



## EU Declaration of Conformity

Heidenheim, 2026-03-10

|                             |  |
|-----------------------------|--|
| <b>Product Group Number</b> | 3648   |
| <b>Manufacturer</b>         | PAUL HARTMANN AG<br>Paul-Hartmann-Str. 12<br>89522 Heidenheim<br>GERMANY |

We herewith declare under our sole responsibility that the product listed above, first placed on the market by PAUL HARTMANN AG, satisfies the applicable provisions of the following listed legislation. The conformity assessment procedure has been performed and the Technical Documentation is kept available.

### Applied legislative act

Medical Device Regulation (EU) 2017/745

|  |   |                             |
|--|---|-----------------------------|
| <b>High Level Intended Purpose</b>     | Non-active, non-implantable devices for incontinence care, worn on the body |                             |
| <b>Classification</b>                  | <b>Risk Class</b>   | <b>Rule</b>                 |
|  | Class I   | Rule 1                      |
| <b>Conformity Assessment Procedure</b> | Article 52 (7)  |                             |
| <b>Notified Body</b>                   | n.a.  |                             |
| <b>Single Registration Number</b>      | Manufacturer: DE-MF-000005861   |                             |
| <b>Basic UDI-DI</b>                    | 40495003648LF   |                             |
| <b>EMDN</b>                            | <b>Code</b>   | <b>Term</b>                 |
|  | T04010102   | SHAPED INCONTINENCE NAPPIES |
| <b>GMDN</b>                            | 35817   | Incontinence pants liner    |
| <b>UMDNS</b>                           | 16-498  | Incontinence Pants Liners   |

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück  
(Vorsitzende des Vorstands/CEO), François Georgelin,  
Stefan Grote, Oliver Neubrand  
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  
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Helps. Cares. Protects.

PAUL HARTMANN AG

**Stefan Grote**  
Member of the Management Board

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**Stefan Fischer**  
Senior Vice President Regulatory Affairs

Valid until: 2031-03-10

List of products falling under the respective Product Group Number:

| REF    | Name - Description                       |
|--------|--|
| 168167 | MoliCare® premium Form +SIZE 8 drops P20 |
| 168168 | MoliCare® premium Form +SIZE 8 drops P1  |
| 168519 | MoliCare® Premium Form +SIZE 8 drops P18 |
| 168974 | MoliCare® premium Form +SIZE 8 drops P2  |

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