Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

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

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70191 Stuttgart
Germany

meets the requirements laid down in Article 32 and Annex VII of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices as conformity assessment body for *in vitro* diagnostic medical devices (Reg.-Nr. BS-IVDR-098.23.01) and is competent to conduct

conformity assessment procedures according to **Annex IX (I) and IX (II)** of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

for the following *in vitro* diagnostic medical devices

devices intended to be used for blood grouping, tissue typing, markers of cancer and non-malignant tumours, human genetic testing, to determine markers of infections / immune status, for non-infectious pathologies, physiological markers, disorders / impairments and therapeutic measures, devices which are controls without a quantitative or qualitative assigned value, Class A devices in sterile condition.

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 https://ec.europa.eu/growth/tools-databases/nando/.

Bonn, 16.01.2023

Dr. Rainer Edelhäuser
Director of ZLG

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