BODE Chemie GmbH

A company of the HARTMANN GROUP

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EU-Declaration of Conformity for Medical Device Class I

Hamburg, 2023-10-11

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

BODE Chemie GmbH

Dr. Henning Mallwitz

Director Research & Development

Raphael Bohner Head of Quality