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REGULATIONS IN THE FIELD OF USING MEDICAL DEVICES. OVERVIEW

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Abstract: *Medical devices are medical-technical products of great complexity in terms of the patients health, of functionality and constructiveness. They are built in a wide range of categories, groups of categories and typo dimensions. They are used worldwide on a wide variety of patients: children, youth, adults, elderly, both men and women. In this context, the paper offers the definitions of medical devices, presented at an international level. Also presents in a systemic manner issues regarding basic rules from the field of using medical devices, developed at an international level. The book is useful for specialists and those interested in this field.*
Keywords: *medical device, medical diagnostics, directive, classification*

1. INTRODUCTION

Medical devices are medical technical-products particularly complex, from sophisticated computers to lingual wooden spatulas [30], important for the health and behavior of humans and living beings in general [1]. They have a very important role in any medical diagnosis (Fig.1). The action of a medical device is specific and personalized, differing from that of a drug, meaning that it is not metabolic, immunological or pharmacological.

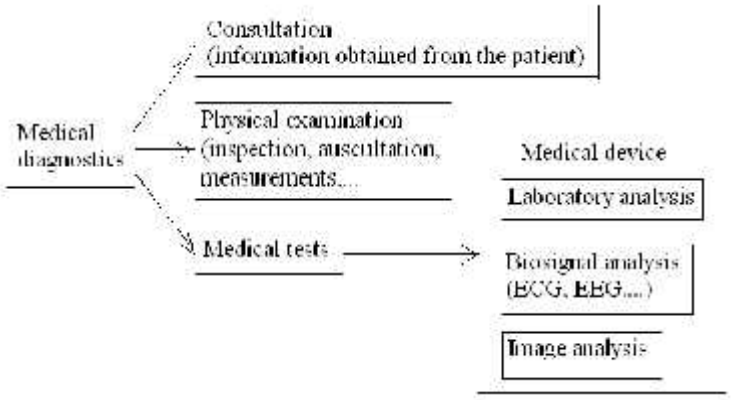

Figure 1 Medical diagnostics and medical device, after Strzelecki [12]

There is a wide range of categories and types are medical devices. For example, in 2011, the World Health Organization (WHO) estimated using 10,000 categories of medical devices in medical practice and manufactured between 90,000 and 1.5 million construction types Cynober [3].
Medical devices are designed, manufactured and used with the help of extensive theoretical and practical knowledge in multiple areas, Lewiner and Le Pape [5]: biomechanics, medicine, biology, chemistry, physics, electronics, computer science etc. At this moment we can talk about the medical device industry, Chriqui [5] as a sub-field of biomedical engineering peak and also a strategic sector in terms of economic and medical health industry.

The definition of the medical device is governed by rules elaborated at European, national, and USA level etc. For instance is presented , selectively, definitions used in the USA, Europe and Romania:

- the Global Harmonization Task Force (USA) [30]: ,,Medical device - means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* examination (reagents, calibrators, sample collection devices, control materials, and related instruments or apparatus), software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

• diagnosis, prevention, monitoring, treatment or alleviation of disease;
• diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
• investigation, replacement, modification, or support of the anatomy or of a physiological process;
• supporting or sustaining life;
• control of conception;
• disinfection of medical devices;
• providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means'';

- in Europe the medical device has the following definition [21]: ,,any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

• diagnosis, prevention, monitoring, treatment or alleviation of disease;
• diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
• investigation, replacement or modification of the anatomy or of a physiological process;
• control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" Brolin [2];

- according to the Food and Drug Administration (FDA)(USA) the medical device is defined as: ,,A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accesory, which is:

• recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
• intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals;
• or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes'';

- ISO 13485 defines the medical device: ,, Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose [31] of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of /or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" [25],

In our country, Romania, Law no. 176/2000 defines the medical device: ,, any instrument, apparatus, machinery, material or other article used alone or in combination, including the software necessary for it to be applied correctly , intended by the manufacturer to be used for human beings and which does not achieve its principal intended in / or on the human body by pharmacological , immunological or metabolic means, but which may be assisted in its function by such means in order:

- diagnosis, prevention, monitoring, treatment or alleviation of pain;
- diagnosis, monitoring, treatment or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological process;

control of conception''.

From the definitions presented can be noticed that medical devices are defined as items used for medical purposes, being characterized by a high constructive and functional diversity. The conditions of design, manufacture and use [10], [15] are determined primarily by operational requirements and the specific properties and behavior of materials (reliability, mechanical, thermal and chemical behavior, etc.) from which they are made, generically referred to as biomaterials. For these reasons, the issue of designing, manufacturing, clinical

use and rehabilitation of medical devices requires collective made up of specialists from different fields: physics, mechanical engineering, metallurgy, bio-engineering, veterinary medicine, industrial design etc. Figure 2 shows, in a systemic form, the issue of manufacturing a medical device.

2. TECHNICAL REQUIREMENTS

For identification and classification of medical devices various criteria are used [4], [6], [8], [28], [29]. The most criterion used is ISO 15225 [24] and the GMDN code (The Global Medical Device Nomenclature). The GMDN code is a comprehensive system of internationally recognised coded descriptors used to generically identify

Table. 1 Classification of medical device, after standard ISO 15225 [24]

Category	Description
01	Active implantable devices
02	Anaesthetic and respiratory devices
03	Dental devices
04	Electro mechanical medical devices
05	Hospital hardware
06	In vitro diagnostic devices
07	Non-active implantable devices
08	Ophthalmic and optical devices
09	Reusable devices
10	Single use devices
11	Assistive products for persons with disability
12	Diagnostic and therapeutic radiation devices
13	Complementary therapy devices
14	Biological-derived devices
15	Healthcare facility products and adaptations
16	Laboratory equipment

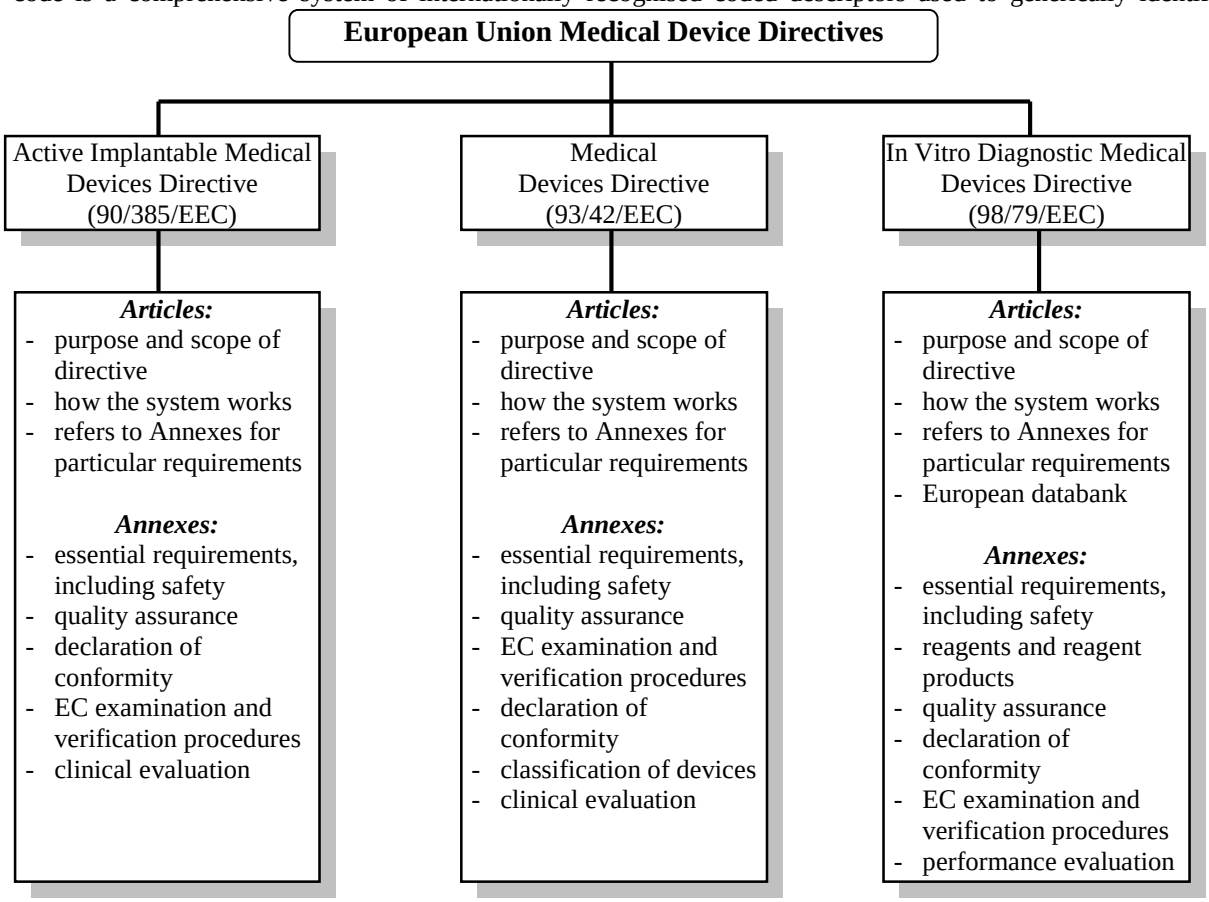

Figure 2 The systemic approach to European regulatorsin the field of medical devices, after Shefelbine et al.[11]

medical devices products'' (Tab.1).
In Europe, the legislation on medical devices is based on three basic directives (Fig.2) [17], [18], [19], [20]:

• Directive 90/385 / EEC. It includes regulations on active implantable medical devices (Active Implantable Medical Devices Directive-AIMD) [18], [14];

• directive 93/42/EEC, Medical Devices Directive MDD [27], [14]. It is amended by Directive 2007/47/EC). Directive 93/42 / EEC is based on the systemic definition of two main terms:,, medical device "and ,,accessory " of the medical device. In the acceptation of the Directive, a product may be considered accessory to a medical device only if specified by the device manufacturer;

• directive 98/79/EC, *InVitro* Diagnostic Medical Devices IVD [19], [31]. According to this directive, in vitro diagnostic medical devices are made [20] of reagents, reaction products, apparatus, equipment, tools, etc. intended for medical examination of samples taken from the human body (living organism) such as tissue, blood, urine, etc. for the purpose of diagnosing the existence of pathological conditions, namely disease, congenital malformations, to monitor the state of health of the individual being investigated, for therapeutic treatment, etc. For example [20]: Hepatitis or HIV tests, Clinical chemical tests, Coagulation test systems , urine test strips etc. In essence [31], directive 98/79 / EC regulates areas and rules that govern the use of medical devices from the conceptul and medical point of view for in vitro diagnostic use in the human body respectively a living organism. In figure 2 are shown, synthetically, issues that are regulated in the three directives.

At international level, many standards are developed [30], [31], [29] more than 100 [26] in which are covered the issues regarding quality characteristics of a medical device Ramakrishna et al. [9], Zhong [13]:

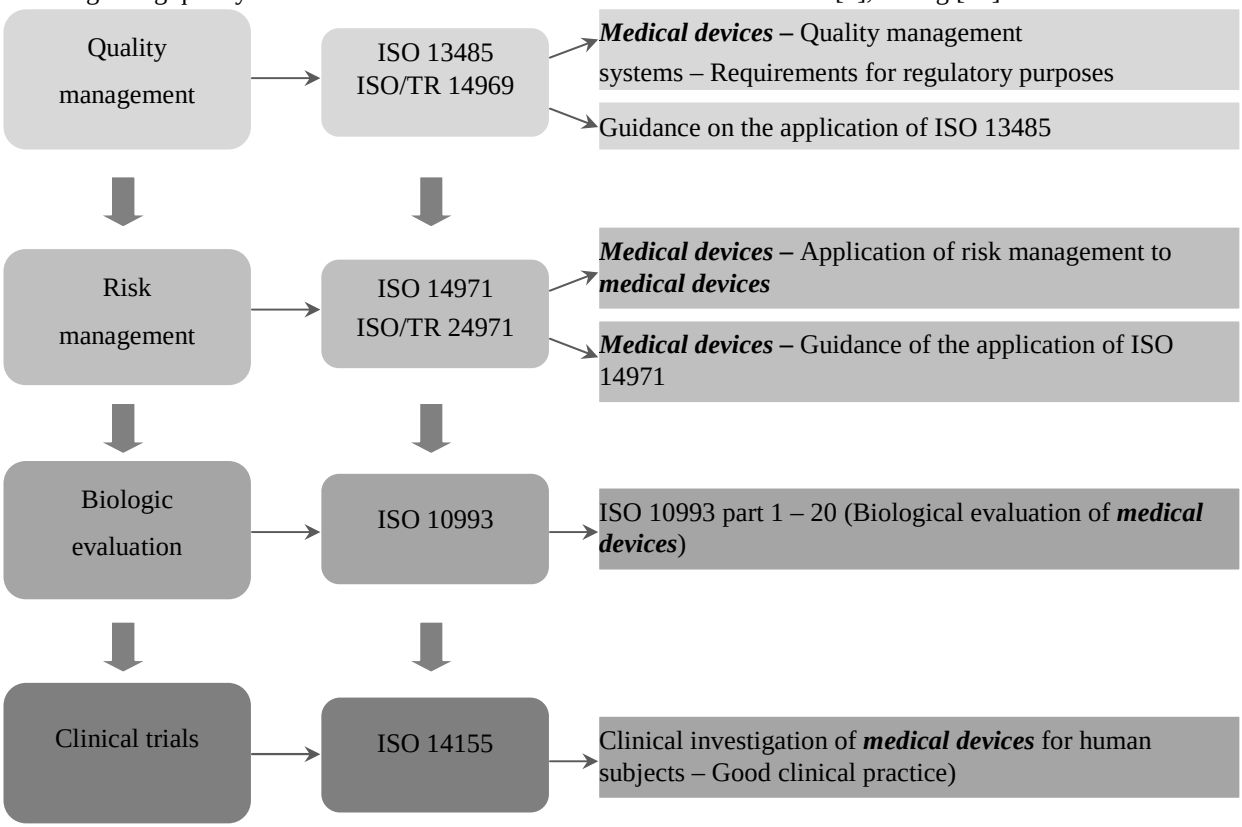

Figure 3 Basic standards ISO for medical devices, after Ramakrishna et al. [9]

- quality management;
- risk management;
- biologic evaluation;
- clinical trials.

In essence, each of the standards mentioned in Figure 3 must be applied in systemic interdependence. The ISO 10993 standard Part 1-20 has a special role regarding biological evaluation of any medical device regardless of manufacturer.

3. CONCLUSION

Medical devices are defined by the following main functional purposes:

- diagnosis, prevention, control, treatment and mitigation of a disease;
- diagnosis, control, treatment, mitigation or compensation for an injury or handicap;
- the study, relocating or modification of the anatomy, or of a physiological process, etc.

The manufacturer of a medical device and the user is obliged to observe the legislation. It builds on the European Union Medical Device Directives: Directive 90/385 / EEC; Directive 93/42 / EEC and Directive 98/79 / EEC. Each of these directives are accompanied by annexes showing the specific requirements from which stands out essential requirements, including safety.

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