

# 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

**Carmonja GmbH**

**Am Wegmannbichl 4, 83246 Unterwössen, 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 sterile, disposable medical products for gastrology, cardiology, enterology, urology and surgery**

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

**435-21-24**

Registered under

**Z/21/04732E**

Valid until

**April 12<sup>th</sup>, 2024**

Valid as of: April 13<sup>th</sup>, 2021

A handwritten signature in blue ink, appearing to read 'P. Uef', is written over a horizontal line.

Certification Body