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

imeco GmbH & Co. KG
Boschstr. 5, 63768 Hösbach, 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 **Manufacture and distribution of single use medical devices from non-woven material and contract manufacture**

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
598-18-1213	**Z/19/04496E**	**March 31st, 2022**

Valid as of: April 1st, 2019

Certification Body

Annex I to Certificate Z/19/04496E

Number of Pages: 1 von 1

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

The scope of this certificate includes the following production sites:

-- Imakon Sp. z o o.
ul. Wlókiennicza 10, 59-800 Luban, Polen

-- imeco GmbH & Co. KG
Neue Str. 2-4, 09471 Königswalde, Deutschland