PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2021-08-03

Object(s) of the declaration:

MoliMed for Men (3121)

We herewith declare under our sole responsibility that the medical devices listed above, first placed on the market by PAUL HARTMANN AG, 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:
Non-active, non-implantable devices for incontinence care, worn on the body

Basic UDI-DI: 40495003135KD

(SRN: Single) Registration Number of Manufacturer: DE/0000007683 (BfArM)

PAUL HARTMANN AG

Stefan Grote
Head of Business Division
Incontinence Management

ppa.

Stefan Fischer
Head of Regulatory Affairs

Valid until (yyyy-mm-dd): 2022-03-01

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Dr. Raymund Heinen, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB 661090