Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

Baden-Württemberg

Bayern

Berlin

Brandenburg

Bremen

Hamburg

Hessen

Mecklenburg-Vorpommern

DESIGNATION

The Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) has determined in a designation procedure that the

mdc medical device certification GmbH

Kriegerstraße 6
70191 Stuttgart
Germany

meets the requirements laid down in Annex XI of Directive 93/42/EEC as **Certification Body for medical devices** and as **Certification Body for quality assurance systems** (Reg.-No. ZLG-BS-246.10.06) and is competent to conduct

conformity assessment procedures according to **Annex II, V** and **VI of Directive 93/42/EEC**

for the following medical devices

general non-active non-implantable medical devices, non-active implants, non-active devices for wound care, non-active dental devices, general non-implantable active devices, devices for imaging, monitoring devices, devices for radiation therapy and thermotherapy.

This designation according to § 15 (1) Medical Devices Act is valid up to 2022-01-26.

This document is valid only in conjunction with the designation notice which contains the binding information on the designation. The scope of the designation is specified in the annex in force of the designation notice. The status of the designation can be found on www.zlg.de.

Bonn, 2017-09-07

Dr Rainer Edelhäuser
Director of ZLG

Thüringen

Schleswig-Holstein

Sachsen

Sachsen-Anhalt

Saarland

Rheinland-Pfalz

Nordrhein-Westfalen

Niedersachsen

Basis of designation

German Act on Medical Devices (Medical Devices Act)

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin

Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices

Rules for Designation of ZLG (www.zlg.de)

- General Rules for Recognition and Designation (200 RE01)
- Rules for Designation (220 RE01)
- Specific Rules for Designation
  Scope "Sterile Medical Devices" (220 RE03)
- Specific Rules for Designation
  Scope "Reprocessing" (220 RE04)
- Specific Rules for Designation
  Scope "Materials of animal origin" (220 RE05)
- Specific Rules for Designation
  Scope "Unannounced Audits" (220 RE06)

Commission Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU)

Document MEDDEV 2.10/2 of the European Commission *Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices*

Designating Authorities Handbook (see www.nbog.eu)

EN ISO/IEC 17021-1 : 2015	Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements
EN ISO/IEC 17065 : 2013-01	Conformity assessment - Requirements for bodies certifying products, processes and services

For the use of indications on the status of designation the document of ZLG 200 HI02 applies (www.zlg.de).