Certificate

ECM - Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Talbotstraße 21, 52068 Aachen, Germany

hereby declares that an examination according to DIN EN ISO/IEC 17021-1:2015 of the undermentioned quality assurance system has been carried out.

ecm

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

ISO 13485:2016

EN ISO 13485:2016 + AC:2018 + A11:2021

DIN EN ISO 13485:2021

"Medical devices — Quality management systems — Requirements for regulatory purposes"

for the scope:

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 for the audit mentioned below.

Any substantial changes of the quality management system have to be notified to ecm and are subject to a separate assessment.

Audit-No.

Registered under

Valid until

0458-25-0408

Z/25/04885E

27 May 2028

Valid as of: 17 June 2025



