BODE Chemie GmbH

A company of the HARTMANN GROUP Melanchthonstr. 27 22525 Hamburg

Germany

T. +49 40 54006-0 F. +49 40 54006-200 bode-chemie.com info@bode-chemie.de



EC-Declaration of Conformity for Medical Device Class Ila

Hamburg, 2019-12-02

We herewith declare, that

Object of the declaration:

Mikrobac forte

Pack size	Article number BODE	Article number Hartmann
20 ml sachet	975392 975392	895665 980901
250x20 ml sachet	975392	980434
5 I canister	975395 981179 973218 981218 973219	980435 981179 980184 981218 980185
200 l drum	975397	980437
640 I bulk container	975398	980438

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