Docusign Envelope ID: EF9C36F9-A314-886F-81B7-AE2893B4A3B6

BODE Chemie GmbH
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EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2026-09-07

Object of the declaration: **Bacillol AF**

Bacillol AF		
Pack size	Article number BODE	Article number HARTMANN
500 ml	973385	980214
500 ml	980214	980214
500 ml	981908	981908
1 L	973380	980212
1 L	980212	980212
1 L	975071	980369
1 L	980369	980369
1 L	981436	981436
5 L	973389	980217
5 L	980217	980217
5 L	981246	981246
200 L	973388	980216
200 L	980216	980216

We herewith declare under our sole responsibility that the medical devices listed above, first placed on the market by BODE Chemie GmbH, comply with the applicable provisions, in particular, the

- General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The objects of the declaration have been identified as medical devices in risk class IIa according to classification rule 16 in Annex VIII of Regulation (EU) 2017/745.

The conformity assessment procedure according to Article 52 (6) and Annex IX has been performed and the Technical Documentation is kept available.

HARTMANN SCIENCE CENTER
Research for
infection protection.

BODE Chemie GmbH
Commercial Register Hamburg
HRB 108924

Managing Director:
Arne-John Roettger

HypoVereinsbank
IBAN: DE83 6002 0290 0611 0224 33
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The conformity assessment procedure is under the supervision of the Notified Body:

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany
Identification No. 0482
Certificate No. 0523GB448251013

(High-Level) Intended Purpose:
Disinfection of non-invasive medical devices

Basic UDI-DI: 40316782658LY
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

Deputy PRRC	Head of Quality
Signiert von: Marina Smit Name des Unterzeichners: Marina Smit Signiergrund: Ich genehmige dieses Dokument Signierzeit: September 7, 2026 | 09:16 MESZ 27BF23530C1744ACBFE5F624BB7F96C4	Signiert von: Name des Unterzeichners: Raphael Bohner Signiergrund: Ich genehmige dieses Dokument Signierzeit: September 7, 2026 | 09:36 MESZ 0474E537F0F24A87AFE69C10ADBA9DB5

Valid until: 2028-09-06

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