DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV
Signatory to the Multilateral Agreements of
EA, ILAC and IAF for Mutual Recognition

Accreditation

The Deutsche Akkreditierungsstelle GmbH attests that the certification body

TÜV NORD CERT GmbH,
Langemarckstrasse 20, 45141 Essen
GERMANY

is competent under the terms of DIN EN ISO/IEC 17021-1:2015 to carry out certifications of management systems in the following fields:

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

The accreditation certificate shall only apply in connection with the notice of accreditation of 28.09.2017 with the accreditation number D-ZM-12007-05 and is valid until 20.11.2021. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 4 pages.

Registration number of the certificate: **D-ZM-12007-05-01**

Frankfurt am Main, 28.09.2017

Dipl.-Ing. Ina Stubenrauch
Head of Division

Translation issued: 28.09.2017

Head of Division

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

See notes overleaf.

DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ZM-12007-05-01 in accordance with DIN EN ISO/IEC 17021-1:2015

Period of validity: 28.09.2017 to 20.11.2021 Date of issue: 28.09.2017

Holder of certificate:

TÜV NORD CERT GmbH,
Langemarckstrasse 20, 45141 Essen
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)

- Non-active medical devices[i]
  - General non-active non-implantable medical devices
  - Non-active implants
  - Devices for wound care
  - Dental devices
- Active non-implantable medical devices[ii]
  - 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
  - Monitoring devices
  - Devices for radiation therapy and thermo therapy
    - Devices utilising ionising radiation
    - Devices utilising non-ionising radiation
- Active implantable medical devices[iii]
- In vitro diagnostic medical devices[iv] except devices listed in Annex II to Directive 98/79/EC, but including devices for the measurement of blood sugar
  - Reagents and reagent products, including related calibrators and control materials for
    - Clinical chemistry
    - Immunochemistry (immunology)
    - Haematology/haemostasis/immunohaematology
  - In vitro diagnostic instruments and software
  - Sample containers
- Sterilisation method for medical devices[v]
  - With ethylene oxide
  - With moist heat
  - With radiation (gamma, electron, X-ray)
  - With hydrogen peroxide
  - Thermal sterilisation methods with dry heat
  - With formaldehyde including low-temperature steam formaldehyde sterilisation
  - With plasma
- Medical devices incorporating/utilising specific substances/technologies[vi]
  - Medical devices incorporating medicinal substances in accordance with Directive 2001/83/EC
  - Medical devices utilising tissues of animal origin
    - Without Regulation (EU) No 722/2012
  - Medical devices which are also machines within the meaning of Directive 2006/42/EC

  - 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 B" 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[vii]
- Custom-made products pursuant to the Medical Devices Act in the area of
  - 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
- Trade of medical devices
- Transport of medical devices

Abbreviations used: see last page

DAkkS Deutsche Akkreditierungsstelle

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

---

[i] Including semi-finished products and components

[ii] Including semi-finished products and components

[iii] Including semi-finished products and components

[iv] Including semi-finished products and components

[v] Restricted to the medical devices included in the scope of application

[vi] Restricted to the medical devices included in the scope of application

[vii] Restricted to the medical devices included in the scope of application