CERTIFICATE

This is to certify that the company

altona Diagnostics GmbH

Mörkenstr. 12
22767 Hamburg
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
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
AUS (a), BRA, CND, USA (a, b, c, d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	504373 MDSAP16
Certificate unique ID	170778965
Effective date	2023-04-24
Expiry date	2026-04-23
Frankfurt am Main	2023-04-21

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 504373 MDSAP16
Certificate unique ID: 170778965
Effective date: 2023-04-24

altona Diagnostics GmbH

Mörkenstr. 12
22767 Hamburg
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
522702 **altona Diagnostics GmbH** Mörkenstr. 12 22767 Hamburg Germany	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 -**AUS (a), BRA, CND, USA (a, b, c, d)** **REPs FEI No.: F004575**
522703 **altona Diagnostics GmbH** Königstr. 4a 22767 Hamburg Germany	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 -**AUS (a), BRA, CND, USA (a, b, c, d)** **REPs FEI No.: F004575**
548812 **altona Diagnostics GmbH** Virchowstr. 17-19 22767 Hamburg Germany	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 -**AUS (a), BRA, CND, USA (a, b, c, d)** **REPs FEI No.: F004575**
551068 **altona Diagnostics GmbH** Schnackenburgallee 45 22525 Hamburg Germany	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 -**AUS (a), BRA, CND, USA (a, b, c, d)** **REPs FEI No.: F004575**

Annex to certificate
Certificate registration No.: 504373 MDSAP16
Certificate unique ID: 170778965
Effective date: 2023-04-24

altona Diagnostics GmbH

Mörkenstr. 12
22767 Hamburg
Germany

Audited site

551069
altona Diagnostics GmbH
Jessenstr. 13
22767 Hamburg
Germany

REPs FEI No.: site scope and country-specific requirements

Productmanagement and Regulatory Affairs of systems for isolation and purification of nucleic acids as well as real-time PCR kits for the detection of pathogens and genetic markers
-AUS (a), BRA, CND, USA (a, b, c, d)
REPs FEI No.: F004575

Annex to certificate
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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821