PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1695
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 legislation. The conformity assessment procedure has been performed and the Technical Documentation is kept available.

Applied legislative act

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class I	Rule 1
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001695LA	
EMDN	Code	Term
	M050201	EXTENSIBLE NON-WOVEN PLASTERS
GMDN	16866	Basic adhesive tape
UMDNS	10-028	Adhesive Strips, Hypoallergenic

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

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ppa.

Jochen Bauer
Vice President R&D Wound Care & Consumer Health

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

List of products falling under the respective Product Group Number:

REF	Name - Description
900601	Omnifix Elastic 10cm x 2m P1
900602	Omnifix Elastic 5cm x 10m P1 Omnifix Elastic FR 5cm x 10m P1
900603	Omnifix Elastic FR 10cm x 10m P1 Omnifix Elastic 10cm x 10m P1
900604	Omnifix Elastic 15cm x 10m P1
900605	Omnifix Elastic 20cm x 10m P1
900606	Omnifix Elastic 2,5cm x 10m P2 Omnifix Elastic FR 2,5cmx10m P2
900607	Omnifix Elastic 30cm x 10m P1
900608	Omnifix Elastic FR 5cm x 5m P1
900609	Omnifix Elastic FR 10cm x 5m P1
900611	Omnifix Elastic PPay 15cm x 2m P1 C8
900622	Omnifix PPay 10cm x 5m P1
900624	Omnifix PPay 5cm x 5m P1
900626	Omnifix PPay 10cm x 2m P1
900660	Omnifix Elastic Private Pay 10cmx5m P1
900661	Omnifix elastic, PPay CZ/SK 10cmx2m

GLN 404 9500 00000 0
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Declaration of Conformity

PPWR

EU DECLARATION NO.*.. **100728779** Date: **10.08.2026**

Product Identification	
Unique identification of the packaging	RL_FB
Manufacturer name and address	Paul Hartmann AG Paul-Hartmann-Straße 12 89522 Heidenheim Germany
Sole responsibility statement	This declaration of conformity is issued under the sole responsibility of the manufacturer.
Identification enabling traceability	Applies to all products packaged using this packaging model
Object of the Declaration	
Description of packaging	Product with release liner in a folding box
Relevant Union Legislation	
Reference to Regulation (EU) 2025/40 and applicable articles	Regulation (EU) 2025/40 of the European Parliament and of the Council, Article 5
Harmonized Standards	
Harmonised standards applied	Not applicable
References to common specifications used	Not applicable
Additional Information	
Heidenheim, 10.08.2026	Heidenheim, 10.08.2026
(Place and Date of Issue)	(Place and Date of Issue)
i.V. Rüdiger Kliewer Rüdiger Kliewer Director Packaging/Materials Handling	i.V. Georgina Bischur Georgina Bischur Teamlead Packaging Development
(Name, Function) (Signature)	(Name, Function) (Signature)