

Certificate

We hereby certify the company

Astra Biotech GmbH
Rudower Chaussee 29
12489 Berlin
Germany

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Development, manufacturing and distribution of in vitro diagnostics based on biochemical and molecular genetic methods and related reagents

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 2025-01-30
Valid until 2028-01-29

Registration No. D1292200016
Report No. P24-01472-315810

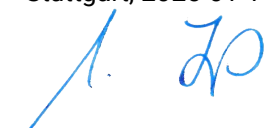
Stuttgart, 2025-01-14


Certification Body

Sites included in the certification:

Location	Scope
Astra Biotech GmbH Rudower Chaussee 29 12489 Berlin Germany	Head office
Astra Biotech GmbH Kekuléstraße 7 12489 Berlin Germany	Development, manufacturing and distribution of in vitro diagnostics based on biochemical and molecular genetic methods and related reagents

Stuttgart, 2025-01-14



Certification Body