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

meets the requirements laid down in Articel 36 and Annex VII of Regulation (EU) 2017/745 on medical devices as conformity assessment body for medical devices (Reg.-Nr. BS-MDR-098.20.01) and is competent to conduct

conformity assessment procedures according to **Annexes IX (I), IX (II) and XI (A)** of Regulation (EU) 2017/745 on medical devices

for the following medical devices

active non-implantable devices for imaging, monitoring and/or diagnosis, active non-implantable therapeutic devices and general active non-implantable devices, non-active implants and long term surgically invasive devices, non-active non-implantable devices.

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 notification can be found on http://ec.europa.eu/growth/tools-databases/nando/.

Bonn, 2020-04-29

Dr Ulrich Poos
Deputy of Director of ZLG

Thüringen | Schleswig-Holstein | Sachsen | Sachsen-Anhalt | Saarland | Rheinland-Pfalz | Nordrhein-Westfalen | Niedersachsen