MDR DOCUMENTATION SUBMISSION

Annex IX section 2.1. of MDR requests submission of several documents during application.

The aim of our guidance is to clarify the way of submission to promote the conformity assessment procedure.

Application: Sending back the accepted Price Offer with the required documents to CE Certiso Kft

1. QMS documentation

Application and submitted documentation shall contain the following:

- the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative, the name of the authorised representative and the address of the authorised representative's registered place of business, and the SRN if applicable

- all relevant information on the device or group of devices covered by the quality management system,

Note: in practice the technical documentation(s)

- a written declaration that no application has been lodged with any other notified body for the same device related quality management system, or information about any previous application 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 the 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.

2. Technical documentation

Content of the technical file is determined in **Annex II of the MDR**.

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a **clear, organised, readily searchable and unambiguous** manner.

CE Certiso Kft request in each case – initial certification, correction, surveillance, renewal, change notification etc. – **submission of a complete technical file**.

3. Route of submission

CE Certiso Kft approves **exclusively** documentation **uploaded** into its own system. For secure upload please request a link at link@cecertiso.hu.

4. Document format

CE Certiso Kft approves documentation in **Hungarian** or in **English**.

You are kindly requested to add a **table of content** to the technical file. Documents shall be submitted in a **fully searchable (bookmarked) pdf** file format. We request to transform the scanned documents using **OCR**. Size of files should not be more than 2 GB for expedite upload.

Technical file is requested to be **collated according to main sections** of Annex II (ie into 6 folders).

Pages containing **signature**s (like technical file, CER, risk management file etc.) are requested to be submitted in a separate folder, also in pdf.

5. Other documents

Before the **on-site audit** CE Certiso also requests the submission of the following documents:

- record of management review
- internal audit report

When submitting documentation verifying a **corrective action of an on-site audi**t you are kindly requested to name the folder as the ID of the nonconformity (like 1_2020_CE).

In case a **consultation** procedure is required for the certification of the product you are kindly requested to upload the documentation to be forwarded to the Competent Authority in a separate folder as well (title of folder: 6.2.a, 6.2.b, 6.2.c or Expert panel).

Note: CE Certiso is not designated for human origin substances

SSCP, PSUR: title of the folder shall contain the document and the year (like SSCP_2022)

Implant cards shall be added to Folder 2 of the technical documentation.

6. Vigilance:

Manufacturer incident reports (MIR) are requested to name unambiguously