Medical grade connectors and its differences to Medical connectors

binder

MEDISCHE ELEKTRONICA

Ontwikkelingen, normen en toepassingen

7 februari 2023 | FHI Leusden

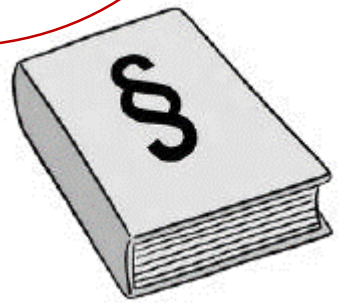
Topics

- Short introduction
- Definition medical grade
- Requirements
- Tests in detail
- Discussion

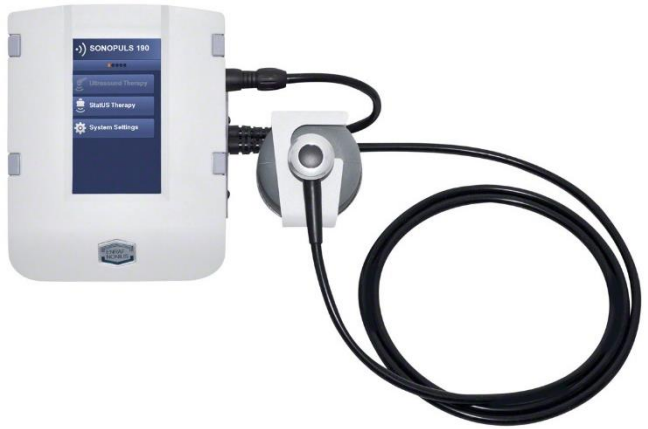
Overview Medical industry

Manufacturer of medical equipment

Supplier (e.g. binder)



Examples of medical devices

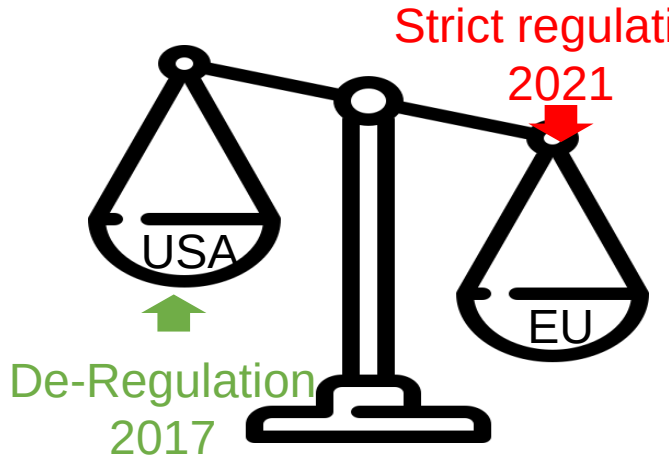


About Medical Device Regulation

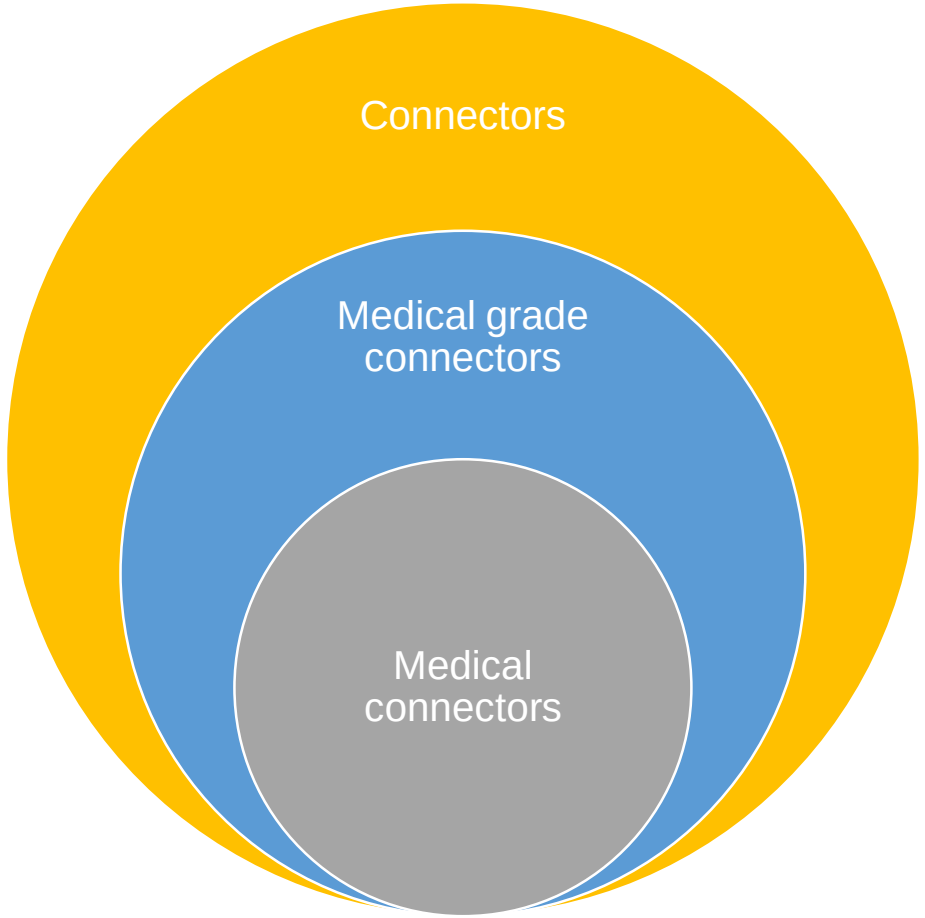
- Definition of a medical product acc. MDR:

  „…medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: …"

- Effective since May 2021 → stringent requirements for medical products and manufacturers → High backlog of authorization of medical equipment

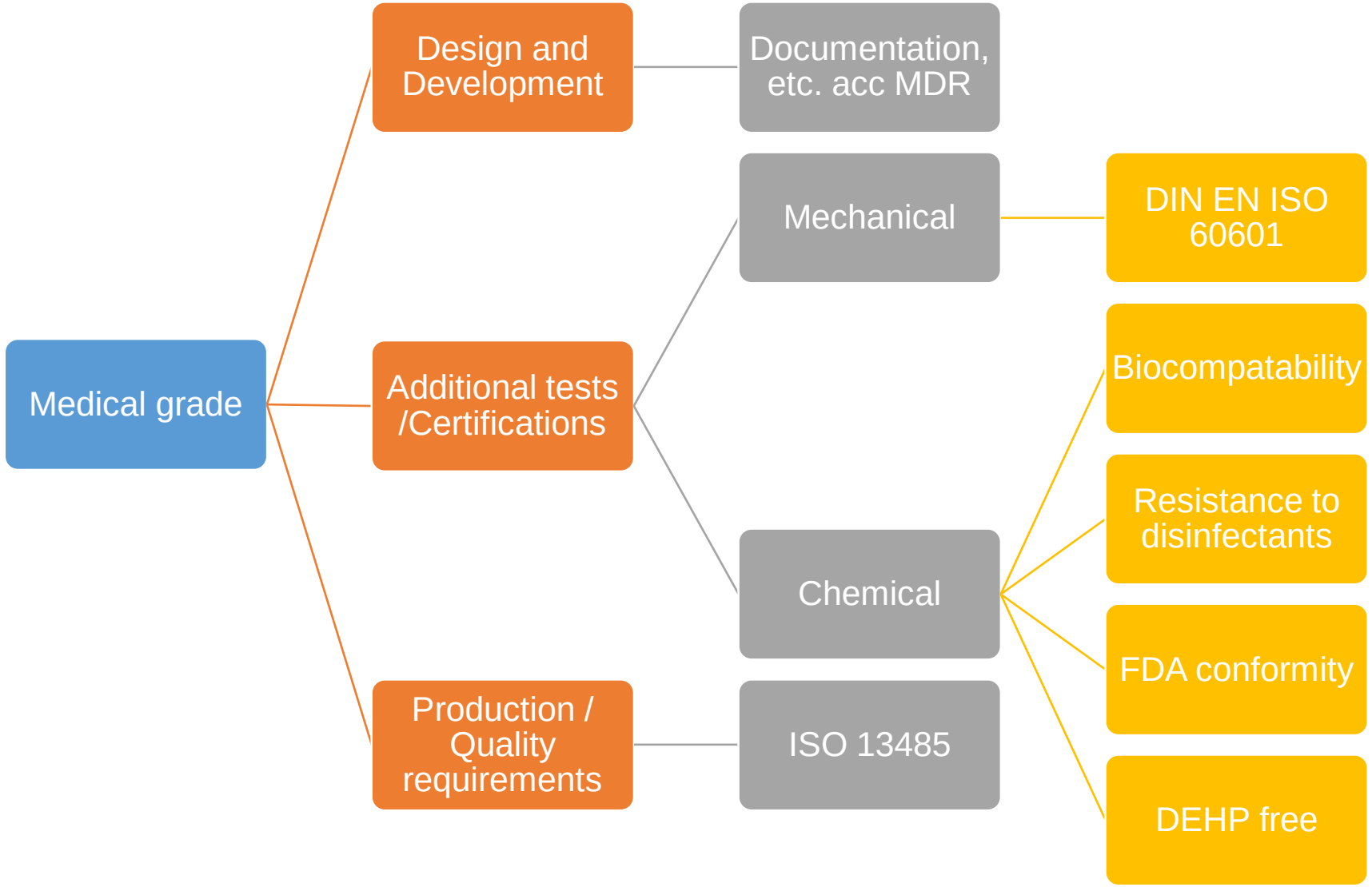


Definition Medical grade



- Describes a product which can be used for medical devices but also is used in other industries
- Not the Medical Device Regulation, nor FDA regulations do apply
- Additional features

Requirements



Documentation acc. MDR

- Documentation
  - For MDR the medical companies need a complex and detailed documentation of the development of each used part within their medical equipment

  → On customer request we are able to support/deliver the needed documents
- Risk management
  - FMEA* analysis during development and production is standard within binder
- Change Management
  - Documentation of changes made for the products is also standard within binder

*FMEA: Failure Mode and Effect Analysis

Additional mechanical tests

- ISO 60601
  - Series of technical standards for the safety and essential performance of medical electrical equipment
  - More than 10 colleteral standards
  - More than 60 particular standards

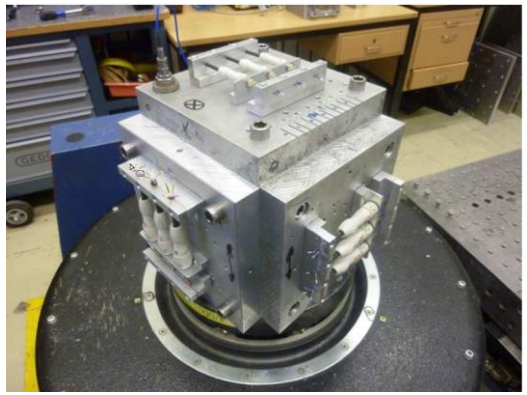
→We defined the following parts as important for connectors:

  - Shock and Vibration
  - Rough handling

Shock and Vibration acc. DIN EN 60601-1-11

- DIN EN 60601-1-11 10.1.3a: Shock: Testing acc. IEC 60068-2-27 : Test Ea and guidance: Shock
  - a=150m/s²; t= 11ms; half sine, 3 shocks/axis

- DIN EN 60601-1-11 10.1.3c Vibration: Testing acc. IEC 60068-2-64: Vibration, broad band random and guidance
  - Broad band random:
    - 10 Hz - 100 Hz → 1,0 [m/s²]²/Hz
    - 100 Hz - 200 Hz → -3 dB/oct
    - 200Hz - 2000 Hz → 0,5 [m/s²]²/Hz
    - t=30min → 3 axis



Rough handling shocks acc. DIN EN 60601-1

- DIN EN 60601-1 15.3.2 Static load reverse acc. IEC 60512-8-1
  - F=250N±10N, t=5s, rate=10N/s
- DIN EN 60601-1 15.3.4.1 Rough handling shocks acc. IEC 60068-2-31
  - Surface:Hardwood plate
  - Fall height: 1m
  - 3 falls

Additional chemical tests

1. Biocompatibility

- Is defined by ISO 10993
  - Series of standards for evaluating the biocompatibility of medical devices
  - The evaluating of biocompatibility can be reached through different testing methods
  - e. g. ISO 10993-5: Tests for cytotoxicity:
    - Can the material harm cells or block the cell growth?

Test acc. ISO 10993-5

Preparation
- Sterilization of the test item (if not delivered steril)

1. Incubation
- Test item with Fibroplastcells for 24 hours at 37°C
- Negative control (a non-cytotoxic film) was treated the same way

Extraction+ 2. Incubation
- Create a cell solution with 10.000 cells/well on a 96-well-plate (test item + negative control)
- Incubation for 72h at 37 °C with regularly control
- Create a positive control

Evaluation
- Evalution of the cells with a microscope (change of the cells:growth and optical change)
- Coloring of the extract to be able to count the cells
- From the ratio of extracted cells in comparison to the negative control the cytoxicity can be calculated

Additional chemical tests

2. Resistance to disinfectants

Defined 11 types of disinfectants

Stored connector parts for 7 days in the disinfectants

Cleaned the parts

Evaluation of the parts

Additional chemical tests

3. Contact with aqeuos food (Migration test)
   - acc. EG596/2009 test method acc. FDA US-CFR Title 21§ 177.2600 (e)

→ Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications

   - Tested with the gravitation method

Simulants	Migration (mg/inch²)
Destilled water (100°C,7h)	<20
Destilled water (100°C,2h)	<1

Additional chemical tests

4. DEHP free
   - Di(2-ethylhexyl)phthalate (DEHP) is a man-made chemical. It is a colorless liquid with a slight odor*
     - Softening agent for plastics

   → Detailed analyzation of all used materials within the connector if DEHP is used

*https://wwwn.cdc.gov/TSP/ToxFAQs/ToxFAQsDetails.aspx?faqid=377&toxid=65

Production / Quality requirements

1. ISO 13485

- Quality management system for the design and production of medical devices

  →Important standard to meet

- The main target is **product safety** (wheras ISO 9001 it is Continuous Improvement and customer satisfaction)

Conclusion

Medical grade connector

- Individual definition by each company
- Industrial connector with additional features for medical industry
- Cost-effective

Medical connector

- Full Fulfillment of DIN EN ISO 60601-1
- Different sterilization methods
- If applicable: Certification acc. MDR

Contact data

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