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

**mdc medical device certification GmbH**
**Kriegerstraße 6, 70191 Stuttgart**

at the locations

**Kriegerstraße 6, 70191 Stuttgart**
**Ernst-Augustin-Straße 2, 12489 Berlin**

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** |

The accreditation certificate shall only apply in connection with the notice of accreditation of 15.07.2021 with the accreditation number D-ZM-16002-06. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 5 pages.

Registration number of the certificate: **D-ZM-16002-06-00**

Frankfurt am Main, 15.07.2021

Dipl.-Ing. Ina Stubenrauch
Head of Division

Translation issued: 15.07.2021

by proxy
Head of Division

*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*

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

See notes overleaf.

# Deutsche Akkreditierungsstelle GmbH

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The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). DAkkS is a signatory to the Multilateral Agreements for Mutual Recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

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## Annex to accreditation certificate D-ZM-16002-06-00 in accordance with DIN EN ISO/IEC 17021-1:2015

**Valid from: 15.07.2021**

Date of issue: 15.07.2021

Holder of certificate:

**mdc medical device certification GmbH**
**Kriegerstraße 6, 70191 Stuttgart**

at the locations

**Kriegerstraße 6, 70191 Stuttgart**
**Ernst-Augustin-Straße 2, 12489 Berlin**

Certification of management systems in the areas of:

**DIN EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes**

- 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
    - Orthopaedic 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

Abbreviations used: see last page

    - Devices for ingestion
  - Non-active implants
    - Cardiovascular implants
    - Orthopaedic 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]
  - General active medical devices
    - Devices for extra-corporal circulation, infusion and haemopheresis
    - Respiratory devices, devices for oxygen therapy (except hyperbaric therapy chambers) and inhalation anaesthesia
    - Devices for stimulation or inhibition (except external pacemakers and defibrillators)
    - 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
- In vitro diagnostics[3]
  - Reagents and reagent products, including related calibrators and control materials for
    - Clinical chemistry
    - Immunochemistry (immunology)
    - Haematology/haemostasis/immunohaematology
    - Microbiology
    - Infection immunology
    - Histology/cytology
    - Genetic testing
  - In vitro diagnostic instruments and software
  - IVD utilising/incorporating materials of human origin
- Sterilisation method for medical devices[4]
  - With ethylene oxide
  - With moist heat
  - With radiation (gamma, electron, X-ray)
  - With hydrogen peroxide
  - With dry heat
  - Aseptic filling
- Medical devices incorporating/utilising specific substances/technologies[5]
  - 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 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"
- Parts and services
  - Raw materials
  - Components
  - Semi-finished products
  - Trade of medical devices
  - Maintenance services[6]
  - Transport of medical devices
  - Other services[7]
    - Training services (application training) for medical devices
    - Advice on regulatory aspects in the conformity assessment procedure
    - Activities of economic operators (e.g. authorised representative, importer, translator) with regard to medical devices
- Custom-made products in the health trade professions
  - Non-sterile
  - Sterile

  In the area of
  - Ophthalmic optics
  - Dental technology
  - Hearing aid acoustics
  - Orthopaedics and orthopaedic shoe technology
  - Rehab technology

**Abbreviations used:**

| | |
|---|---|
| DIN | Deutsches Institut für Normung e.V. (German Institute for Standardisation) |
| EC | European Community |
| EN | European Standard |
| EU | European Union |
| ISO | International Organization for Standardization (Internationale Organisation für Normung) |
| IEC | International Electrotechnical Commission |

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[1] Including raw materials, semi-finished products and components
[2] Including raw materials, semi-finished products and components
[3] Including raw materials, semi-finished products and components
[4] Restricted to the medical devices included in the scope of application
[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



Issue date: 15.07.2021
**Valid from: 15.07.2021**