

Certificate

mdc medical device certification GmbH
certifies that

**Astra Biotech GmbH
Rudower Chaussee 29
12489 Berlin
Germany**

with the locations listed in the attachment
for the scope

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

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	2022-01-30
Valid until	2025-01-29
Registration no.	D1292200012
Report no.	P21-01727-218513
Stuttgart	2022-01-19


Head of Certification Body



Attachment of the certificate

No. D1292200012

date 2022-01-19

Page 1 of 1

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





Head of Certification Body