



EU Declaration of Conformity

Heidenheim, 2025-05-14

Product Group Number	1317
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	40495001317K7	
	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: 2025-05-14

Valid until: 2030-05-13

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:

REF	Name - Description
992460	Foliodress cap comfort ASTRO, 100 pcs Helmet-shaped surgical caps
992461	Foliodress cap comfort ASTRO PLUS, 100 pcs Helmet-shaped surgical caps with integrated sweatband
992462	Foliodress cap comfort APART, 100 pcs Scrub caps with ties at the back
992463	Foliodress cap comfort RONDO, 100 pcs Round surgical caps
992464	Foliodress cap comfort FORM, 100 pcs Surgical caps with shaped neck section and elasticated back
992467	Foliodress cap comfort RONDO PLUS, 100 pcs Round surgical caps with elastic gathering
992468	Foliodress cap comfort FORM PLUS, 60 pcs Surgical caps with shaped neck section, elasticated back and integrated sweat band
992469	Foliodress cap comfort HELMET, 40 pcs Surgical caps with full shoulder coverage
992477	Foliodress cap comfort BANBANA, 100 pcs Bandana style surgical caps with ties at the back
992489	Foliodress cap comfort DINO, 100 pcs Surgical caps with shaped neck section, elasticated back and central stitching

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