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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2021-08-03

Object(s) of the declaration:

MoliMed Ultra (3135)

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