

Certificate

mdc medical device certification GmbH
certifies that



altona Diagnostics GmbH
Mörkenstraße 12
22767 Hamburg
Germany

with the locations listed in the attachment
for the scope

**Design & Development, manufacturing and distribution of
systems for isolation and purification of nucleic acids as well as
real-time PCR kits for the detection of
pathogens and genetic markers**

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	2021-05-17
Valid until	2023-04-29
Registration no.	D1267700025
Report no.	P20-01897-191478
Stuttgart	2021-05-17

A handwritten signature in blue ink, appearing to read "ALC", is positioned above the title "Head of Certification Body".

Head of Certification Body



Attachment of the certificate

No. D1267700025

date 2021-05-17

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Location	Scope
altona Diagnostics GmbH Eschelsweg 14 22767 Hamburg	Storage and shipping of systems for isolation and purification of nucleic acids as well as real-time PCR kits for the detection of pathogens and genetic markers
altona Diagnostics GmbH Königstraße 4a 22767 Hamburg	Design & Development of systems for isolation and purification of nucleic acids as well as real-time PCR kits for the detection of pathogens and genetic markers
altona Diagnostics GmbH Mörkenstraße 12 22767 Hamburg	Manufacturing of systems for isolation and purification of nucleic acids as well as real-time PCR kits for the detection of pathogens and genetic markers
altona Diagnostics GmbH Virchowstraße 17-19 22767 Hamburg	Distribution and order processing of systems for isolation and purification of nucleic acids as well as real-time PCR kits for the detection of pathogens and genetic markers




Head of Certification Body