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 IX of Directive 98/79/EC as **Certification Body for *in vitro* diagnostic medical devices** and as **Certification Body for quality assurance systems for *in vitro* diagnostic medical devices** (Reg.-No. ZLG-BS-247.10.05) and is competent to conduct

conformity assessment procedures according to **Annex III, IV** and **VII of Directive 98/79/EC**

for

- **in vitro diagnostic medical devices according to Annex II List A**
- **in vitro diagnostic medical devices according to Annex II List B**
- **in vitro diagnostic medical devices for self testing.**

This designation according to § 15 (1) Medical Devices Act is valid up to 2024-05-26.

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, 2019-12-16

Dr Ulrich Poos
Deputy of 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)

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic 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 "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).