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

Hamburg, 2019-12-02

We herewith declare, that

Object of the declaration: **Bacillol 30 Tissues**

Pack size	Article number BODE	Article number Hartmann
Bacillol 30 Tissues, Flow-Pack (80 T.)	981312 981403 981434	981312 981403 981434
Bacillol 30 Tissues, Flow-pack (40 XXL T.)	981560	981560
Bacillol 30 Tissues, Flow-Pack (24 T.)	981673	981673

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