The Technical File of Medical Devices

What is a Technical File?

The Directive on Medical Devices (Dir. 93/42/CEE revised by Dir. 2007/47/CE) often mentions in its annexes the "documentation" which the manufacturer has to prepare to demonstrate that the Medical Device (MD) complies with the Essential Requirements imposed by the Directive. The content of such documentation depends on the type of MD and on what the manufacturer considers necessary, from a technical point of view, to prove such compliance.

The Directive's articles, though, do not provide a definition for this group of documents, thus they are conventionally referred to as "Technical File" (TF) or "Technical Documentation".

Indications on the content of the TF are available in the Recommendation NB-MED/2.5.1/Rec5 "Technical Documentation" by the Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

What should a TF include?

As a general rule, the TF should at least provide indications on design, manufacturing and intended use of the MD, but it usually includes several other characteristics about installation, preparation for use, pre-usage checks as well as maintenance and calibration according to the peculiar type of MD involved. The description of the MD, engineering drawings, technical specifications, materials used and methods of manufacturing play an essential role in the documentation of the TF.

It is also crucial to define the intended use, classification, functional features, shelf life and/or expiration date of the MD, as well as the exact indication of models and compatibility, the description of interfaces with other connectable devices and of packaging and instructions for use. Moreover, the TF should include schemes of design and of component parts, engineering drawings, methods of manufacturing, manufacturing processes and procedures involved.

These aspects do not make a TF complete, since it varies according to the type of MD and to what the manufacturer holds as necessary to demonstrate its compliance with the Essential Requirements.

How is conformity guaranteed?

The essential safety requirements that any MD must meet are listed in Annex I of the Directive. For reasons of completeness, the manufacturer fills out a Table of Correspondence with the Essential Requirements where all requirements are proved to be fulfilled. Such demonstration lies on argumentations that can only be provided by the manufacturer given its better acquaintance with the MD. The manufacturer often issues a rationale and/or declares the application of "harmonized" technical norms, allowing to presume the compliance of the MD with the requirements of the harmonized norm without no need of any further argumentations.

If the manufacturer demonstrates the conformity of the MD to the Essential Requirements, is the device supposed to be considered safe?

Conformity to the Essential Requirements of the Directive is mandatory for the manufacturer, but it does not guarantee that there aren't any risks for patients' health or safety of the operator. The manufacturer must, in fact, prove to have evaluated and eliminated – or at least reduced to an acceptable level – the risks involved in the use of the MD compared to the benefits it produces. On this purpose, the manufacturer issues a further document, included in the TF, known as "Risk Assessment" where he individuates, estimates, evaluates and demonstrates to have kept under control the risks carried by the MD. The manufacturer also has to set up a procedure to update the Risk Assessment as part of a "Risk Plan" by taking into consideration the information coming from the market after the MD has been launched.

Does the Directive 2010/37/CE on MD introduce some novelties as far as the preparation of the TF is concerned?

Directive 2007/47/CE became mandatory from 21st March 2010, without any provision for a transitional period. Therefore, MDs put in commerce or in service after this date must already satisfy the requirements of the revised directive. Amendments made to the directive relate to the Essential Requirements to be met by the MD in order to be legally put on the market, to the corresponding procedures of conformity assessment and to the classification of the devices.

For example, the requirement to specify the final user of the MD has been introduced. Manufacturers are required to prepare detailed instructions for use for their devices, considering competences and know-how of the final users. This is particularly important for MDs intended for non-professional use.

The new directive underlines the need to provide clinical evidence for all devices, included Class I devices. This means more strict requirements as for what constitutes a "clinical evidence". Annex X on clinical evaluation has been revised: manufacturers now have to check the clinical evaluation report in their TF to find any features of the MD that need further investigation from a clinical point of view. This check is to be included in the Risk Assessment document both at the stage of design but also after the device has been placed on the market, in order to keep technical data up-to-date with the "state of the art". In fact, demonstration of conformity of a MD also requires to apply a procedure for re-examination of the product after its sale on the market, with mandatory report of accidents or calling in of the device to the authorities. Clinical data may come, for instan-

ce, from the following sources: a) clinical investigation conducted for the device; b) clinical investigation or other studies published in scientific literature, concerning similar devices that will need proof of equivalence in any case; c) reports published on other clinical procedures related to the device or other similar devices whose equivalence can be demonstrated.

Ergonomic design is now considered as an Essential Requirement of the MD to guarantee patient's safety. Ergonomic features of medical products are becoming a central point in the development process. Particular care is necessary to ensure that re-usage of MD does not carry any risks for patients' health and safety. Therefore, manufacturers of single-use MD must provide all information on known features and technical factors that may involve a risk should the device be used more than once.

Directive 2007/47/CE also indicates that the software, when specifically intended by the manufacturer to be used for one or more of the medical purposes included in the definition of MD, must be considered as a MD. So the software must be approved according to the state of the art, with regards to the principles of the development cycle, risk management, validation and verification. Moreover, software that is considered as a MD must be classified according to the classification rules defined by the directive 93/42. Stand-alone software is considered as an active MD (Annex IX, rule 1.4). For instance, software operating on PCs or Smartphones, allowing to make diagnosis (telemedicine application) or intervening on a therapeutic level (such as simulation of surgical implants) are now considered as active diagnostic or therapeutic devices. Consequently, stand-alone software must bear CE mark to prove its compliance with the provisions of the directive in order to circulate without limitation within the European Community and to be put into service according to their intended purpose.

For further information and legal consultancy on CE certification:
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