

PAUL HARTMANN AG  
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## UK Declaration of Conformity

Heidenheim, 2022-05-05

### 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)           |
|----------------------------------|---------------------------|
| MoliCare Premium Lady Pad (3118) | MoliCare Premium Lady Pad |

### Device Nomenclature:

| REF Number(s) |
|---------------|
| 168670        |
| 168438        |

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



### Device Nomenclature:

| Nomenclature | Code      | Term                     |
|--------------|-----------|--------------------------|
| EMDN         | T04010102 | Profiled nappies         |
| GMDN         | 35817     | Incontinence pants liner |
| UMDNS        | 16-498    | Inkontinenzeinlage       |

### 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

i.V.

**Jens Hahn**  
Director Regulatory Affairs Operations

This document is valid until: 2023-03-01

ILN 040 9500 00000 0

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