



EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1148
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 4 main paragraph + 1st indent
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001148K8	
EMDN	Code	Term
	M020102	COTTON GAUZES, FOLDED
GMDN	48134	Woven gauze pad
UMDNS	10-281	Verbandmaterial, Gaze (Bandages, Gauze)

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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Helps. Cares. Protects.

PAUL HARTMANN AG

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
206001/1	ZZ Gauze 100cmx50m P1
206046	ZZ Gauze 90cm x 100 m P1
206113	ZZ Gauze 105cmx50m P1
206402	Verbandmull ZZ BW gebl 20fd 8f 80cm P1m
206403	Verbandmull ZZ BW gebl 20fd 8f 80cm P2m
206405	Verbandmull ZZ 20fd 8f 80cm P5m
206406	Verbandmull ZZ BW gebl 20fd 8f 80cm P10m
206407	Verbandmull ZZ 20fd 8f 80cm P40m

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