

# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
0523GB448251013

Final Assessment Report no.  
0523AU32F

Effective date  
2025-11-13

Expiry date  
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**

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



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

BS-MDR-096

**Dr. Ralf Reimer-Guénou**  
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](mailto:medcert-info@dnv.com)



# DNV

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





**DNV**

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## 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