

PAUL HARTMANN AG  
Paul-Hartmann-Strasse 12  
89522 Heidenheim  
P.O. Box 1420  
89504 Heidenheim  
Germany

Phone: +49 (0) 7321 36-0  
Fax: +49 (0) 7321 36-3636  
[www.hartmann.info](http://www.hartmann.info)



Helps. Cares. Protects.

9477617, 9477147, 9477627, 9477157, 9477907, 9477957, 9478007, 9477917, 9477967,  
9478017, 9477927, 9477977, 9478027, 9477937, 9477987, 9478037, 9477947, 9477997,  
9478047, 9477897, 9478157, 9478257, 9478307

**Device Nomenclature:**

Nomenclature	Code	Term
EMDN	T04010104	NET PANTS
GMDN	35120	Incontinence pants, reusable
UMDNS	12-111	Inkontinenz-Hosenwindel

**Risk Classification:**

The objects of the declaration have been qualified as medical devices, and the risk classification has been determined according to the classification rules in Annex IX of Council Directive 93/42/EEC. The risk classification, the classification rule and the conformity assessment procedure used to demonstrate conformity are listed below. The technical documentation is kept available.

Risk Classification	Classification Rule	Conformity Assessment Procedure
I	1	Annex 11(5) and Annex VII

PAUL HARTMANN AG

**Stefan Grote**  
Head of Business Division  
Incontinence Management

ppa.

**Stefan Fischer**  
Senior Vice President Regulatory Affairs

This document is valid until: 2023-03-01

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück  
(Vorsitzende des Vorstands/CEO), François Georgelin,  
Stefan Grote, 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

PAUL HARTMANN AG  
Paul-Hartmann-Strasse 12  
89522 Heidenheim  
  
P.O. Box 1420  
89504 Heidenheim  
Germany

Phone: +49 (0) 7321 36-0  
Fax: +49 (0) 7321 36-3636  
[www.hartmann.info](http://www.hartmann.info)



Helps. Cares. Protects.

## UK Declaration of Conformity

Heidenheim, 2022-05-25

### Manufacturer Information:

Manufacturer: PAUL HARTMANN AG  
Single Registration Number (SRN): DE-MF-000005861

We hereby declare under our sole responsibility that the medical devices listed below comply with the applicable provisions of the UK Medical Devices Regulations 2002 (SI 2002 No 618), amended by the Medical Devices (EU Exit) Regulations 2019 and the Medical Devices (EU Exit) Regulations 2020.

### UK Representative

PAUL HARTMANN LTD,  
Unit P2, Parklands, Heywood Distribution Park, Pilsworth Road  
Heywood, Lancs., OL10 2TT

### Objects [and Scope] of this Declaration:

Objects	Product Name(s)
1018 MoliCare Fixpants short leg	MoliCare Fixpants short leg
3063 MoliCare Premium Fixpants long leg	MoliCare Premium Fixpants long leg
3138 MoliCare Premium Fixpants short leg	MoliCare Premium Fixpants short leg
3139 MoliCare Fixpants long leg	MoliCare Fixpants long leg

### Device Nomenclature:

#### REF Number(s)

9477457, 9477467, 9477487, 9477477, 9477507, 9477419, 9477637, 9477427, 9477647,  
9477437, 9477659, 9477447, 9477667, 9477117, 9477597, 9477127, 9477607, 9477137,

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück  
(Vorsitzende des Vorstands/CEO), François Georgelin,  
Stefan Grote, 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