

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

Helago-Pharma GmbH

An der Schleifmühle 2, 50374 Erftstadt, 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

development, manufacture and distribution of cleansing and disinfecting products for dentures and other medical devices as well as manufacture and distribution of other medical devices for denture and dental care.

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

327-18-109

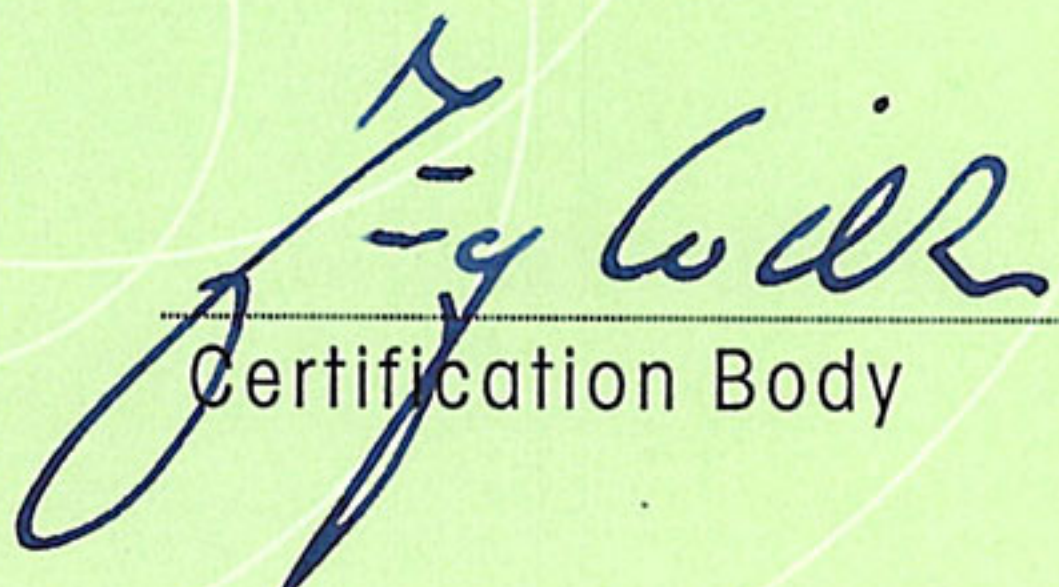
Registered under

Z/19/04418E

Valid until

March 31st, 2022

Valid as of: April 1st, 2019


Certification Body