

EU Declaration of Conformity

Heidenheim, 2025-01-07

Product Group Number	4197
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	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495004197LA	
EMDN	Code	Term
	M030101	HYDROPHILIC GAUZE BANDAGES
GMDN	58964	Non-adhesive device retention bandage
UMDNS	15-557	Binde

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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PAUL HARTMANN AG

ppa.

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

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
300108	Hydrophilic inelastic bandage (467) 6cm
300109	Hydrophilic inelastic bandage (467) 8cm
300116	Hydr. inelast. bandage (467) 10cmx5m P10
300117	Hydr. inelast. bandage (467) 12cmx5m P10
300118	Hydr. inelast. bandage (467) 8cmx10m P10
300120	Hydr. inelastic bandag (467) bulk 8cmx5m
300121	Hydr. inelast. bandag (467) bulk 10cmx5m
300122	Hydr. inelastic bandag (467) bulk 12cmx5m
300123	Hydr. inelast. bandage (467) 12cmx10m P10
300134	Hydrophilic inelastic bandage (467) 6cm
300135	Hydrophilic inelastic bandage 8cmx5m P1
300136	Hydrophilic inelastic bandage 10cmx5m P1
300137	Hydrophilic inelastic bandage 12cmx5m P1

GLN 404 9500 00000 0

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