

EU Quality Management System Certificate

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

BODE CHEMIE GmbH
Melanchthonstraße 27
22525 Hamburg
Germany

SRN: not available

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

Effective date: 2021-03-29
Expiry date: 2025-11-13

Final assessment report No.: 0523IA27F
Procedure No.: QS – 0523
Certificate No.: 0523GB448210329A

Preceding certificate No.: –
Preceding certificate date: –
Identification of changes: –

Hamburg, 2021-03-29



MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
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MEDCERT Notified Body Identification Number: 0482



Appendix of EU Quality Management System Certificate

Procedure No.: QS – 0523
Certificate No.: 0523GB448210329A

Class IIa medical devices

Category of devices	Medical devices/groups of medical devices	
MDN 1211	D010101	Disinfectants, medical devices, glutaraldehyde
	D0701	Disinfectants, medical devices, ethanol
	D0799	Disinfectants, medical devices, alcohols – others
	D99	Disinfectants and antiseptics for medical devices - others

This appendix is integral part of the above-referenced certificate.
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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 0523
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Class IIb medical devices

Category of devices	Medical devices/groups of medical devices	
MDN 1211	D010101	Disinfectants, medical devices, glutaraldehyde Intended purpose: Disinfection of non invasive and invasive Medical Devices
	D05010	Disinfectants, medical devices, peracetic acid Intended purpose: Disinfection of non invasive and invasive Medical Devices
	D0599	Disinfectants, medical devices, oxygen producers – others Intended purpose: Disinfection of non invasive and invasive Medical Devices
	D99	Disinfectants and antiseptics for medical devices – others Intended purpose: Disinfection of non invasive and invasive Medical Devices

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 BS-MDR-096