CERTIFICATE

This is to certify that the company

Andreas Hettich GmbH & Co.KG

Föhrenstraße 12
78532 Tuttlingen
Germany

with the organizational units/sites as listed in the annex

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

Scope of certification:
Design and development, Manufacturing, Distribution and Servicing of laboratory centrifuges for IVD and general laboratory purposes, centrifuges for separation of blood components for transfusion purposes, microbiological incubators for IVD purposes and general laboratory purposes.
-AUS (a), BRA, CND, JPN, 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.	546262 MDSAP16
Certificate unique ID	170777224
Effective date	2022-06-10
Expiry date	2025-06-09
Frankfurt am Main	2022-06-10

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Digitally signed by Chiot Natalia
Date: 2023.02.16 09:10:05 EET
Reason: MoldSign Signature
Location: Moldova

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 546262 MDSAP16
Certificate unique ID: 170777224
Effective date: 2022-06-10

Andreas Hettich GmbH & Co.KG

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78532 Tuttlingen
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
546262 **Andreas Hettich GmbH & Co.KG** Föhrenstraße 12 78532 Tuttlingen Germany	Design and development, Manufacturing, Distribution and Servicing of laboratory centrifuges for IVD and general laboratory purposes, centrifuges for separation of blood components for transfusion purposes, microbiological incubators for IVD purposes and general laboratory purposes. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F002477**

Annex to certificate
Certificate registration No.: 546262 MDSAP16
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78532 Tuttlingen
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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

Certificate

mdc medical device certification GmbH
certifies that

Andreas Hettich GmbH & Co. KG
Föhrenstraße 12
78532 Tuttlingen
Germany

for the scope

Design, development, manufacturing, distribution and servicing of laboratory centrifuges for IVD applications and general laboratory use, centrifuges for separation of blood components for transfusion purposes and microbiological incubators for IVD applications and general laboratory use

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:2018 + A11:2021 - ISO 13485:2016

Valid from	2022-10-25
Valid until	2025-10-24
Registration no.	D1459300003
Report no.	P21-01967-222238
Stuttgart	2022-10-25

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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