

# 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

### **ROLAN Instruments GmbH**

Eisenbahnstr. 65-67, 78604 Rietheim-Weilheim, 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

### **distribution and manufacturing of surgical instruments and sterilization containers**

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

692-18-74

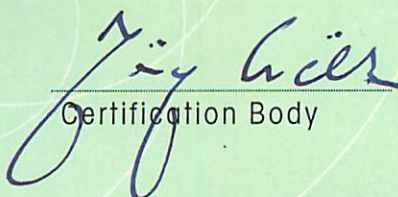
Registered under

Z/19/04532E

Valid until

September 29<sup>th</sup>, 2021

Valid as of: May 02<sup>nd</sup>, 2019

  
Certification Body