

Certificate

We hereby certify the company

Biotype GmbH
Moritzburger Weg 67
01109 Dresden
Germany



the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

development, manufacturing, distribution and services of molecular and bioanalytical test systems
for in-vitro diagnostic applications

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2025-02-24
Valid until 2028-02-23

Registration No. D1419300011
Report No. P23-01226-278920

Stuttgart, 2025-02-24


mDC
Certification Body


DAkkS
Deutsche
Akkreditierungsstelle
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