



EU Declaration of Conformity

Heidenheim, 2025-05-15

Product Group Number	1319
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)	
Notified Body	n.a.	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001319KB	
	Code	Term
EMDN	T0207	Caps and headwear (excluding Personal Protective Equipment – PPE)
GMDN	32297	Surgical cap, single-use
UMDNS	11-901	Gowns, Operating room, Disposable

PAUL HARTMANN AG

ppa.

Martin Walther
Senior Vice President
Risk Prevention

i.V.

Hofmann Christiana
Head of Regulatory Affairs, PRRC
Risk Prevention

Valid from: 2025-05-15

Valid until: 2030-05-13

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List of products falling under the respective Product Group Number:

REF	Name - Description
992465	Foliodress cap comfort UNIVERSAL, green, 100 pcs Bouffant style surgical caps, green
992466	Foliodress cap comfort UNIVERSAL, white, 100 pcs Bouffant style surgical caps, white
992471	Foliodress cap protect UNIVERSAL, 130 pcs Bouffant style surgical caps with elastic

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