

EU-Declaration of Conformity for Medical Device Class I

Hamburg, 2022-12-05

Object(s) of the declaration: **Single-Use Pump**

| Single-Use Pump | | |
|-----------------|---------------------|-------------------------|
| Pack size | Article number BODE | Article number HARTMANN |
| 200 p. | 981600 | 981600 |
| | 981601 | 981601 |
| | 981602 | 981602 |
| | 981603 | 981603 |
| | 981736 | 981736 |
| 20 p. | 981813 | 981813 |
| | 981814 | 981814 |
| | 981737 | 981737 |

We herewith declare under our sole responsibility that the medical devices listed above, first placed on the market by BODE Chemie GmbH, comply with the applicable provisions, in particular, the

- General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The objects of the declaration have been identified as medical devices in risk class I according to classification rule 1 in Annex VIII of Regulation (EU) 2017/745. The conformity assessment procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

Intended Purpose:

Single-use pump for the application of liquid or gel hand disinfectants, washing and skin care lotions.

Basic UDI-DI: 40316783780M5

Single Registration Number: DE-MF-000005851

Certificate No. 0523GB448210329A

BODE Chemie GmbH



Dr. Henning Mallwitz
Director Research & Development

06. DEZ. 2022



Dr. Ralf Meier
Head of Quality Assurance

Valid until: 2024-12-05



HARTMANN SCIENCE CENTER
Research for
infection protection.

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