XCDC Trading & Consultancy B.V.B.A.
Veldstraat 57
B-8780 Oostrozebeke
BTW nr. : BE 0524 895 308

TECHNICAL FILE

In conformity with MDD93/42/EC

(Amended by 2007/47/EC)

For the Directive Medical Devices, the manufacturer must always draw up a technical design and Construction file.

The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

- A general description of the type, including any variants planned
- Design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits, etc.
- The descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product
- A list of the (harmonized) standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards have not been applied in full
- The results of the design calculations
- The risk analysis
- A quality plan / inspection plan
- The investigations, technical tests, etc. carried out
- A statement indicating whether or not the device incorporates, as an integral part, a substance as referred to in Section 7.4 of Annex I and data on the tests conducted in this connection,
- The clinical evaluation (annex X of the directive)
- The draft label
- The instructions for use.
- The EC Declaration of conformity

We can assist you with the preparation and validation of your technical files. Don’t hesitate to contact us.