A medical device consulting company
with a focus on quality management

Regulatoriske krav fra direktivet om medicinsk udstyr

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CE-marking of medical devices – Legislation and regulation

Medical Device Directive 93/42/ECC Art. I, §2(a)[1]:

"'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 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;"

(1): Bekendtgørelsen om medicinsk udstyr nr. 1263 af 15 dec. 2008

CE-marking of medical devices – Legislation and regulation

Active medical device[2]:

"any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient without any significant change, are not considered to be active medical devices. ***Stand alone software is considered to be an active medical device"***

(2): Annex IX, section 1.4, of Directive 93/42/EEC

Standalone Software

Annex I Essential Requirements, §12.1a:

"For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification."

Compliance to Harmonized Standards:

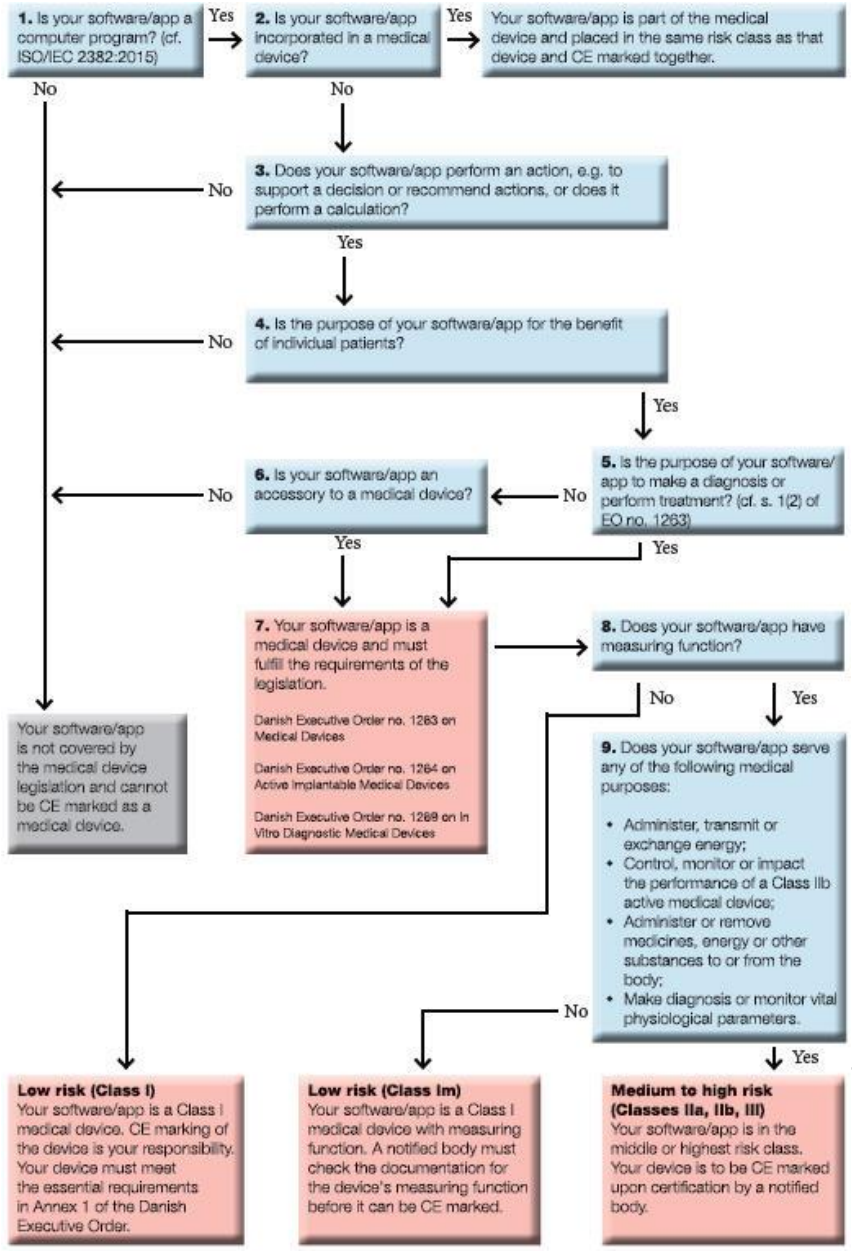
- EN 62304:2006 Medical device software – Software life-cycle processes
- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices

Guideline MEDDEV 2.1/6 Qualification and Classification of stand alone software – July 2016

Standalone Software

Intended Purpose

Medical Device (or not?)



Standalone Software

Examples of software that is Medical Device:

- **Decision support apps**
  This could be apps applying automated reasoning such as a simple calculation, or a series of complex algorithms, e.g. for dose calculations, symptom tracking or clinicians guides.
- **Diagnostic apps**
  An app which serves as a diagnostic aid, e.g. by analyzing an image of a mole to detect skin cancer, is a medical device.
- **Monitoring apps**
  An app which monitors a patient and collects information, entered by the user or measured automatically by the app or delivered by another device, would generally be considered as a medical device if the output data has decision-supporting or decision-making potential and thus may affect the treatment of an individual patient. It could also be an app which makes specific recommendations about treatment on the basis of data analysis or which analyses the results of a specific treatment and monitors therapeutic measures. Apps acting as accessories to medical devices: for example measurement of temperature, blood pressure and blood sugars or other physiological.

Standalone Software

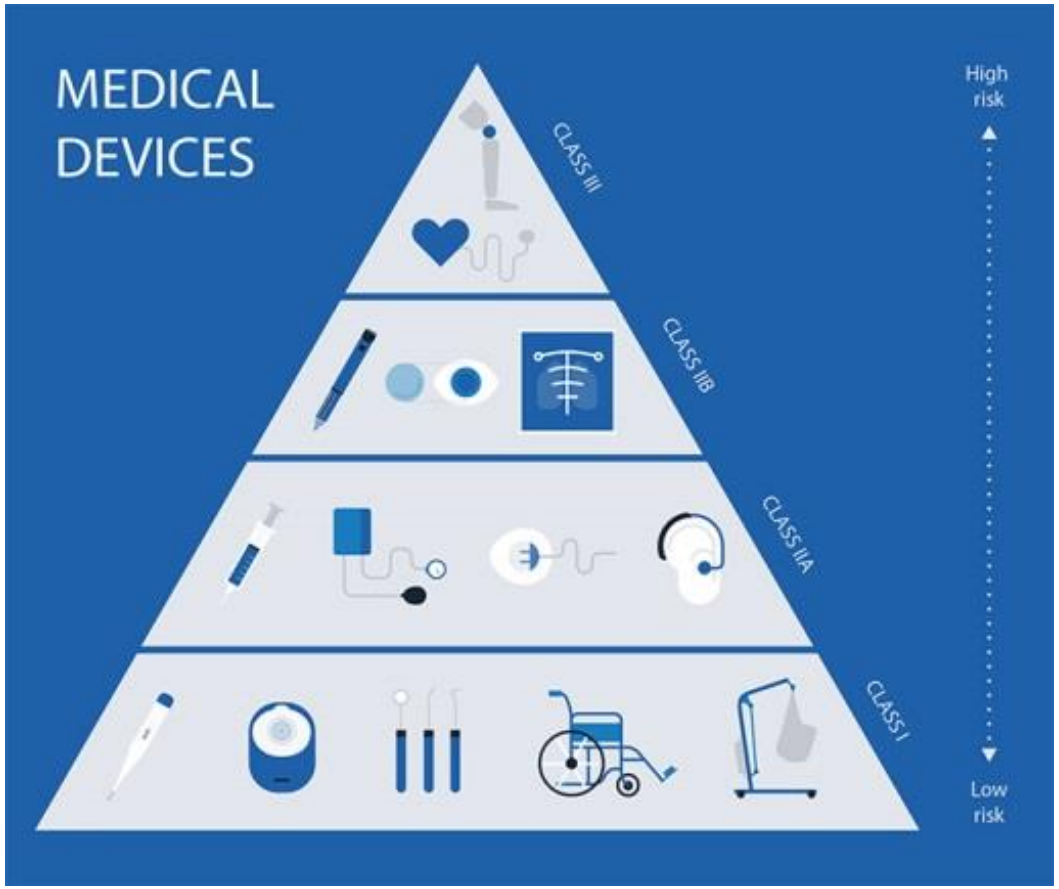
Examples of software that is not medical device:

- **Apps designed to remind users to take their medication are not medical devices**
  They may also provide general information about how to take medicine correctly and general information about medicines
- **Health apps that measure the heart rate during exercise**
  The majority of these health-related apps are considered to be fitness or wellness apps to be used for various purposes related to diet, exercise, lifestyle, etc.
- **Electronic Patient Record Systems**
  The electronic patient records themselves are not computer programs, therefore, they should not be qualified as a medical device i.e. an electronic patient record that simply replaces a patient's paper file does not meet the definition of a medical device.

  However, the modules used with electronic patient record system modules that might be qualified in their own right as medical devices are for example:
  - an image viewer with functionality for diagnosis based on digital images;

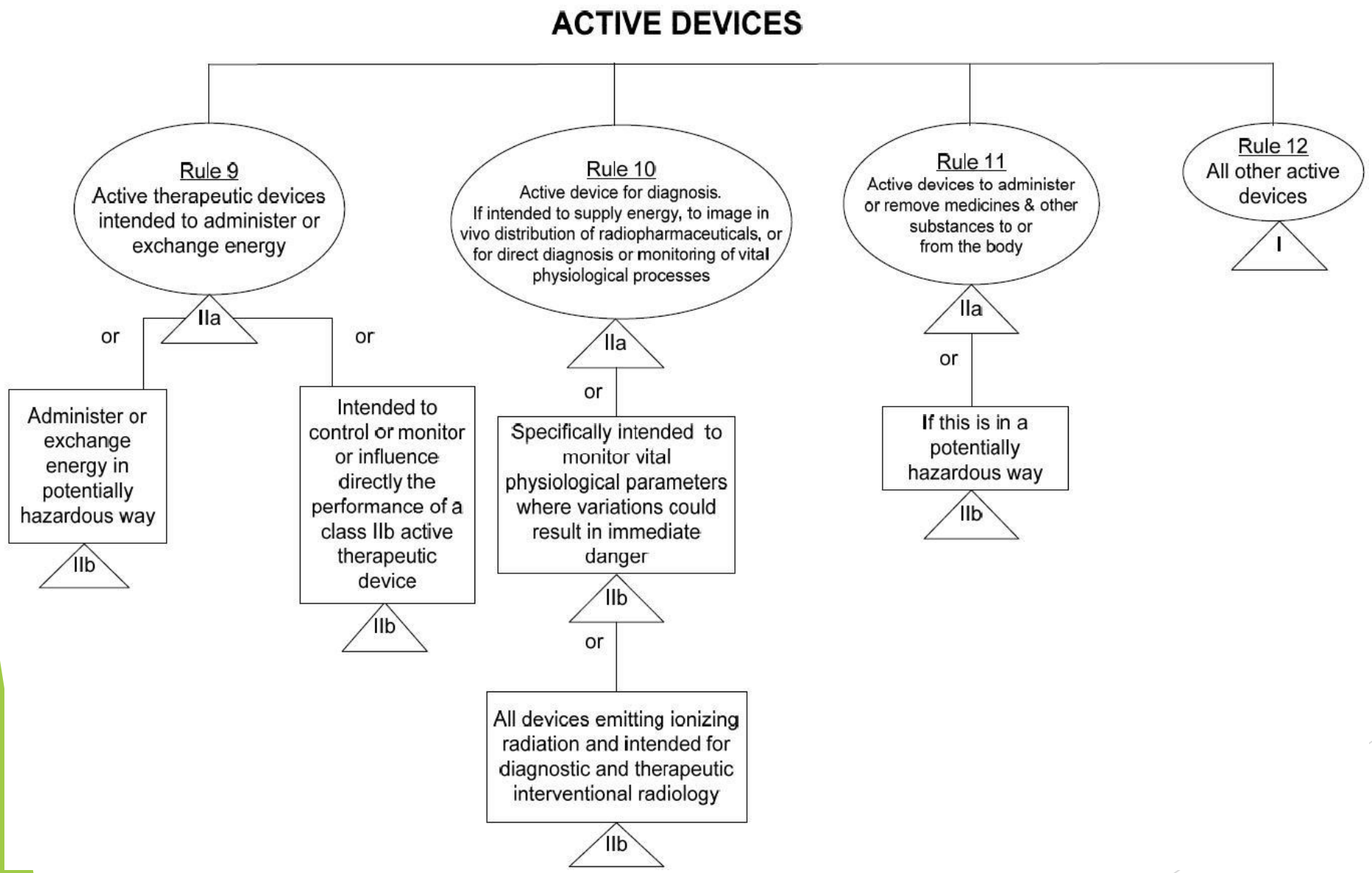
Classification

MEDDEV 2.4/1 rev. 9 Classification of medical devices - June 2010



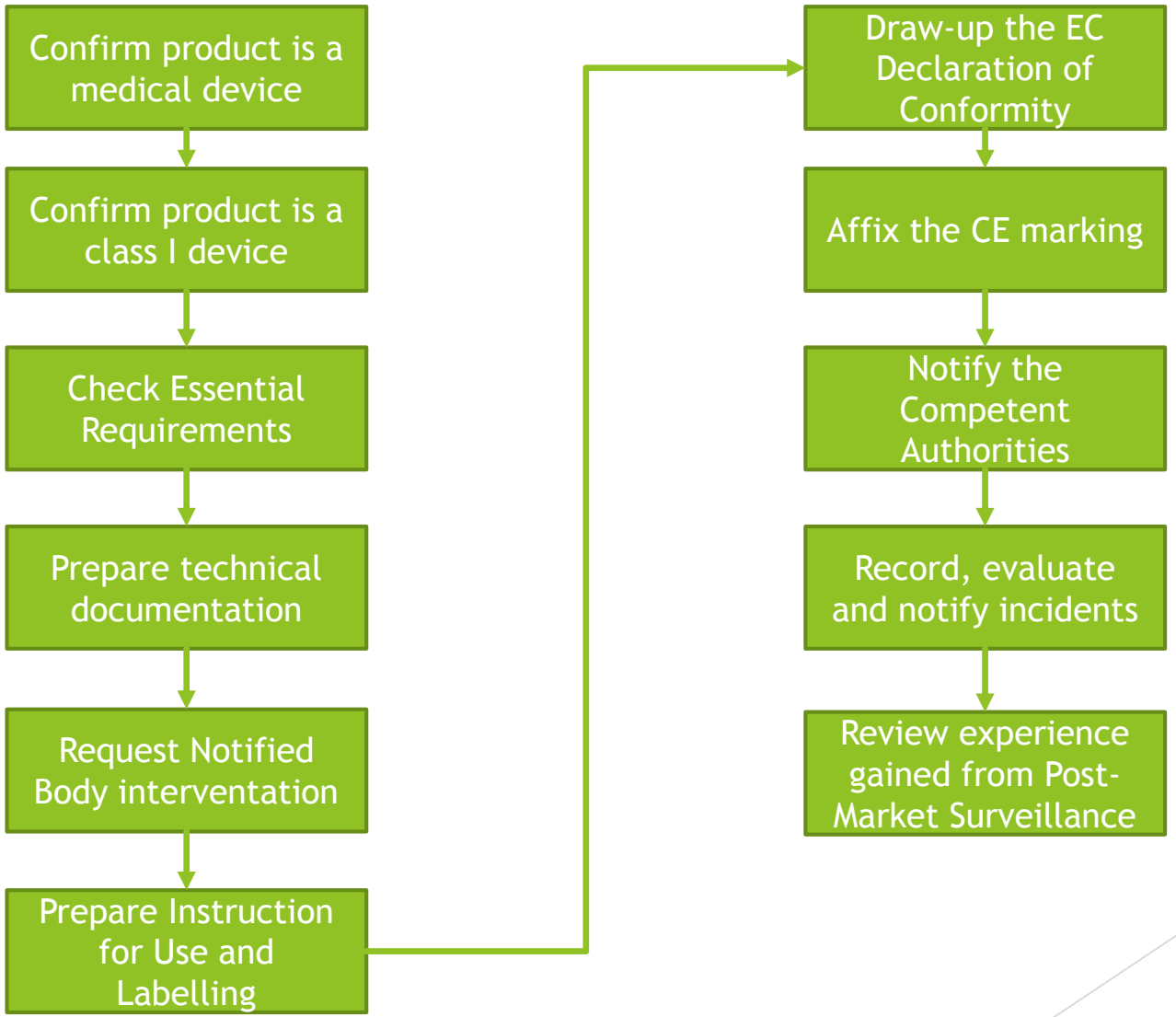
Source: Danish Medicines Agency web site

Classification – active devices



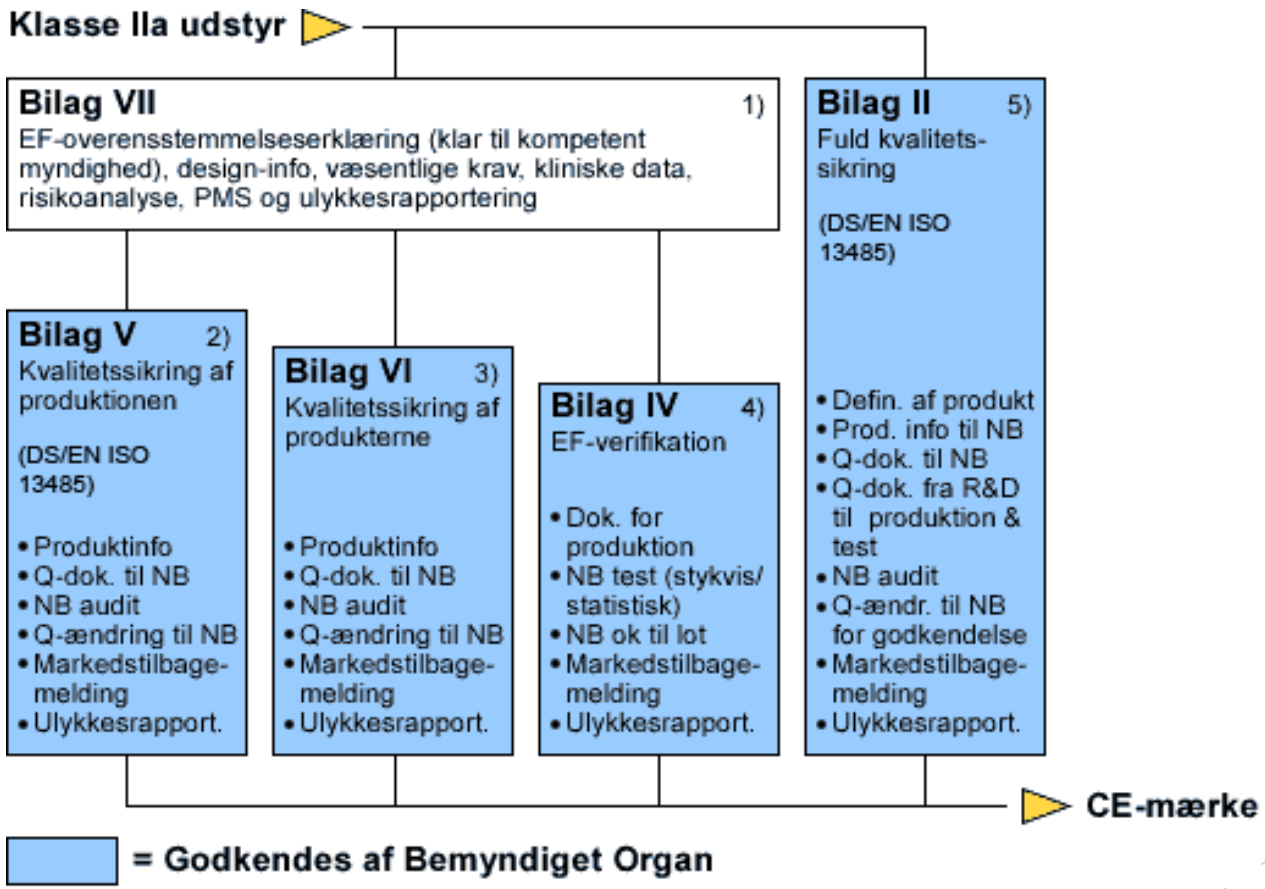
Routes to CE-mark

Class I:



Routes to CE-mark

Class IIa:



Future – New Medical Device Regulation

- Combine Medical Device Directive (93/42/EEC) and Active Implantable Medical Device Directive (90/385/EEC) into one directive
- Stricter requirements on clinical evaluation and post-market clinical follow-up
- Stricter requirements for Notified Bodies
- Better traceability of devices (UDI – Unique Device Identification)
- Formal adoption expected in Spring 2017
  - Transition period:
    - 3 years for the Medical Devices Regulation
    - Certificates issued in the transition period will remain valid up to 4 years after the end of the transition period

References

- Lovgivning og vejledning om medicinsk udstyr: https://laegemiddelstyrelsen.dk/da/udstyr/lovgivning-og-vejledning
- Guidance MEDDEV's: http://ec.europa.eu/growth/sectors/medical-devices/guidance_en
- Medical Device Directive – Consolidated version: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF