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8 steps of European Medical Device Directive Conformity Assessment Process

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1. Understand what a medical device is

A medical device is an apparatus, instrument, in vitro reagent, implant or similar or related article that is used to diagnose or treat disease or prevent diseases or certain other conditions, and does not attain its purposes through chemical action within or on the body (which would make it a drug). The Medical Device Directive is applicable to medical devices and its accessories. All medical device accessories must also be compliant with the MDD.

2. Classification of Medical Device

The conformity estimation route is ascertained by the categorization of the medical device by a manufacturer. One of the important differences of conformity assessment is whether you require a Notified Body to conduct the assessment or you may proclaim your conformity by self evaluation.

3. Components of Conformity Assessment Routes

Conformity assessment routes must comprise the following activities: Annex II EC Conformity Declaration: Full Quality Assurance System, Annex III EC Type Examination, Annex IV EC Verification, Annex V EC statement of Conformity: Production Quality Assurance, Annex VI EC statement of Conformity: Product Quality Assurance, The classification of laws depends on the terms related to duration of contact with the patient, amount of invasiveness and the part of the body harmed by the use of the device. A manufacturer must make the classification with the assistance of a notified body when necessary.

4. Ascertain Conformity Assessment Route

Only Class I devices (except for sterilizing or with measuring function) are self-declared by the manufacturer without involvement of a notified body.

5. Weigh Devices With Essential Requirements

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All medical devices despite their classification must meet the terms with the Essential Requirements of the Medical Device Directive. This is a significant procedure in the CE Marking process. The important requirements of the Medical Device Directive are contained in Annex I of the MDD. The Essential Requirements are described in general by listing principles such as: General Requirements, No. 1~6, Requirements with regards to Design and Construction, Physical, Biological and Chemical properties: 7.1~7.6, Infection and contamination by other micro organisms. 8.1~8.7 and many more.

6. European Harmonized Standards

The general requirement lays down critical principles of the safety and efficacy of a medical device in a general way. The manufacturer shall ascertain proper technical supplies of its medical device to show the conformity. The European Union provides a list of coordinated Standards for medical device manufacturer reference. The application of European Harmonized Standards is not pushed it is voluntary. The conformity with EU Harmonized Standard is supposed to please the applicable General Requirements.

7. Technical Documentation

After assessing your medical device based on Essential Requirements, you must bring together a Technical Documentation as per Annex VII to prove its conformity. Technical Documentation must be given to European Representative and make it readily available for Competent Authority for post market supervision purpose. The Technical Documentation must be made ready at least 5 years after the medical device is manufactured.

8. Vigilance System

The manufacturer must set up a vigilance system to evaluate experiences collected from post-production phase. Preventive and corrective actions must be taken as and when necessary

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