#### **BODE Chemie GmbH**

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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 Tissues**

Pack size	Article number BODE	Article number Hartmann
Bacillol Tissues, dispenser (100 T.)	975670	980503
Bacillol Tissues, refill sachet (100 T.)	975673	980504
Bacillol Tissues, dispenser East EU (100 T.)	975680	980505
Bacillol Tissues refill sachet East EU (100 T.)	975683	980506

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

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Head of Quality Assurance

This document is valid until: 2021-12-02