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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

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