## 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

## **KOBI Medizintechnik 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

manufacturing and distribution of endoscopy instruments, electro-endoscopic surgical accessories and 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

902-21-56

Z/21/04735R

14 May 2024

Valid as of: 15 May 2021

Gertification Body