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.

Through an audit performed on behalf of

C. Hedenkamp GmbH & Co. KG
Schierbusch 1, 33161 Hövelhof, 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:

design, development, manufacturing and contract manufacturing of medical devices as capsules, chewable tablets, tablets to swallow, lozenges and effervescent tablets and devices in powder form

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
0656-24-0424	**Z/24/04856E**	**20 October 2027**

Valid as of: 21 October 2024

Certification body

DAkkS Deutsche Akkreditierungsstelle D-ZM-21753-01-00

ID 0374