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

Legart Forschungsatelier GmbH
Angererstraße 6, 83064 Raubling am Inn, 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 subcontracted production of non-sterile bulk solutions for non-active, non-implantable medical devices in terms of wound management and skin treatment as well as to disinfect, cleanse and rinse

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
0942-23-1115	**Z/23/04848E**	**17 December 2026**

Valid as of: 29 January 2024

Certification body

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

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