

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

**development, manufacturing and sales 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	2018-09-27
Valid until	2021-09-26
Registration no.	D1267700013
Report no.	P18-00875-123948
Stuttgart	2018-09-27

A handwritten signature in black ink, appearing to be "J. A.", is written over a light blue horizontal line.

Head of Certification Body



Attachment of the certificate

No. D1267700013

date 2018-09-27

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Location	Scope
altona Diagnostics GmbH, Königstraße 4a, 22767 Hamburg	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 and sales 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