PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	3213
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	40495003213K8	
	Code	Term
EMDN	M030401	ELASTIC COMPRESSION BANDAGES
GMDN	61223	Pressure bandage, non-latex, non-sterile, reusable
UMDNS	15-557	Binde (Binders)

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
332300	Rhena Varidress 6cmx5m P10
332301	Rhena Varidress 8cmx5m P10
332302	Rhena Varidress 10cmx5m P10
332303	Rhena Varidress 12cmx5m P10
332310	Rhena Varidress 6cmx5m P1
332311	Rhena Varidress 8cmx5m P1
332312	Rhena Varidress 10cmx5m P1

GLN 404 9500 00000 0
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