

PAUL HARTMANN AG
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Germany

Phone: +49 (0) 7321 36-0
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www.hartmann.info



EU Declaration of Conformity

Heidenheim, 2026-05-04

Product Group Number	4148
Manufacturer	PAUL HARTMANN AG Paul Hartmann Straße 12 89520 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 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 devices for wound and skin care	
Classification	Risk Class	Rule
	Class I	Rule 1 (compression bandage kit), Rule 13 (sensor bandage)
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495004148KV	
EMDN	Code	Term
	M030401	Elastic compression bandages
GMDN	58983	Compression bandaging kit
UMDNS	15-557	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
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Restriction of Hazardous Substance Directive 2011/65/EU

The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Applicable Harmonised Standards

EN IEC 63000:2018

Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

PAUL HARTMANN AG

Francois Georgelin

Member of the Management Board

i.V.

Jens Hahn

Director Regulatory Affairs Excellence

Valid until: 2031-05-03

GLN 404 9500 00000 0

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Helps. Cares. Protects.

List of products falling under the respective Product Group Number:

REF	Name - Description
332162	PuetterPro 2 Lite Vintens 10cm Kit C16
332265	PuetterPro 2 Lite Vintens 10cm Kit P6 set

Note: "Vintens Compression App - Global version" (Art. 3321690, covered by DoC for PGN4108-PuetterPro 2 Vintens) is also intended for use with PGN4148.

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