



## EU Declaration of Conformity

Heidenheim, 2025-06-30

<b>Product Group Number</b>	3076
<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	40495003076KN	
	Code	Term
EMDN	T0205	Non-surgical gowns
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



List of products falling under the respective Product Group Number: **3076**

REF	Name - Description
992622	Foliodress suit Comfort Shirt, XS Single-use shirt to minimise air contamination by inhibiting particle transmission
992623	Foliodress suit Comfort Shirt, S Single-use shirt to minimise air contamination by inhibiting particle transmission
992624	Foliodress suit Comfort Shirt, M Single-use shirt to minimise air contamination by inhibiting particle transmission
992625	Foliodress suit Comfort Shirt, L Single-use shirt to minimise air contamination by inhibiting particle transmission
992626	Foliodress suit Comfort Shirt, XL Single-use shirt to minimise air contamination by inhibiting particle transmission
992627	Foliodress suit Comfort Shirt, XXL Single-use shirt to minimise air contamination by inhibiting particle transmission
992628	Foliodress suit Comfort Shirt, XXXL Single-use shirt to minimise air contamination by inhibiting particle transmission