



CERTIFICATE



This is to certify that the company

altona Diagnostics GmbH

Mörkenstraße 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:

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.

- 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	170753601
Effective date	2020-04-24
Expiry date	2023-04-23
Frankfurt am Main	2020-04-24



DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.

Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



Annex to certificate
Certificate registration No.: 504373 MDSAP16
Certificate unique ID: 170753601
Effective date: 2020-04-24



altona Diagnostics GmbH

Mörkenstraße 12
22767 Hamburg
Germany

Audited site

altona Diagnostics GmbH
Mörkenstraße 12
22767 Hamburg
Germany

altona Diagnostics GmbH
Königstraße 4a
22767 Hamburg
Germany

DUNS No., site scope and country-specific requirements

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.

DUNS.-No. 312597593

- **AUS (a), BRA, CND, USA (a, b, c, d)**

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.

DUNS.-No. 312597593

- **AUS (a), BRA, CND, USA (a, b, c, d)**

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. 16/2013 RDC ANVISA n. 23/2012 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