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

Acti-Med GmbH
Philipp-Reis-Straße 2, 36399 Freiensteinau, 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 **development, manufacture and distribution of minimal invasive medical single use products and components**

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
228-21-71	**Z/21/04753E**	**June 27th, 2024**

Valid as of: October 1st, 2021

Certification Body

Annex I to Certificate Z/21/04753E

Number of Pages: 1 von 1

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

The production site:

Acti-Med Polska Sp. z.o.o.
Ulica Generala Orlicz-Dreszera 31A
05-825 Grodzisk Mazowiecki-Kozerki
Poland

includes the scope:

manufacture and distribution of minimal invasive medical single use products and components