Practice-oriented summary of the most important aspects and requirements contained in Directive 93/42/EEC incl. 2007/47/EC

**What exactly is a Medical Device?**
Medical Device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the following purposes:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for injuries or handicaps
- Investigation, replacement or modification of the anatomy or of a physiological process
- Conception control

**Differentiation to medicines**
The main effect is not achieved by pharmacological, immunological or metabolic means.

**What can be regarded as an accessory?**
These articles can be classified separately either as stand-alone product or as part of a Medical Device according to Annex IX of the Medical Devices Directive.

**Exception to the rules**
1. Custom-made devices, which are
   - specifically made in accordance with a duly qualified medical practitioner’s written prescription
   - and are intended for the sole use of a particular patient.

2. Devices intended for clinical investigation.

Both types of devices are falling under this Directive, but CE-marking is not possible.

**Who is the manufacturer according to the Directive?**
The Directive defines the manufacturer as the natural or legal person who is responsible for the design, manufacture, packaging and labeling of a Medical Device with regard to marketing in his own name, regardless of whether these actions are performed by that person himself or a third party deputizing for this person. Manufacturers outside the EU require, in addition, a representative within the EU.
Essential requirements
Annex I of the directive requires (examples):

- that the devices are designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

- that the solutions adopted by the manufacturer for the design and construction of the devices conform to safety principles, taking account of the generally acknowledged state of the art.

- that the devices achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions as specified by the manufacturer.

- that the characteristics and performances of the devices are not adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

- that the devices are designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

- that any undesirable side effect does constitute an acceptable risk when weighed against the performances intended.

- that demonstration of conformity with the essential requirements include a clinical evaluation in accordance with Annex X.

In addition to these general requirements there are other requirements referring to the design:

- Chemical, physical and biological properties (toxicity, compatibility, etc.)
- Protection from infection and microbial contamination (processing, packaging)
- Features with regard to construction and the environmental conditions (minimizing of risks)
- Measuring function (accuracy, displays)
- Protection against radiation (intentional or unintentional radiation, ionizing radiation)
- Devices with external or internal energy source (protection against electrical or thermal risks)
- Protection from hazards as a result of administration of energy or substances to patients
- Provision of information by the manufacturer (labeling, instructions for use)
- Establishment of clinical data

Classification of Medical Devices by their risk potential
Annex IX of the Directive stipulates the classification of devices – according to the hazard potential – in classes I (low), IIa, IIb, and III (high). Depending on classification of the product, different conformity assessment procedures apply. The Directive includes 18 classification rules.

Classification criteria:

- Duration of use:
  - Transient (under 60 min)
  - Short term (up to 30 days)
  - Long term (more than 30 days)
- Level of invasiveness:
  - Noninvasive
  - Invasive through body orifices
  - Surgically invasive
  - Implantable
- Location of use:
  - Central circulatory system
  - Central nervous system
  - Outside of both
- Energy supply:
  - Non-active
  - Active

If you have any questions regarding classification of your product, our specialists will be happy to help you.
Layout of Annex contents

**Annex I:**
**Essential requirements**

**Annex II:**
**Full quality management system**
The manufacturer has a quality management system, e.g. in compliance with EN ISO 13485:2012, fulfills the additional requirements of the Directive (e.g. market surveillance, reporting, document storage, fulfillment of the essential requirements as laid down in Annex I), and declares the conformity of his products with the Directive. In the case of devices belonging to class III, a product design review is also stipulated.

**Annex III:**
**EC type examination**
A Notified Body carries out a type examination according to the essential requirements of Annex I of the Directive and issues a type examination certificate.

**Annex IV:**
**EC verification**
A Notified Body tests the products in the final production phase, either by checking all products or by means of random samples on a statistical basis.

**Annex V:**
**Production quality assurance**
The manufacturer has a quality management system for his production, testing and final inspection, e.g. in compliance with EN ISO 13485:2012 (see Annex II). The requirements regarding design and development are excluded.

**Annex VI:**
**Product quality assurance**
The manufacturer has a quality management system for the final product inspection and testing e.g. in compliance with EN ISO 13485:2012 (see Annex II). The requirements regarding design and development, control of production and service provision, and validation of processes for production and service provision are excluded.

**Annex VII:**
**EC declaration of conformity**
The manufacturer issues a declaration of conformity without involving a Notified Body. He is, however, obliged to provide a technical documentation stating that the product fulfills the valid requirements, and he must have installed a system for market surveillance (vigilance system), reporting, document storage, etc.

**National variations**
The transition of the Directive into national law allows several variations such as language, registration of devices with the authorities and requirements for operation.

In Germany, the Directive was correspondingly converted on August 2, 1994 in the Medical Devices Law (MPG).
This directive was last amended on July 21, 2014.
TÜV SÜD Product Service – Medical and Health Services. Your partner for medical device approval

TÜV SÜD Product Service provides you with comprehensive support in fulfilling the requirements arising from the Directive.

A long-standing experience and industry-specific know-how enable us to cover all medical devices and conformity assessment procedures in accordance with Directive for Active Implantable Medical Devices 90/385/EEC (AIMD), Directive on Medical Devices 93/42/EEC (MDD), and Directive on in vitro diagnostic Medical Devices 98/79/EC (IVDD). As Notified Body for medical devices, our identification number is 0123.

We are able to provide you with the legally required testing and certification services; you can also profit from our comprehensive expertise in all phases of development – worldwide. More than 1,000 customers around the world trust in our competence and thus make us the world leader.

With more than 44 branches on all continents, TÜV SÜD Product Service provides support through fast, unbureaucratic service. Our international cooperations give us access to further markets, e.g. North and South America, Australia, and the Asia-Pacific region.

With our voluntary TÜV SÜD certification mark, we also provide you with an optimal way to effectively signal your own competence to the public.

Whether product testing, system certification, or a combination of both: the TÜV SÜD mark represents a symbol of your efforts to achieve quality in all areas.
Survey of the various conformity assessment procedures

Annex II.3
EC declaration of conformity QM and Annex II.4
Examination of product design

Notified Body

Active implants class III
Class Ia + IIb

Annex II.3
EC declaration of conformity QM

Active implants class I* + IIa class IIb + III
Active implants class I* + IIa class IIb + III

Annex III
EC type examination, type examination certificate by Notified Body

Class I* (sterile products, products with measuring function) and class Ia products

Annex II.4
Examination of product design

Notified Body

Active implants class I* + IIa
Class Ia + IIb

Annex IV
EC verification based on statistical methods
Notified Body

Active implants class I* + IIa
Active implants class I* + IIa

Class I* + IIa

Annex V
EC declaration of conformity QM system in production
Notified Body

Active implants class I* + IIa

Class IIb

Annex VI
EC declaration of conformity QM system product
Notified Body

Active implants class I* + IIa

Class IIb

Annex VII
EC declaration of conformity issued by manufacturer for class I products

Keeping documentation available

Active implants class I* + IIa
Class Ia + IIb

Class I* + IIa

Active implants class I* + IIa

Class IIb

Active implants class I* + IIa

Class Ia + IIb
Conformity assessment procedure for class I devices

**Examples:** spectacle frames, walking aids

Conformity assessment procedure for class IIa products

**Examples:** hearing aids, cannulas
Conformity assessment procedure for class IIb devices

Examples: infusion pumps, blood bags, contact lenses

Conformity assessment procedure for class III devices

Examples: heart catheters, sewing material for use on the heart

Your contact partner at TÜV SÜD Product Service can provide further information.

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