

Certificate

mdc medical device certification GmbH
certifies that

**Biotype GmbH
Moritzburger Weg 67
01109 Dresden
Germany**

for the scope

**sales, development, manufacturing and services of
molecular tests for in-vitro diagnostic applications**

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:2016 - ISO 13485:2016

Valid from	2019-11-30
Valid until	2022-11-29
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Head of Certification Body

