CE-marking of Medical Devices and complete Medical Gas Pipeline Systems (MGPS)

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Agenda

- My background
- Why CE-marking?
- How to obtain CE-marking?
- What shall be CE-marked?
- Maintenance, Repair and Changes
- CE-marking of Medical Gas Pipeline Systems "MGPS"
- Change from MDD to MDR
- Questions as we go !

My background

- Master of Science, Industrial Economy and Mechanical Engineering

- 16 years Business and Product Owner for Medical Devices and Hospital Services

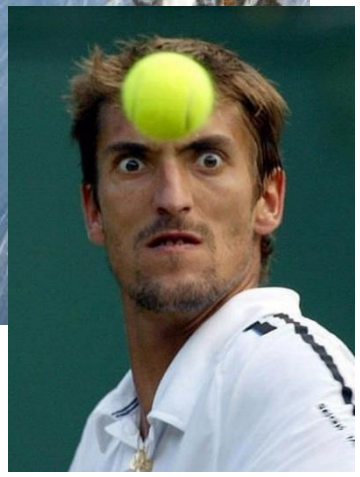
- CE-marked 17 medical devices

- Now: Central Gas Equipment +related services Linde (AGA) Europe Middle East and Africa

- 12 years Swedish and ISO standardization committees

- 6 years ISO-expert - Medical Gas Systems

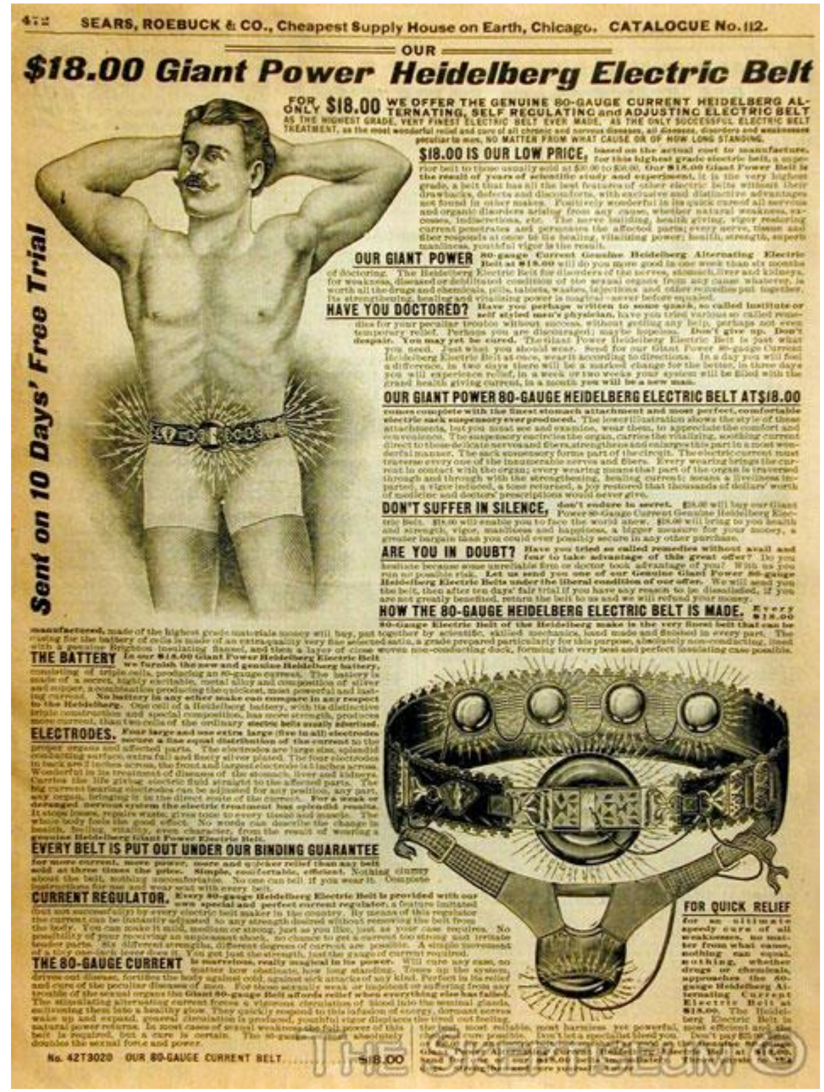
+ Family, ski, surf, tennis



Why CE-marking?

"………the most wonderful relief and cure of all chronic and nervous diseases, all diseases , disorders, and weaknesses peculiar to men, NO MATTER FROM WHAT CAUSE OR HOW LONG STANDING"

-Sears Roebuck & Co, product catalogue 1902



Why CE-marking?
Standards, Regulations and Laws ➔ Patient Safety !!

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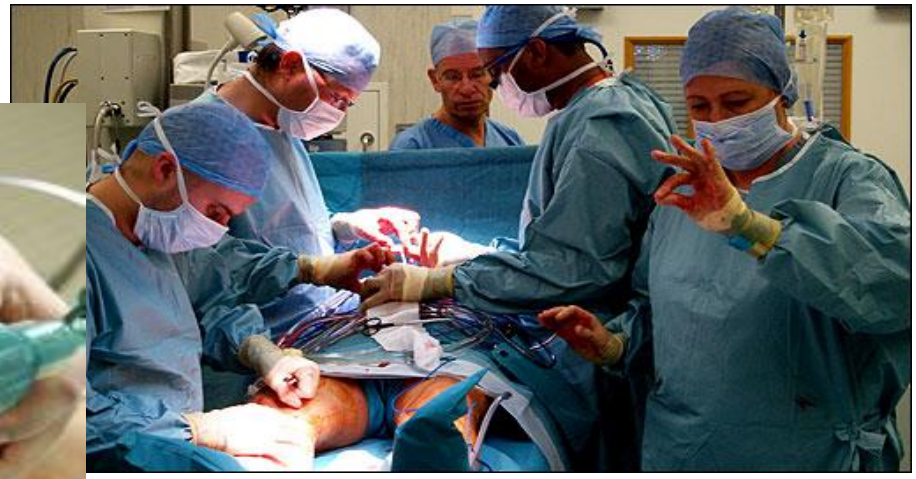
- Defects or disturbances in the function of medical devices

  ➔ Serious risk to patients, staff or 3P

- Medical Device Directive (MDD) ➔ Safety, Performance and free trade in EU

- CE-marking in accordance with MDD is a legal requirement when making medical devices available (sell/lease/lend...) to the EU market since 1998



How to obtain CE-marking?

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- CE-marking = Medical Device Manufacturer claim the product safe by fulfilling all essential requirements in European Medical Device Directive (MDD).

- MDD essential requirements (60) outlines safety and performance requirements needed to be sold in EU.

- Harmonized product standards (e.g. ISO7396-1)

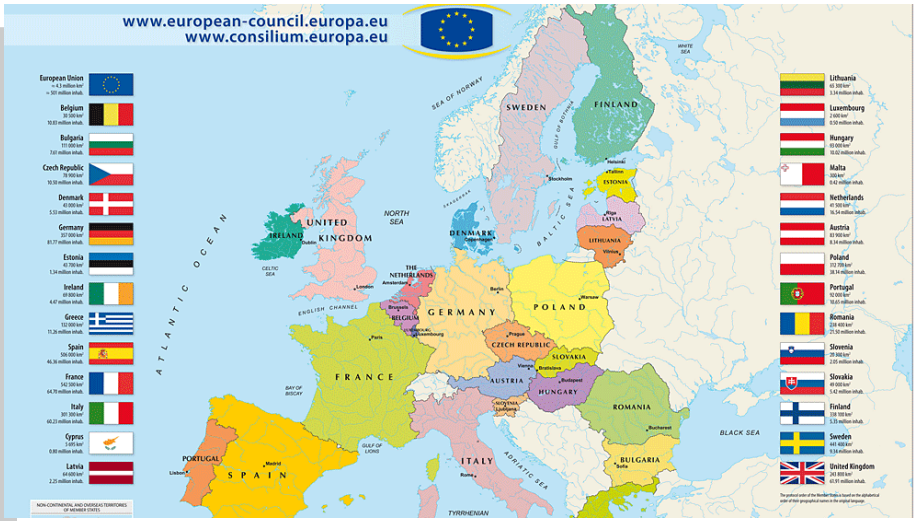
- ISO13485 QMS Production of Medical Devices
- ISO14971 Risk Management

- Technical File audited by Notified bodies "NB" (DNV, TÜV, BSI...)
➔CE, Class I, IIa, IIb or III.

- NB are authorized by Medical Product Agencies (Sundhetsstyrelsen)

- MDD – EU-Directive, but also implemented into national laws.

E.g. According to Swedish law
17 § Den som med uppsåt eller av oaktsamhet släpper ut en medicinteknisk produkt på marknaden eller använder en sådan produkt i Sverige utan att produkten uppfyller de krav och villkor som gäller enligt 5 § eller enligt föreskrifter som beslutats av regeringen med stöd av 6 § döms till böter eller fängelse i högst ett år.



I. GENERAL REQUIREMENTS

1. The devices must be 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 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.

CE 0086

CE 0123

e

What products/devices shall be CE-marked?

2. For the purposes of this Directive, the following definitions shall apply:

(a) 'medical device' means 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,

Examples:

All types of Medical Gas Regulator

A, Part of treatment of e.g. lung diseases

B, Active device (since changes energy/property of the gas)

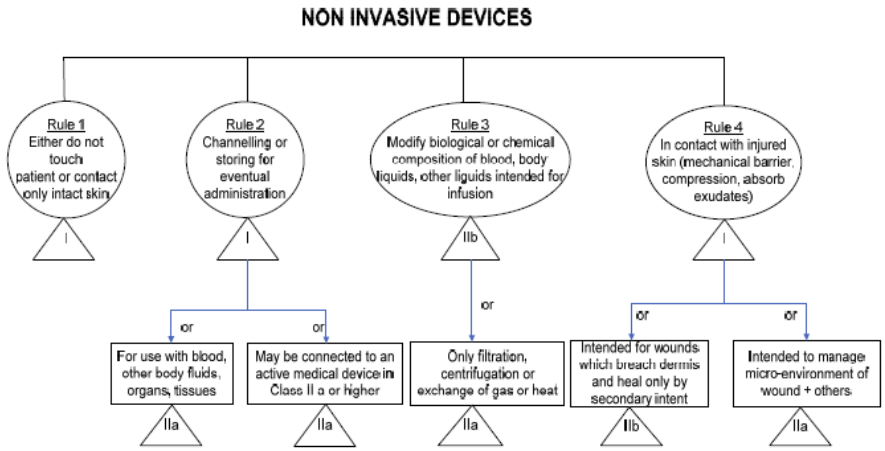
➔ Rule 11, class IIb

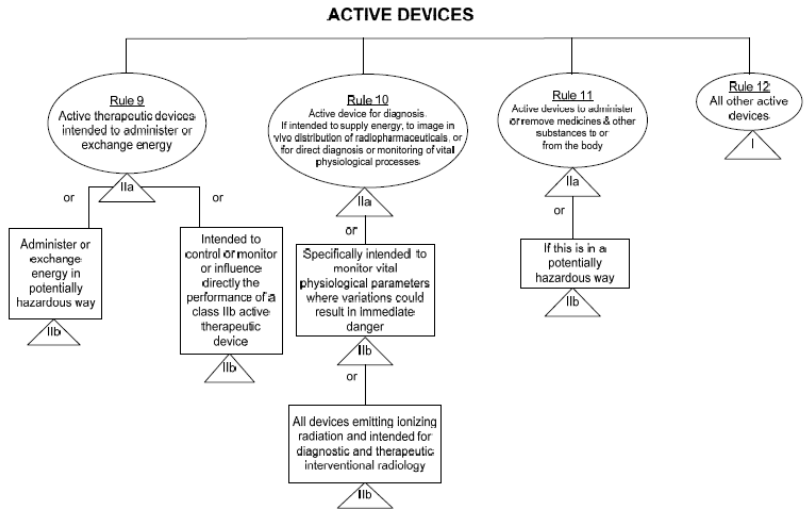
Medical Gas Pipes

A, Part of treatment of e.g. lung diseases

B, Non invasive device used for channeling or storing a medicine

➔Rule 2, class IIa





Maintenance, Repair and Changes to Medical Devices

Maintenance & Repair
- Always follow the instructions for use (+intended use)

13.6. Where appropriate, the instructions for use must contain the following particulars:

(a) the details referred to in Section 13.3, with the exception of (d) and (e);

(b) the performances referred to in Section 3 and any undesirable side-effects;

(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

(d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

- Training needed?
- Approved spare parts?
- Only authorized technicians (inhouse or external person)?

- Decided by the manufacturer´s Notified Body

- If you do not follow instruction for use:

A, Unclear if the device is fit for its purpose

B, The CE-marking of the device is invalid

➔ the product is not a medical device

C, Manufacturers Product Liabilities invalid

D, Product Warranties (typical 2-5 years) are invalid

E, Can change to in-house manufactured?

Changes
- Can only be permitted by manufacturer
- Written instruction including final test

CE-marking of Medical Gas Pipeline Systems, "MGPS"

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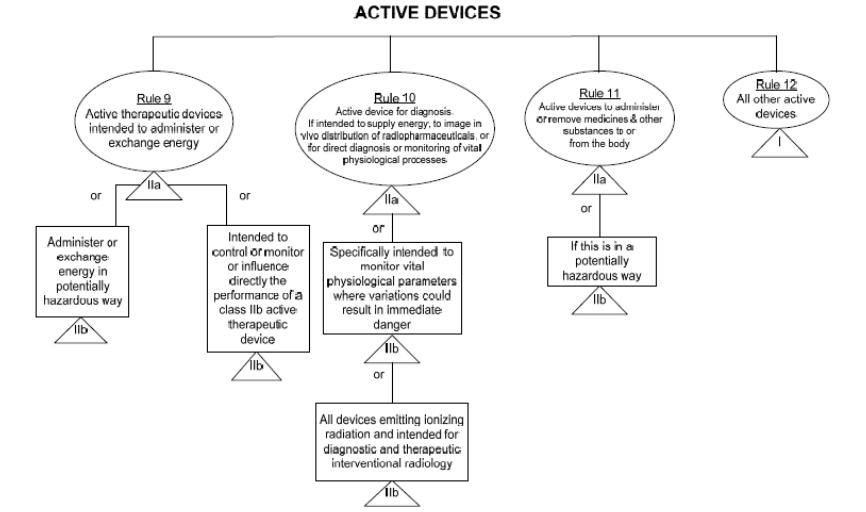
- The MGPS is used for treatment of e.g. lung deceases.

➔ Rule 11: class IIb, A Medical Device to be CE-marked by the manufacturer (hospital or installation company)

Fully CE-marked MGPS systems
- 6 countries in Europe

In-house manufacturing
- 22 countries
- Hospital is the legal manufacturer
- Not allowed to be placed on the market (sell/lease/lend to 3P)
- Up to national legislation.
- Sweden: Same essential requirements from MDD are required, but no formal CE-marking
- Swedish authorities are demanding a written "Declaration of Conformity" from hospitals that MDD and applicable standards (e.g. ISO7396-1) are fulfilled.



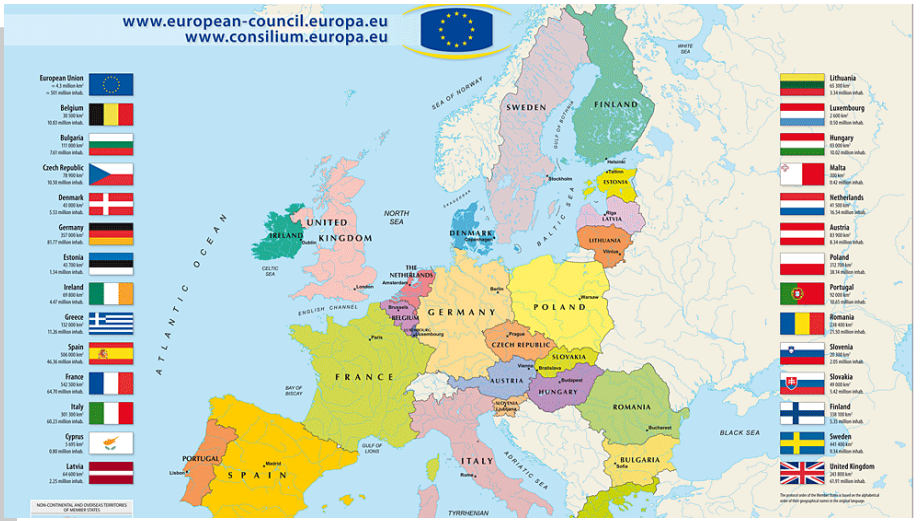
Change from MDD to MDR

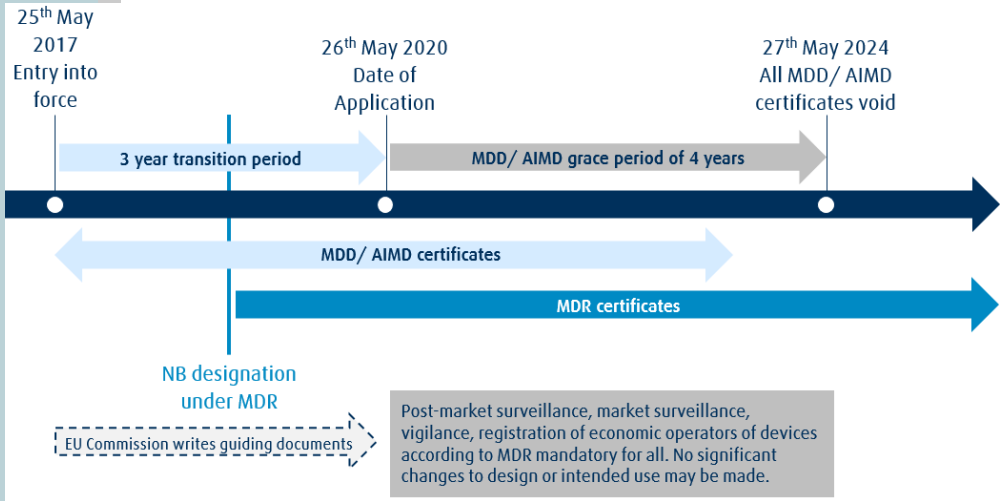
- MDD = Medical Device Directive
- MDR = Medical Device Regulation

- Most important is that a regulation must be implemented directly in all of EU, no interpretations into national laws.

High Lights:
- MDR is 4 times longer than MDD
- Esthetic and single use devices are included
- Stronger reinforcement of rules for clinical evaluations
- Stronger reinforcement of post market surveillance
- Creation of EUDAMED-database (Device, market, distributor etc)
- Introduction of UDI (Unique Device Identifier)
- Stricter requirements on Notified Bodies (DNV, TÜV, BSI..)

Specific for MGPS
- According to MDR no in-house manufacturing if CE-marked exist in the market.
- Swedish MPA has asked for a guiding document.





The System that must NEVER fail !

At least 3 sources of supply !

QI® Services – Quality Improvement

Services designed to help healthcare facilities managing the demands, laws and regulations related to distribution and use of medical gases.

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QI® Services overview