Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ZM-14137-01-01 according to DIN EN ISO/IEC 17021-1:2015

Period of validity: 08.02.2018 to 07.02.2023 Date of issue: 08.02.2018

Holder of certificate:

TÜV Technische Überwachung Hessen GmbH
Managementsysteme – Zertifizierungsstelle,
Robert-Bosch-Straße 16, 64293 Darmstadt

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)**

Description of the Scope:

- **Non-active Medical Devices**
  - General non-active, non-implantable medical devices
    - Non-active devices for injection, infusion, transfusion and dialysis
    - Non-active orthopedic and rehabilitation devices
    - Non-active instruments
  - Devices for wound care
    - Bandages and wound dressings

- **Active Medical Devices (Non-Implantable)**
  - 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
    - Active surgical devices
    - Active dental devices
    - Active rehabilitation devices and active prostheses
    - Active devices for patient positioning and transport
    - Software

- Devices for imaging
  - Devices utilizing ionizing radiation
  - Devices utilizing non-ionizing radiation

- Monitoring devices
  - Monitoring devices of non-vital physiological parameters
  - Monitoring devices of vital physiological parameters

- Devices for radiation therapy and thermo therapy
  - Devices utilising ionizing radiation
  - Devices utilising non-ionizing radiation
  - Devices for (extracorporal) shock-wave therapy (lithotripsy)

- **Medical devices incorporating/utilising specific substances/technologies[1]**
  - Medical devices which are also machines within the meaning of Directive 2006/42/EC
  - Medical devices containing or using software or controlled by software

- **Repair, maintenance and installation of medical devices[1]**

- **Custom-made products pursuant to the Medical Devices Act in the area of**
  - Non-sterile

  In the area of
  - Orthopedics and orthopedic shoe technology
  - Rehab technology
  - Including health care facilities

- **Trade of medical devices**

- **Transport of medical devices**

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

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