Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ZM-19630-04-00 according to DIN EN ISO/IEC 17021-1:2015

Valid from: 31.01.2020

Date of issue: 31.01.2020

Holder of certificate:

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2, 20355 Hamburg
Germany

Certifications of management systems in the fields:

DIN EN ISO 13485:2016 Medical devices - Quality management systems – Requirements for regulatory purposes (German version EN ISO 13485:2016)

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
https://www.dakks.de/en/content/accredited-bodies-dakks

- Non-active medical devices[1]
  - General non-active non-implantable medical devices
    - Devices for anaesthesia, emergency and intensive care
    - Devices for injection, infusion, transfusion and dialysis
    - Orthopedic and rehabilitation devices
    - Non-active medical devices with measuring function
    - Ophthalmologic devices
    - Instruments
    - Contraceptive devices
    - Devices for disinfecting, cleaning and rinsing
    - Devices for in vitro fertilisation and assisted reproductive technologies
    - Devices for ingestion
  - Non-active implants
    - Cardiovascular implants
    - Orthopedic implants
    - Functional implants, other
    - Soft tissue implants
  - Devices for wound care
    - Bandages and wound dressings
    - Suture material and clamps
    - Other medical devices for wound care
  - Dental devices
    - Equipment and instruments
    - Dental materials
    - Dental implants
- Active non-implantable medical devices[2]

[1] Including raw materials, semi-finished products and components

[2] Including raw materials, semi-finished products and components

-Translation-

- General active medical devices
    - Devices for extra-corporal circulation, infusion and haemopheresis
    - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
    - Devices for stimulation or inhibition
    - Surgical devices and surgical aids
    - Ophthalmologic devices
    - Dental devices
    - Devices for disinfection and sterilisation
    - Rehabilitation devices and active prostheses
    - Devices for patient positioning and transport
    - Software
    - Medical gas supply systems and parts thereof
- Devices for imaging
    - Devices utilising ionising radiation
    - Devices utilising non-ionising radiation
- Monitoring devices
    - Monitoring devices of non-vital physiological parameters
    - Monitoring devices of vital parameters
- Devices for radiation therapy and thermo therapy
    - Devices utilising ionising radiation
    - Devices utilising non-ionising radiation
    - Devices for hyperthermia / hypothermia
    - Devices for (extracorporal) shock-wave therapy (lithotripsy)

- Active implantable medical devices[3]
    - Active implantable medical devices for stimulation or inhibition
    - Active implantable medical devices for support or replacement of organ functions
- Non-active accessories for active implantable medical devices delivering drugs or other substances

[3] Including raw materials, semi-finished products and components

- In vitro diagnostics[4]
  - In vitro diagnostic instruments and software
- Sterilisation method for medical devices[5]
  - With ethylene oxide
  - With moist heat
  - With radiation (gamma, electron, X-ray)
  - With hydrogen peroxide
  - With dry heat
  - With formaldehyde including low-temperature steam formaldehyde sterilisation
  - Aseptic filling
- Medical devices incorporating/utilising specific substances/technologies[6]
  - Medical devices incorporating medicinal substances in accordance with Directive 2001/83/EC
  - Medical devices utilising tissues of animal origin
    - Including Regulation (EU) No 722/2012
  - Medical devices which are also machines within the meaning of Directive 2006/42/EC
  - Medical devices utilising/incorporating micromechanics
  - Medical devices utilising/incorporating nanomaterials
  - Medical devices utilising/incorporating biological active coatings and/or materials or being wholly or mainly absorbed
  - Medical devices containing or using software or controlled by software
- Processing of medical devices
  Up to risk classification "Critical C" in accordance with the recommendations of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Requirements for hygiene in the processing of medical devices"
- Repair, maintenance and installation of medical devices[7]

[4] Including raw materials, semi-finished products and components
[5] Restricted to the medical devices included in the scope of application
[6] Restricted to the medical devices included in the scope of application
[7] Restricted to the medical devices included in the scope of application

- Custom-made products pursuant to the Medical Devices Act
  - Non-sterile
  - Sterile

  in the area of
  - Ophthalmic optics
  - Dental technology
  - Hearing aid acoustics
  - Orthopedics and orthopedic shoe technology
  - Rehab technology
  - Including health care facilities
- Distribution services of medical devices
- Transport of medical devices

Abbreviations used:

DIN	Deutsches Institut für Normung e.V. (German Institute for Standardisation)
EN	European standard
ISO	International Organisation for Standardisation
IAF	International Accreditation Forum