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Regulatory fundamentals

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Regulatory Fundamentals – Medical Devices

EU Regulatory System – Conformity Assessment

US Regulatory System – Pre Market Approval

EU Regulatory system

New and Global Approach – Blue Guide

EU New approach Directives – Blue Guide

Directive reference	Subject of directive
90/396/EEC	Appliances burning gaseous fuels
2000/9/EC	Cableway installations designed to carry pe[illegible]ons
89/106/EEC	Construction products
2004/108/EC	Electromagnetic compatibility
94/9/EC	Equipment and protective systems in pote[illegible]
93/15/EEC	Explosives for civil uses
95/16/EC	Lifts
2006/95/EC	Low voltage equipment
2006/42/EC	Machinery safety
2004/22/EC	Measuring instruments
90/385/EEC	Medical devices: Active implantable
93/42/EEC	Medical devices: General
98/79/EC	Medical devices: In vitro diagnostic
92/42/EEC	New hot-water boilers fired with liquid or gaseous fluids (efficiency requirements)
90/384/EEC	Non-automatic weighing instruments
94/62/EC	Packaging and packaging waste
89/686/EEC	Personal protective equipment

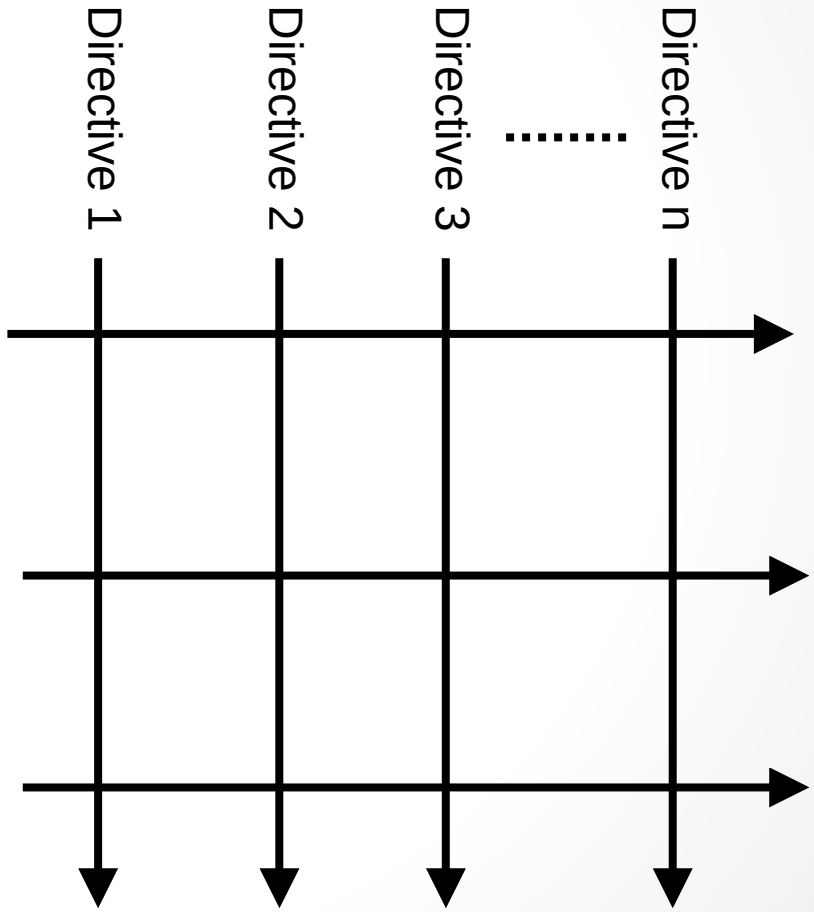
Directives providing for CE-Marking

New Approach and other Directives

REACH
Registration, Evaluation, Authorisation and Restriction of Chemicals

RoHS
Restriction of the use of certain hazardous substances in electrical and electronic equipment

WEEE
Waste Electrical and Electronic Equipment



Medical Devices, legal framework

	EU-Directives
Mandatory	National Legislation
Voluntary (not really: either you have proven by objective evidence that you ensure the same level of safety by other means or you better follow the guidelines !)	Standards (ISO, EN, CEN) State of the Art Guidance Documents

Transposition to National Legislation, example: Switzerland

93/42 EEC
90/385 EEC
98/79 EC

Bilateral treaty – MRA EU / CH

HmG – SR 812.21

MepV – SR 812.213

HFG - SR 810.30
KlinV – SR 810.305

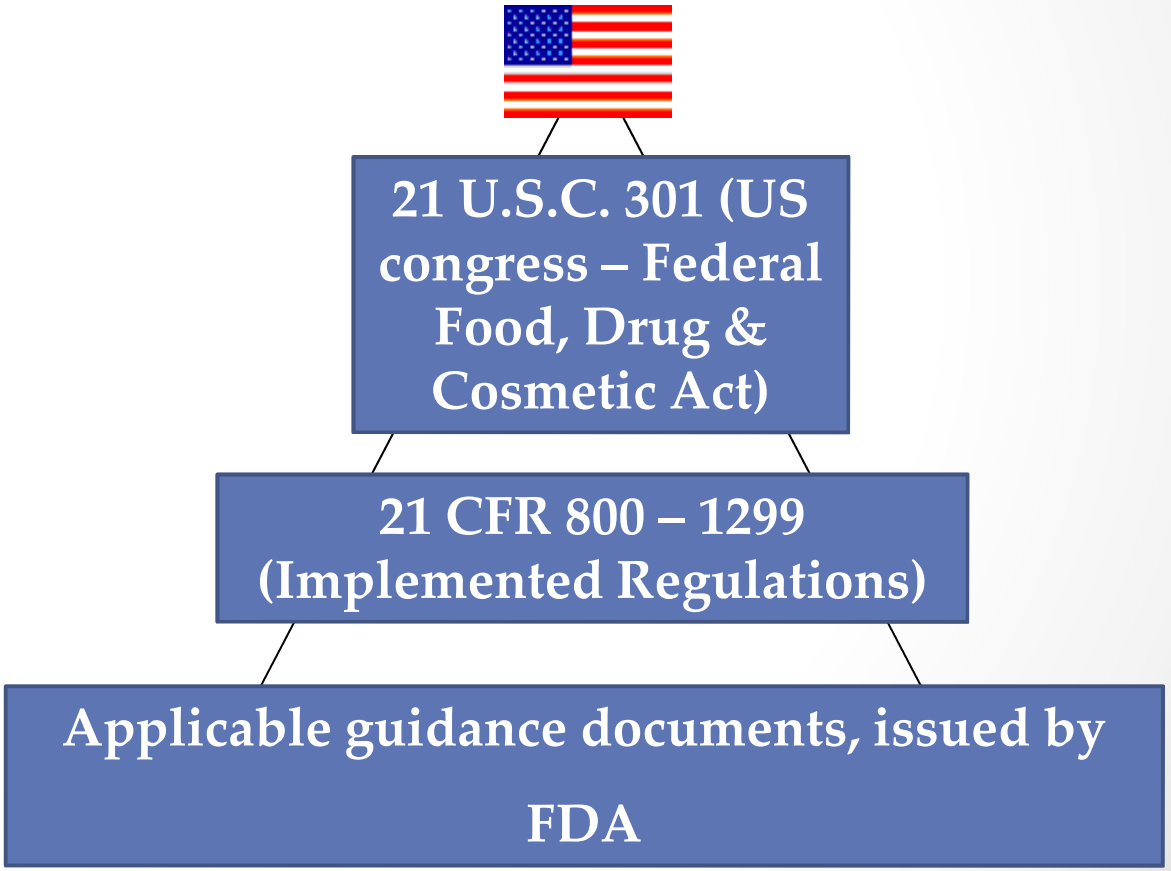
Conformity Assessment

- Market access requires for devices from of a risk class > I to mandate a Notified Body
- The manufacturer fulfils the requirements of the directive / national transpositions
- A Notified Body verifies due state of the Art of the evidence for fulfilling the requirements
- Conformity assessment pathways may be chosen by the manufacturer in relation to the class of risk of medical devices
- The manufacturer gets a confirmation from the Notified Body that the requirements have been fulfilled – CE certificate e.g. CE0123
- The manufacturer declares conformity with the applicable directives: DoC – declaration of conformity

US Regulatory system

Pre-market approval and notification system

USA - law and regulations

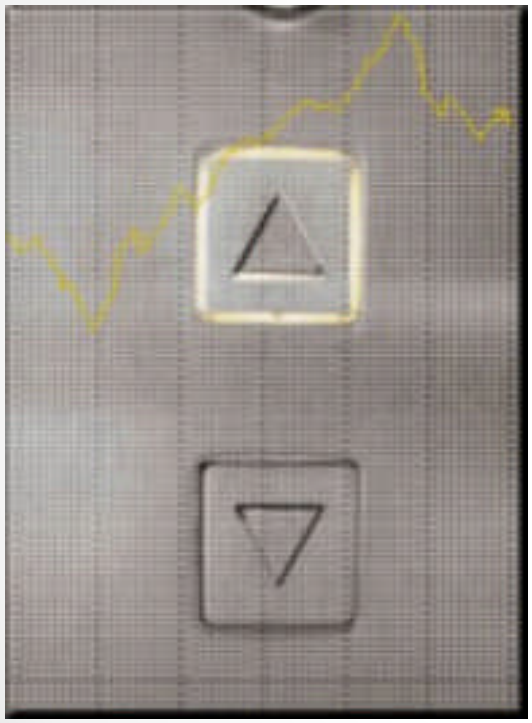


USA – Pathways for Medical Devices

2 Pathways for medical devices…

- **Pre Market Notification (510k)**
  - **Product already on US market ?**
  - **Is my product „substantial equivalent“ ?**
  - **Is my product in a risk level eligeble for 510(k)?**
    - **…If yes, then 510 (k)**
- **Pre Market Approval**

FDA – Market access USA



Fundamental difference to EU :

- Approval by competent authority ! (Food, Drug and Cosmetic Act)
- Subjects governed under standards in EU are directly addressed in the regulations (21CFR)
- Verification of GMP by the „competent authority (FDA)“

Conformity assesment vs. Pre Market Approval

2 different philosophies for accessing a market

Conformity Assessment vs. Pre Market Approval

Conformity assessment EU / GHTF

- Responsible: Legal Manufacturer (LMFG)
- LMFG applies regulatory and statutory requirements for device design, development & manufacturing
- LMFG demonstrates conformity by evidence that essential principles of safety an performance are fulfilled
- LMFG involves a conformity assessment body for higher risk classes
- LMFG declares conformity with a DoC

Pre Market Approval USA

- Responsible: Competent Authority (FDA)
- LMFG applies regulatory an statutory requirements for device design, development & manufacturing
- LMFG demonstrates legal compliance by evidence that essential principles of safety and performance are fulfilled
- CA reviews submission for higher risk classes
- CA grants market approval upon positive review of submission

Conformity Assessment vs. Pre Market Approval

Conformity assessment

- GHTF Regulatory framework
- EU Regulatory System
- Applied by several Asian countries
- Main characteristic:
  - CA not involved in the pre market control
  - CA performs (post-) market surveillance

Pre Market Approval

- USA regulatory system
- Applied by
  - USA, Canada
  - China, Brazil…and others
- Main characteristic:
  - Market approval granted by Competent Authority
  - CA performs pre market control and post market surveillance

Conformity Assessment vs. Pre Market Approval

Mixed approach

- EU for Drug & Device combination products (also human blood derivate…): kind of PMA for Drug Part
- Australian Regulatory System for high risk: PMA
- Japan Regulatory System for high risk: PMA
- Others…

End of part 3. Regulatory Fundamentals

Coffee Break

Followed by part 4 GMP-ISO - GLP introduction (PSO)