

# 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

### **INFINIDENT Solutions GmbH**

Röntgenstraße 88, 64291 Darmstadt, 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

### **production of customised intermediate products for dental applications**

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

**928-18-1025**

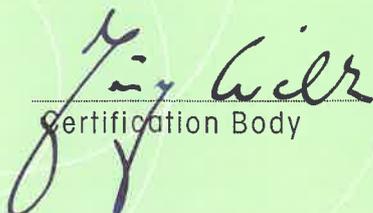
Registered under

**Z/19/04521E**

Valid until

**April 11<sup>th</sup>, 2022**

Valid as of: April 12<sup>th</sup>, 2019

  
Certification Body