

EU Declaration of Conformity

Heidenheim, 2025-06-30

Product Group Number	3291
Manufacturer	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	40495003291KU	
	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

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

List of products falling under the respective Product Group Number: **3291**

REF	Name - Description
992682	Foliodress Suit Comfort Shirt, XS Single-use shirt to minimize air contamination by inhibiting particle transmission
992683	Foliodress Suit Comfort Shirt, S Single-use shirt to minimize air contamination by inhibiting particle transmission
992684	Foliodress Suit Comfort Shirt, M Single-use shirt to minimize air contamination by inhibiting particle transmission
992685	Foliodress Suit Comfort Shirt, L Single-use shirt to minimize air contamination by inhibiting particle transmission
992686	Foliodress Suit Comfort Shirt, XL Single-use shirt to minimize air contamination by inhibiting particle transmission
992687	Foliodress Suit Comfort Shirt, XXL Single-use shirt to minimize air contamination by inhibiting particle transmission

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