



## EU Declaration of Conformity

Heidenheim, 2025-04-16

<b>Product Group Number</b>	3340
<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	40495003340KG	
	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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List of products falling under the respective Product Group Number:

REF	Name - Description
992652	Foliodress Suit Comfort Pants green XS, P38
992653	Foliodress Suit Comfort Pants green S, P37
992654	Foliodress Suit Comfort Pants green M, P35
992655	Foliodress Suit Comfort Pants green L, P35
992656	Foliodress Suit Comfort Pants green XL, P30
992657	Foliodress Suit Comfort Pants green XXL, P30
992658	Foliodress Suit Comfort Pants green XXXL, P28
992720	Foliodress Suit Comfort Pants green XS
992721	Foliodress Suit Comfort Pants green S
992728	Foliodress Suit Comfort Pants green M
992729	Foliodress Suit Comfort Pants green L
992730	Foliodress Suit Comfort Pants green XL
992731	Foliodress Suit Comfort Pants green XXL

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