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

AMEFA GmbH
In den Fritzenstücker 9-11, 65549 Limburg, 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:

wholesale and import 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
0648-24-1111	**Z/24/04862E**	**15 December 2027**

Valid as of: 16 December 2024

Certification body

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

ID 0374