



## EU Declaration of Conformity

Heidenheim, 2025-06-30

<b>Product Group Number</b>	3341
<b>Manufacturer</b>	PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim 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	40495003341KJ	
	Code	Term
EMDN	T0205	NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
GMDN	58382	Scrub suit, single-use, non-sterile
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 until: 2030-06-30

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: 3341

REF	Name - Description
992834	Foliodress Jacket Comfort, M Single-use jacket to minimize air contamination by inhibiting particle transmission
992835	Foliodress Jacket Comfort, L Single-use jacket to minimize air contamination by inhibiting particle transmission
992836	Foliodress Jacket Comfort, XL Single-use jacket to minimize air contamination by inhibiting particle transmission

GLN 404 9500 00000 0

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