

Certificate

mdc medical device certification GmbH
certifies that

Human

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

with the production site

Stegelitzer Straße 3
39126 Magdeburg
Germany

for the scope

**development, manufacturing and distribution of
in vitro diagnostic products and analyzers**

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 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2014-03-12
Valid until	2019-03-11
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Report no.	E-D10300_2014-03-10
Stuttgart	2014-03-10



Head of Certification Body

