GENERAL APPROACH IN DEVELOPING TECHNICAL DOCUMENTATION OF A MEDICAL DEVICE

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***Abstract**: In the following report are shown the main criteria for development of a Technical documentation for a medical device according to Council Directive 93/42/EEC. A general approach is presented as a result of a systematisation of the requirements of the European technical legislation. This approach can be used as a base for developing the technical documentation of all classes of medical devices.*

Key words: EUROPEAN TEHCNICAL LEGISLATION, TECHNICAL DOCUMENTATION, MEDICAL DEVICE, ESSENTIAL REQUIREMENSTS, CLASSIFICATION

1. Introduction

The contemporary development of the medical science goes in parallel with the new technology and instrumentation that is used to examine or treat conditions of the human health. Because medicine has a lot of branches, and health conditions of the human body differ in a great variety, so does the number of Medical devices (MD).

After joining the European Union (EU) all countries are obliged to incorporate the European technical legislation in their own law systems. Industrial manufacturers must meet all the requirements for their products that are described in the directives and regulations.

MDs are not an exception and they are categorized as industrial products that should have characteristics that meet the safety requirements stated in the directives:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
OJ L 169 of 12 July 1993;

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
OJ No L 189 of 20 July 1990;

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
OJ L 331 of 7 December 1998

The responsibility of the manufacturer is to justify the safety of its product according to the mandatory requirements given in the above mentioned directives. This justification is called conformity assessment and is done by developing and collecting full documentation to which the legislator gives the name: Technical documentation (TD). The basic content of TD is described in the chapters of the directives. The manufacturer of MD can easily choose under which directive falls the product according to its general purpose.

The majority of MD falls under the directive Council Directive 93/42/EEC . The MD manufacturer should provide conformity assessment and prepare TD according to all the essential requirements that are presented.

The basic and common requirements for the content of TD are:

- Basic description of the product
- Technical drawings and specification of the product's assembly and parts.
- Descriptions , explanations of the drawings and specifications
- List of harmonized standards used
- Results of calculations and tests
- Examination protocols

2. Main chapters and annexes of Council Directive 93/42/EEC that have tight relation to the design of the structure of the TD

The process of designing the specific structure of TD of MD isn't described by the EU legislator and is an obligation of the manufacturer to find the most adequate approach in its development. The purpose of this report is to stress upon the main chapters (Annexes) of Council Directive 93/42/EEC that give the most specific requirements of the content for a TD and their interrelations that describe a path leading the process of TD development.

2.1 Classification of MD

The first step in the design of TD of MD is to make a classification of the MD. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX. Following the basic rules the MD should answer the questions [3]:

- how long the device is intended to be in continuous use
- whether or not the device is invasive or surgically invasive,
- whether the device is implantable or active
- whether or not the device contains a substance, which in its own right is considered to be a medicinal substance and has action ancillary to that of the device.

2.2 Essential requirements.

[1]The devices must meet the essential requirements described in Annex I which apply to them, taking account of the intended purpose of the devices concerned. [2]Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to this Directive.

2.3 EC TYPE-EXAMINATION

According to the procedures of conformity assessment described in Article 11 of [1] the manufacturer should follow the procedure relating EC TYPE-EXAMINATION in Annex III of the [1]. All classes of MD except Class I have to include notified body in the conformity assessment of their MD. [4] EC TYPE-EXAMINATION may be carried out in the following manners: assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design
type).

Point 3. Of Annex III of [1] gives the following description of the documentation to be include in TD:

— 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 standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full,

— The results of the design calculations, risk analysis, 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 data referred to in Annex X,

— The draft label and, where appropriate, instructions for use.

2.4 TD of Class I MD

Class I MD is the only class of product, which conformity assessment can be carried out without the participation of a notified body. As [1] states: “In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.”

The list of documentation for this case is described from [1] as follow in annex VII p.3:

— A general description of the product, including any variants planned,

— Design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.

— The descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operations of the product,

— the results of the risk analysis and a list of the standards referred to in Article 5 , applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full,

— In the case of products placed on the market in a sterile condition, description of the methods used,

— the results of the design calculations and of the inspections carried out, etc.; 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,

— The test reports and, where appropriate, clinical data in accordance with Annex X,

— The label and instructions for use.

3.Design of a systematic path in a flowchart description for developing a TD of a MD

After studying the chapters and annexes of [1] a systematic approach has been built to relate the MD characteristics and purposes to the requirements in [1] a step by step system is presented as a flowchart in Fig.1. The scheme in fig.1 has the same expression as in [2] but is unique in its purpose.

Step 1. Decision made by the manufacturer of MD, which directive (93/42/EEC; 90/385/EEC; 98/79/EEC) should be approached.

Step 2. Applying the rules in Annex IX Classification

Step 3. Choosing the class of the MD

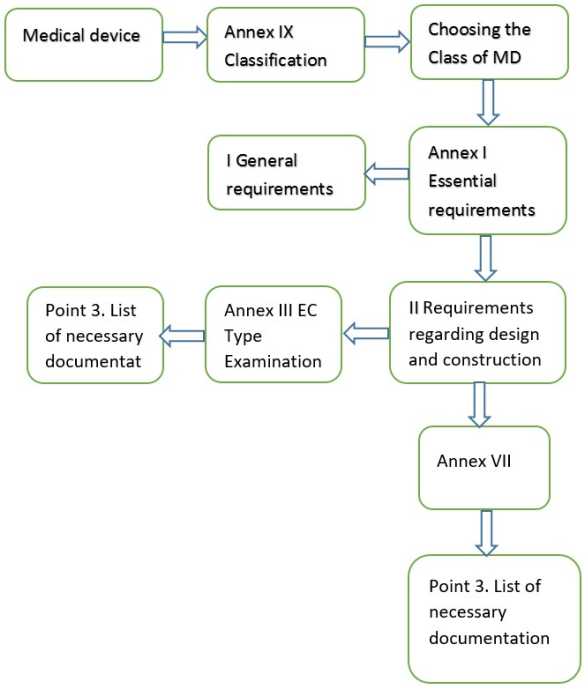
Step 4. Examination of essential requirements in Annex I and selecting the one applicable with the class of the MD.

Step 5. Selecting and applying the specific requirements of the MD in design and construction in p.II Annex I

Step 6 .Developing the documentation listed in Annex III EC-Type examination

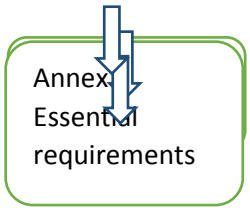
Step 7. Developing the documentation listed in Annex VII p.3 – List of necessary documentation.

Fig.1 *flowchart description for developing a TD*



4.Conclusion

The systematic approach shown as “flowchart description for developing a TD” in Fig.1 is designed on a very basic conceptual level that underlies the concrete requirements that could be changed during the years to follow. It gives a firm base upon which a proper Technical documentation of a medical device can be developed.



5.Refferences:

[1] Council Directive 93/42/EEC

[2] http://www.ce-marking.com/medical-devices.html (visited in 22.11.2016)

[3]https://www.emergogroup.com/resources/regulations-europe/regulations-EU-MDD93-42-EEC (visited in 22.11.2016)

[4] http://www.icqc.co.uk/en/EC-type-examination.php (visited in 22.11.2016)