EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
0523GB448251013	0523AU32F	2025-11-13	2030-11-12

This is to certify that the quality system of

BODE CHEMIE GmbH

Melanchthonstraße 27, 22525 Hamburg, Germany

SRN: DE-MF-000005851

For design & development, manufacturing and final product inspection/testing of

Medical devices/groups of medical devices at locations as listed on the following pages

has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2025-10-13

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Dr. Ralf Reimer-Guénon
Certification Body Operations

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact medcert-info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820111 EN Rev. 6 2025.07.16

Certificate no.: 0523GB448251013
Place and date: Hamburg, 2025-10-13

Preceding certificate

Certificate no.	Issue date	Identification of changes
0523GB448210329A	2021-03-29	Renewal of certificate
0523GB448210329A	2021-03-29	Extension of scope acc. to WO-014829
0523GB448210329A	2021-03-29	Reduction of scope acc. to WO-014830

SAFEGUARDING LIFE, PROPERTY AND THE ENVIRONMENT - DNV 1864

Certificate no.: 0523GB448251013
Place and date: Hamburg, 2025-10-13

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1211	D0101	GLUTARALDEHYDE AND ASSOCIATES FOR THE DISINFECTION OF MEDICAL DEVICES
MDN 1211	D0701	ETHANOL FOR THE DISINFECTION OF MEDICAL DEVICES
MDN 1211	D0799	ALCOHOLS FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
MDN 1211	D99	DISINFECTANTS, ANTISEPTICS, STERILIZING AGENTS AND DETERGENTS FOR MEDICAL DEVICES – OTHERS
MDN 1211	D0502	HYDROGEN PEROXIDE FOR DISINFECTION OF MEDICAL DEVICES

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1211	D010101	GLUTARALDEHYDE FOR THE DISINFECTION OF MEDICAL DEVICES

Intended purpose

Disinfection of invasive and non-invasive medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1211	D0599	OXYGEN PRODUCERS FOR DISINFECTION OF MEDICAL DEVICES - OTHER

Intended purpose

Disinfection of invasive and non-invasive medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1211	D99	DISINFECTANTS, ANTISEPTICS, STERILIZING AGENTS AND DETERGENTS FOR MEDICAL DEVICES – OTHERS

Intended purpose

Disinfection of invasive and non-invasive medical devices

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 0482: DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com