Certificate

ECM – Zertifizierungsgesellschaft
für Medizinprodukte in Europa mbH,
Talbotstraße 21, 52068 Aachen, Germany

hereby declares that an examination according to
DIN EN ISO/IEC 17021-1:2015 of the undermentioned
quality assurance system has been carried out.

Through an audit performed on behalf of

Chempatex Medizinische Vertriebsgesellschaft m.b.H.
Stöckenhoop 27A, 21465 Wentorf bei Hamburg, Germany

it could be demonstrated that a quality management system
according to

ISO 13485:2016
EN ISO 13485:2016 + AC:2018 + A11:2021
DIN EN ISO 13485:2021
„Medical devices – Quality management systems – Requirements for regulatory purposes"

for the scope:

Foreign trade of medical devices

has been established and implemented.

This certificate is only valid under the conditions stated in the audit report for the audit mentioned below.

Any substantial changes of the quality management system have to be notified to ecm and are subject to a separate assessment.

Audit-No.	Registered under	Valid until
0949-25-0812	**Z/25/04896E**	**01 September 2028**

Valid as of: 02 September 2025

Certification body

DAkkS Deutsche Akkreditierungsstelle D-ZM-21753-01-00

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