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

QUALITY ASSURANCE SYSTEM

In conformity with MDD93/42/EC (Amended by 2007/47/EC)

Based on the standard EN ISO13485 (2012)

Depending on the classification of the medical device, the manufacturer may choose to establish and implement a quality assurance system. The system should describe the following elements:

a) The manufacturer's quality objectives
b) The organization of the business and in particular:
   - the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,
   - the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform.
c) The procedures for monitoring and verifying the design of the products and in particular:
   - a general description of the product, including any variants planned
   - the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,
   - the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,
   - if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer
   - 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 data referred to in Annex X
   - the draft label and, where appropriate, instructions for use.

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d) The inspection and quality assurance techniques at the manufacturing stage and in particular:
   - the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents
   - the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture.

e) He appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

For the establishment of the Quality Assurance System for Medical Devices, reference is made to the **harmonized standard EN ISO13485**. A quality system in accordance with this standard gives you a manufacturer automatically a "presumption of conformity" with the requirements described here above.

We can assist you with the establishment, implementation and certification of your Quality Management System. Do not hesitate to contact us.