## **BODE Chemie GmbH**

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## **EC-Declaration of Conformity for Medical Device Class Ila**

Hamburg, 2021-11-16

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, Germany

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

Head of Quality Assurance

This document is valid until: 2023-02-08