METHODOLOGICAL INSTRUCTION

Procedure for submitting an application for a medical device conformity assessment

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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 a request 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 request 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.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 communications between applicants and CMI. Applicants may send their questions either to the e-mail address medical@cmi.czor 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.cz/mdr)

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

According to the legislation, CMI may not provide consultancy services to conformity assessment applicants. Therefore, questions of this type cannot be answered.

3. Obligation to register manufacturers and authorised representatives

Before submitting a request 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. This number is then used as an identifier for communication with the CMI.

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 Non-binding inquiry form (P01_880-MP_C002), which is Annex 1 to this procedure and which is published together with it on the CMI website in the CMI Medical - Medical Device Certification Centre section (https://www.cmi.cz/mdr).

Once all the information in the Non-Binding Inquiry Form has been duly and truthfully filled in and the form is signed by the responsible person, the applicant shall send it (together with the required attachments) to the CMI, either by email to medical@cmi.cz or via the CMI data box (the data box number can be found on the Non-binding inquiry form (P01_880-MP_C002).

Contract Administrator, in cooperation with the appropriate CMI Medical personnel, will review the non-binding inquiry and connected information and documents in accordance with internal procedures. This review will include, inter alia, a check of the information provided, initial brief verification of the product qualification and classification and verification of the correctness of the MDR codes assigned. In addition, the CMI will evaluate the medical device with respect to the scope of its appointment and make a preliminary determination as to whether it is authorised to assess compliance for the medical device and whether it has sufficient capacity to do so.

If necessary, the Contract Administrator will request additional information from the applicant.

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.

If CMI concludes that it cannot carry out the conformity assessment for a given medical device for any reason, the Contract Administrator will inform the applicant of this fact.

5.2. Sending a non-binding offer to the applicant

If the CMI can carry out a conformity assessment for a given medical device, the Contract Administrator will prepare a non-binding quotation for conformity assessment services for the applicant, based on the non-binding inquiry received. This non-binding offer shall include, in particular, a preliminary estimated price for the conformity assessment. This quotation will then be sent back to the applicant by the Contract Administrator at the provided contact address.

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.

6. Procedure for submitting a request for conformity assessment

6.1. Completing the request form on the website

Following the receipt of a non-binding quotation (which CMI has prepared based on a non-binding inquiry submitted by the applicant), the applicant may submit a formal request for conformity assessment to the CMI.

At the same time, the applicant may not submit the same request for conformity assessment for the same medical device simultaneously with another notified body (see MDR, Article 53, paragraph 1). If the manufacturer has done so and the date of submission to CMI is later than the date of submission to the other notified body, CMI will reject such request and inform the applicant of this fact through the Contract Administrator.

The applicant shall start the request process by completing, signing and submitting the relevant electronic request form (according to the templates provided in the documents "Request for assessment of the quality management system" P02_880-MP_C002 (Appendix No. 2 of this procedure) and "Request for assessment of technical documentation" P03_880-MP_C002 (Appendix No. 3 of this of the procedure) which can be found on the CMI website in the CMI Medical - Centre for Certification of Medical Devices section (https://www.cmi.cz/mdr)). The request shall include complete and truthful information and all documentation required in accordance with the MDR Regulation and the instructions mentioned above. The request must contain the information and declarations of the manufacturer required by the chosen conformity assessment procedure according to Annexes IX to XI of the MDR and shall be signed by an authorised person of the applicant using a qualified electronic signature. In case it is not possible to use the electronic form on the CMI website for the submission of the request, the applicant shall submit the signed request via a data box.

According to the requirements of the MDR, the applicant shall submit one or more requests 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 a request for assessment of the technical documentation for the medical device in addition to the request for assessment of the quality management system).

Based on the request form received, the Contract Administrator will assign it a registration number (which will be used for subsequent communication between CMI and the applicant). He/She will also check whether the applicant has been assigned an SRN, whether he/she has submitted an identical request to another notified body and whether he/she has fulfilled the registration obligation regarding the entry of information about the medical device into the UDI database (if applicable) so that the medical device in question has been assigned a UDI-DI. If any of these obligations are not fulfilled, the Contract Administrator shall inform the applicant of this fact.

If the form is duly completed and all the above-mentioned obligations are fulfilled, the Contract Administrator accepts the form and files the official request in the MEDECA electronic software system, uploading the previously received documents at the same time. He/She will then generate the applicant's login details for this system and send them to the contact email address provided.

Further procedure, including mutual communication, is then carried out via MEDECA software.

6.2. Login of the applicant to the MEDECA software system and finalization of the request

After receiving the login details, the applicant will make the first login to the MEDECA software system. 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.

Furthermore, the applicant will be asked by the Contract Administrator to provide part of the documentation in accordance with the chosen conformity assessment procedure and to finalise the submission of the request. In this part, the applicant shall further follow the instructions given. In the MEDECA software, the applicant has access to the user manual or can ask questions related to the MEDECA software.

Once the applicant has finalised the request, the Contract Administrator will enter this information into the EUDAMED database.

As for the technical documentation, the applicant has the option to either attach it immediately when submitting the request or use the extended deadline for its 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.

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.cz/mdr). Payment of the fee is a condition for initiating the review of the submitted request.

6.3. Review of the request and signature of the general contract for medical devices conformity assessment

The finalisation of the request, its submission and payment of the fee by the applicant, is followed by a review of the request by the CMI in accordance with its internal procedures. This review includes, in particular, a formal check of the completeness of the request, a check of the qualification and classification of the product, an assessment of the ability to assess the conformity of the medical device with respect to the scope of the CMI designation and its capacity, and then a rough planning of the project.

Should any information need to be added from the applicant during the request review process, the Contract Administrator will contact the applicant, either through the MEDECA software or at the contact information provided by the applicant.

If the request is successfully reviewed and all requirements are met by the applicant, the Contract Administrator on behalf of CMI will send the applicant a draft of the general contract for medical device conformity assessment. This contract must then be signed directly between the applicant and CMI.

7. Requirements for each type of conformity assessment request

This chapter lists the requirements for each type of conformity assessment request that an applicant may submit to the CMI. The three types of requests are as follows:

- Request for assessment of quality management system according to MDR, Annex IX, Chapter I and III
- Request for assessment of the technical documentation according to MDR, Annex IX, Chapter II
- Request for assessment based on product conformity verification – production quality assurance according to MDR Annex XI, Part A

7.1. Request for assessment of quality management system

The request for assessment of the quality management system according to MDR, Annex IX (2.1) shall include:

- the name of the manufacturer, its SRN and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the

manufacturer's request is lodged by its authorised representative, the name of the authorised representative and the address of the authorised representative's registered place of business,
- all relevant information on the device or group of devices covered by the quality management system,
- a written declaration that no request has been lodged with any other notified body for the same device-related quality management system, or information about any previous request for the same device-related quality management system,
- a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure,
- the documentation on the manufacturer's quality management system,
- a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under MDR and the undertaking by the manufacturer in question to apply those procedures,
- a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,
- the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92,
- a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,
- documentation on the clinical evaluation plan, and
- a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

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 request. 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.

7.1.1. Quality management system documentation

The documentation to be submitted for the assessment of the quality management system must fulfil all requirements in accordance with the MDR Regulation. According to Annex IX, Section 2.2 of the MDR, the documentation shall include an adequate description of, in particular:

- the manufacturer's quality objectives,
- the organisation of the business and in particular:
    - the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority,
    - the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform,
    - where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of

monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party, and
    - where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate,
- the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:
    - the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,
    - identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account,
    - risk management as referred to in Section 3 of Annex I,
    - the clinical evaluation, pursuant to Article 61 and Annex XIV, including post-market clinical follow-up,
    - solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,
    - solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I,
    - the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture, and
    - management of design or quality management system changes,
- the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents; and
- the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place,
- the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in chapter 7.2. of this document.

7.2. Request for assessment of the technical documentation

The assessment of the technical documentation is carried out for those medical devices to be assessed in accordance with the MDR, Annex IX, Chapter II.

The applicant shall submit to CMI, together with the Request for assessment of technical documentation, the Request for assessment of quality management system (see chapter 7.1. of this document)

The Request for assessment of the technical documentation must include:

- description of the design, manufacture and performance of the medical device
- technical documentation as referred to in Annexes II and III of the MDR

7.2.1. Technical documentation

The technical documentation must meet all the requirements of the MDR and in particular comply with the general safety and performance requirements of Annex I of the MDR and be prepared in accordance with Annexes II and III of the MDR.

According to Annex II of the MDR, the technical documentation must contain at least the following items:

1) Device description and specification, including variants and accessories
   - Product name;
   - All trade names of the device;
   - General description of the device;
   - Intended purpose;
   - Intended user's profiles;
   - The Basic UDI-DI (if applicable);
   - all additional UDI-DI;
   - intended patient population;
   - medical conditions to be diagnosed, treated and/or monitored;
   - or patient selection criteria / indications;
   - contra-indications;
   - warnings for user;
   - principles of operation of the device and its mode of action, scientifically demonstrated if necessary (i.e. with evidence of relevant tests and/or references to scientific publications);
   - the rationale for the qualification of the product as a device;
   - the risk class of the device;
   - justification for the classification rule(s) applied in accordance with Annex VIII of the MDR;
   - an explanation of any novel features;
   - a description of the accessories for a device;
   - a description of other devices, which are intended to be used in combination with it;
   - a description of other products that are not devices, which are intended to be used in combination with it;
   - complete list of the various configurations, modifications, variants and models of the device;
   - a general description of the key functional elements (e.g. its parts, components, software, formulation, composition, qualitative and quantitative composition) and where appropriate, labelled pictorial representations (e.g. diagrams, photographs and drawings) including sufficient explanation to understand the drawings and diagrams;
   - a description of the raw materials incorporated into key functional elements;
   - a description of the raw materials making either direct contact with the human body or indirect contact with the body, (e.g., during extracorporeal circulation of body fluids);
   - technical specifications, such as features, dimensions and performance attributes, of the device and any variants, modifications, configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications;
   - an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;
   - an overview of identified similar devices available on the Union or international markets, where such devices exist;
2) Information to be supplied by the manufacturer
   - A description and examples of all labels on the device (including all language variants and target Member States)
   - A description and examples of all labels on the packaging, such as single unit packaging, sales packaging and transport packaging (including all language variants and target Member States);
   - the instructions for use (including all language variants and target Member States);
3) Design and manufacturing information
   - Sufficient information to allow the design stages applied to the device to be understood
   - Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing;
   - identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed;
4) General safety and performance requirements

- A list of the general safety and performance requirements (GSPR) applied to the device (check-list)
- for each GSPR not applied by the manufacturer, a sufficient justification for that decision;
- for each GSPR not applied by the manufacturer, method or methods used to demonstrate conformity with each the GSPR (including justification, validation and verification of the solution);
- the harmonised standards, CS or other solutions applied;
- For each GSPR applied by the manufacturer, the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements (the information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation);

5) Benefit-risk analysis and risk management
   - the benefit-risk analysis
   - the risk management plan;
   - the risk management system;
   - the solutions adopted and the results of the risk management;
6) Product verification and validation
   - the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of the MDR;
7) Pre-clinical evaluation
   - Pre-clinical evaluation plan or other relevant document(s) demonstrating that the manufacturer has adequately addressed
     - the planning, conduct, assessment and, where appropriate, updating and reporting of the pre-clinical evaluation
     - the nature and duration of body contact and the specific associated biological risk;
     - the interface with the risk management process;
     - the appraisal and analysis of the available pre-clinical data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I (GSPR);
   - the scientific pre-clinical literature search or other relevant document(s) demonstrating an evaluation of the published literature applicable to the MD or similar MDs (separate comprehensive document or individual sub-evaluations as part of the planning of specific trials);
   - results of tests regarding the pre-clinical safety of the device and its conformity with the specifications, to the extent of the performed plan, i.e. results of:
     - engineering and laboratory tests;
     - simulated use tests;
     - animal tests;
   - detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:
     - the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;
     - physical, chemical and microbiological characterisation;
     - electrical safety and electromagnetic compatibility;
     - software verification and validation;
     - stability, including shelf life;
     - performance and safety;
   - where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council shall be demonstrated;
   - Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision;

- where applicable, details of the testing carried out to the extent of the preceding bullets, documenting the additional information required in specific cases within the meaning of Section 6.2 of Annex II MDR, if relevant to the MD;
- Pre-clinical evaluation report or other relevant document(s) summarising the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of the MDR and in particular the applicable general safety and performance requirements (GSPR) demonstrating the manufacturer's conclusions on the overall preclinical safety of the MD in relation to the plan carried out

8) Clinical data
   - Manufacturer's documents relating to clinical evaluation and its conduct procedures (both for initial conformity assessment and on an ongoing basis) demonstrating that the manufacturer has adequately addressed:
     - the planning, conduct, assessment and updating of the clinical evaluation as referred to in Annex XIV and reporting on clinical evaluation
     - post-market surveillance and PMCF,
     - the interface with the risk management process,
     - the appraisal and analysis of the available data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I (GSPR),
     - the conclusions drawn with regard to the clinical evidence and drawing up of the clinical evaluation report.
   - therefore at least corresponding to:
     - the clinical evaluation plan and the clinical evaluation report (their original version and any updates) referred to in Article 61 and Annex XIV, Part A, including all relevant data/documents, such as:
       - documentation of author(s) qualifications
       - the methodology and documentation for the literature search – a document of a systematic review of the literature identifying available clinical data related to a given PI and its intended purpose and any deficiencies in the clinical evidence;
       - evaluation of the state-of-the-art;
       - documentation relating to clinical investigations referred to in Annex XV (all clinical investigation plans and reports, ethics committee approval, competent authority approval, justifications in relation to non-performance of clinical investigations) or sufficient demonstration of equivalence
   - the post-market clinical follow-up (PMCF) plan and post-market clinical follow-up report according to Annex XIB, part B or justifications in relation to non-performance of PMCF
   - appropriate documentation in specific cases, such as the procedure under Article 54, the procedure under Article 61(2), and the procedure under Article 61(10).

   The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, and manufacturers can therefore be recommended to use them (e.g. relevant MDCG documents for clinical investigations and clinical evaluation).

9) Additional information required in specific cases according to Section 6.2. of Annex II of the MDR
   - In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I, the justification referred to in Section 10.4.2 of that Annex;
   - In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps;
   - In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility (the validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues);

- In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications;
- If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer;

10) A draft of an EU declaration of conformity in accordance with Article 19 and Annex IV;

In addition, the technical documentation shall contain items relating to post-market surveillance according to Annex III of the MDR:

1) A post-market surveillance plan shall cover at least:
   - proactive and systematic process to collect following information (this process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market):
     - information concerning serious incidents, including information from periodic safety update reports (PSURs), and field safety corrective actions (FSCA)
     - records referring to non-serious incidents and data on any undesirable side-effects;
     - information from trend reporting;
     - relevant specialist or technical literature, databases and/or registers;
     - information, including feedbacks and complaints, provided by users, distributors and importers; and
     - publicly available information about similar medical devices;
   - effective and appropriate methods and processes to assess the collected data;
   - suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management;
   - effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;
   - methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;
   - methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;
   - reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86 of the MDR;
   - systematic procedures to identify and initiate appropriate measures including corrective actions;
   - effective tools to trace and identify devices for which corrective actions might be necessary;
   - PMCF plan as referred to in Part B of Annex XIV of the MDR, or a justification as to why a PMCF is not applicable;
2) The periodic safety update report PSUR referred to in Article 86 of the MDR (or post-market surveillance report for class I devices referred to in Article 85 of the MDR) shall cover at least:
   - Summary of the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan
   - a justification and description of any preventive and corrective measures taken in accordance with the point above;
   - the conclusions of the benefit-risk determination;
   - the main findings of the PMCF;
   - the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device;
3) The draft of the summary of safety and clinical performance referred to in Article 32 of the MDR (only for class III devices and implantable devices).

7.3. Request for assessment based on product conformity verification

The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an EU type-examination certificate has been issued

Conformity assessment based on product conformity verification – the product conformity verification procedure shall apply, within the scope of the CMI designation, only to risk class I devices placed on the market in a sterile condition, with a measuring function or for reusable surgical instruments, as well as to class IIa medical devices (for this risk class the procedure according to MDR, Annex XI, Part A, Section 10 will be applied).

The manufacturer shall lodge a request for assessment of its quality management system with a notified body – see chapter 7.1. of this document.

The request for assessment of the quality management system must be accompanied by:

- Quality management system documentation according to the MDR, Annex IX, Section 2.1.
- Technical documentation (for class IIa medical devices) according to the MDR, Annexes II and III.

8. 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.