Certificate

Quality Management System

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2016.

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 **DIN EN ISO 13485:2016**
"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the **wholesale and import of medical devices**

has been established and implemented.

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

Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report number	Registered under	Valid until
648-21-1026	**Z/21/04769E**	**20 December 2024**

Valid as of: 21 December 2021

Certification body

ID no. 0045

Annex I to Certificate Z/21/04769E

Number of Pages: 1 von 1

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

The scope of this certificate includes the following production site:

AMEFA GmbH
Industriestraße 11-13
65549 Limburg
Germany