

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

ZSB Verpackung GmbH

Chiemgaustr. 3, 83233 Bernau am Chiemsee, 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

contract manufacturing of liquid, semi-solid and pasty medical devices for topical application

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

458-22-427

Registered under

Z/22/04831E

Valid until

22 May 2025

Valid as of: 23 May 2022


Certification body