

Certificate

mdc medical device certification GmbH
certifies that

Human



Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden
Germany

with the location

Stegelitzer Straße 3
39126 Magdeburg

for the scope

development, manufacturing and distribution of reagents, reagent products, calibrators and control materials for clinical chemistry, haematology, haemostasis, immune chemistry as well as analyzers for in-vitro diagnosis.

distribution of test kits for molecular biology analyses as well as rapid tests for the diagnosis of infectious diseases.

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-03-17
Valid until	2025-03-11
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Head of Certification Body

