CERTIFICATE

This is to certify that the company

DR. WEIGERT
SYSTEMATIC HYGIENE

Chemische Fabrik Dr. Weigert GmbH & Co. KG

Mühlenhagen 85
20539 Hamburg
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, production and distribution of cleansing- and disinfecting agents and dosing equipment for medical devices.
- AUS (a), CND, USA (a,b,c,d,e)

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.	001549 MDSAP16
Certificate unique ID	1000263161
Effective date	2026-05-19
Expiry date	2029-05-18
Frankfurt am Main	2026-05-19

MDSAP
Medical Device Single Audit Program

DQS Medizinprodukte GmbH

Sven Hoffmann
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt a. M., Germany
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
The validity of the certification can only be verified by the QR-code.

413.01 Version 7.0

Annex to certificate
Certificate registration No.: 001549 MDSAP16
Certificate unique ID: 1000263161
Effective date: 2026-05-19

Chemische Fabrik Dr. Weigert GmbH & Co. KG

Mühlenhagen 85
20539 Hamburg
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
001549 **Chemische Fabrik Dr. Weigert GmbH & Co. KG** Mühlenhagen 85 20539 Hamburg Germany	Design and development, production and distribution of cleansing- and disinfecting agents and dosing equipment for medical devices. **- AUS (a), CND, USA (a,b,c,d,e)** **REPs FEI No.: F009051**

Annex to certificate
Certificate registration No.: 001549 MDSAP16
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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 Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 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