Certificate

mdc medical device certification GmbH
certifies that

Biotype GmbH
Moritzburger Weg 67
01109 Dresden
Germany

for the scope

development, manufacturing, distribution 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:2018 + A11:2021 - ISO 13485:2016

Valid from	2022-11-30
Valid until	2025-11-29
Registration no.	D1419300008
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Head of Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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