

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

Ardoz Healthcare B.V.

**Kasteleinenkampweg 9C, 5222 AX s´ Hertogenbosch,
The Netherlands**

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

**design and development, manufacturing and
distribution of products for oral and dermal
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

459-18-612

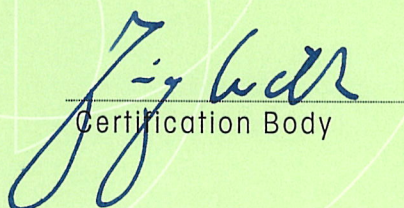
Registered under

Z/18/04294E

Valid until

September 14th, 2021

Valid as of: September 15th, 2018


Certification Body