

EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	1846
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	40495001846L7		
EMDN	Code	Term	
	M030101	HYDROPHILIC GAUZE BANDAGES	
	GMDN	58964	Non-adhesive device retention bandage
	UMDNS	15-557	Non-adhesive device retention bandage

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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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
304040	Peha-Mullbinde 4cmx4m cel 20x(P1)
304041	Peha-Mullbinde 6cmx4m cel 20x(P1)
304042	Peha-Mullbinde 8cmx4m cel 20x(P1)
304043	Peha-Mullbinde 10cmx4m cel 20x(P1)
304044	Peha-Mullbinde 12cmx4m cel 20x(P1)
304050	Peha-Mullbinde 4cmx4m (P20)
304051	Peha-Mullbinde 6cmx4m (P20)
304052	Peha-Mullbinde 8cmx4m (P20)
304053	Peha-Mullbinde 10cmx4m (P20)
304054	Peha-Mullbinde 12cmx4m (P20)
304055	Peha-Mullbinde 15cmx4m (P20)

GLN 404 9500 00000 0

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