adequate quality without any non-conformities. In the event that during the conformity assessment process the notified body incurs additional costs, such as (but not limited to) the need to carry out additional actions due to any non-conformities identified, review of the settlement of these non-conformities, additional rounds of iteration, unexpected consultations with external authorities, the need to subcontract certain actions or tests (e.g. conducting a test in an external laboratory) etc., these costs will be billed on the basis of an amendment to the contract, according to the product of the relevant hourly rates indicated in the current valid published CMI price list and the number of actual hours necessary to perform the acts in question.

The ultimate final price is thus only known at the full completion of the conformity assessment and corresponds to the actual scope of all services provided by CMI.

The Contract Administrator will then send a draft contract on behalf of the CMI to the applicant for approval and signature, together with information on the further procedure.

The contract is sent in electronic form and signed with certified electronic signatures. If this procedure is not possible, the contract is signed manually.

If there are changes to the standard contract wording as a result of negotiations with the applicant, the Contract Administrator will ensure that the relevant amendments and additions to the standard contract are reviewed by the CMI Legal Department. If no agreement is reached on the wording of the contract and the contract is not concluded, the relationship between CMI and the applicant shall terminate and the provisions of the General Terms and Conditions shall apply. In such a case, the Contract Administrator will simultaneously submit information to EUDAMED.

If the applicant agrees to the draft of the implementation contract for the medical device conformity assessment, he/she shall sign it. Upon receipt of the signed contract, the Contract Administrator will forward it to the Director of CMI Medical for signature and store it in SW MEDECA for the contract.

When signing the implementation contract, CMI will issue another tax document to the applicant, an invoice for 20% of the preliminary estimated price. This will set off the full amount of the advance against the advance invoice.

9. Final provisions

This procedure is permanently available to the public via the CMI website in the CMI Medical - Medical Device Certification Centre section.

This procedure is binding for all employees of the CMI Medical - Medical Device Certification Centre.