



## EU Declaration of Conformity

Heidenheim, 2025-04-16

|                             |  |
|-----------------------------|--|
| <b>Product Group Number</b> | 3299   |
| <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 legislations. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

### Applied legislative acts

#### Medical Device Regulation (EU) 2017/745

|                                 |  |  |
|---------------------------------|--|--|
| High Level Intended Purpose     | Non-active, non-implantable clothing for prevention of infection |  |
| Classification                  | Class I  | Rule 1   |
| Conformity Assessment Procedure | Article 52 (7)   |  |
| Single Registration Number      | Manufacturer: DE-MF-000005861                                    |  |
| Basic UDI-DI                    | 40495003299LC  |  |
|                                 | Code   | Term   |
| EMDN                            | T0205  | Non-surgical gowns (excluding Personal Protective Equipment – PPE) |
| GMDN                            | 58382  | Scrub suit, single-use   |
| UMDNS                           | 15-037   | Gowns, Isolation   |

PAUL HARTMANN AG

ppa.

**Martin Walther**

Head of Business Division  
Risk Prevention

i.V.

**Christiana Hofmann**

Head of Regulatory Affairs  
Risk Prevention

Valid from: 2025-04-16

Valid until: 2030-04-16

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 661090

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Helps. Cares. Protects.

List of products falling under the respective Product Group Number:

| REF    | Name - Description                            |
|--------|---|
| 992642 | Foliodress Suit Comfort Shirt green XS, P47   |
| 992643 | Foliodress Suit Comfort Shirt green S, P47    |
| 992644 | Foliodress Suit Comfort Shirt green M, P47    |
| 992645 | Foliodress Suit Comfort Shirt green L, P42    |
| 992646 | Foliodress Suit Comfort Shirt green XL, P37   |
| 992647 | Foliodress Suit Comfort Shirt green XXL, P37  |
| 992648 | Foliodress Suit Comfort Shirt green XXXL, P32 |
| 992710 | Foliodress Suit Comfort Shirt green XS        |
| 992711 | Foliodress Suit Comfort Shirt green S         |
| 992712 | Foliodress Suit Comfort Shirt green M         |
| 992713 | Foliodress Suit Comfort Shirt green L         |
| 992714 | Foliodress Suit Comfort Shirt green XL        |
| 992715 | Foliodress Suit Comfort Shirt green XXL       |

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