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EC-Declaration of Conformity for Medical Device Class Ila

Hamburg, 2019-12-02

We herewith declare, that

Object of the declaration:

Bacillol AF

Pack size	Article number BODE	Article number Hartmann
1 I bottle	973380	980212
	975071	980369
	975170	980402
	981436	981436
50 ml bottle	973381	980213
	981473	981473
500 ml bottle	973385	980214
	973655	980241
	975075	980373
	977365	980604
	981435	981435
5 I canister	973389	980217
	975079	980375
	981246	981246
200 l drum	973388	980216
20 x 50 ml bottles	981247	981247

which is first placed on the market by BODE Chemie GmbH, meet the applicable provisions, especially the which is manufactured and/or placed on the market by BODE Chemie GmbH, meet the applicable provisions, especially the essential health and safety requirements of the following EC-Directive:

Council Directive 93/42/EEC of 14th June, 1993

The required conformity assessment procedure according to Annex II excluding (4) has been performed and the technical documentation is kept available.

This EC-Declaration of Conformity is issued under the sole responsibility of the BODE Chemie GmbH.

The conformity assessment procedure is under the supervision of the Notified Body:

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH, Pilatuspool 2, 20355 Hamburg, Deutschland

Identification No. 0482

Medical Device: Class IIa acc. to rule 15 (acc. to Annex IX of the directive)

BODE Chemie GmbH

Dr. Henning Mallwitz

Director Research & Development

André Maack Head of Quality Assurance

This document is valid until: 2021-12-02