

# 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"

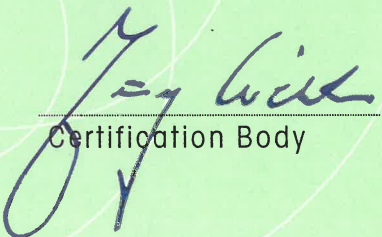
for the **Manufacture and distribution of single use  
medical devices from non-woven material  
and contract manufacture**

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 31 <sup>st</sup> , 2022

Valid as of: April 1<sup>st</sup>, 2019

  
Certification Body

**Annex I to Certificate Z/19/04496E**

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Zertifizierungsgesellschaft für  
Medizinprodukte in Europa mbH

**The scope of this certificate includes the following production sites:**

- Imakon Sp. z o o.  
ul. Wlóknienna 10, 59-800 Luban, Polen
- imeco GmbH & Co. KG  
Neue Str. 2-4, 09471 Königswalde, Deutschland