



EU Declaration of Conformity

Heidenheim, 2025-05-15

Product Group Number	1308
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	40495001308K6	
	Code	Term
EMDN	T020604	Medical use face masks Type II and IIR
GMDN	66199	Surgical/medical face mask, non-antimicrobial, single-use
UMDNS	12-458	Masks, Surgical

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
992530	Foliodress mask comfort ANTI FOGGING, 50 pcs Surgical face masks, type 2 with anti-fog band, for wearers of glasses

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