

EU-Declaration of Conformity for Medical Device Class I

Hamburg, 2022-01-03

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.

(High-Level) 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

BODE Chemie GmbH



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This document is valid until: 2024-01-03