

EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	1398
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	Single-use, non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class Is	Rule 4 main paragraph + 1st indent
Conformity Assessment Procedure	Article 52 (7) and Annex XI part A with respect to sterility (a)	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Production Quality Assurance Certificate (MDR) No. G26 011858 0077 Rev. 00, Device Group: M020102 - COTTON GAUZES, FOLDED, Device Properties: MDS 1005.2 - Sterilisation by irradiation	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001398KZ	
EMDN	Code	Term
	M020102	COTTON GAUZES, FOLDED
GMDN	48134	woven gauze pad
UMDNS	10-966	Kompresse, Mull (Compresses, 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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PAUL HARTMANN AG

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid from: 2025-11-30

Valid until: 2030-11-29

List of products falling under the respective Product Group Number:

REF	Name - Description
401503	Schlitzkomp st 7,5x7,5 17fd 12f P25x2 Peha-Slit Dressing 7,5x7,5 17fd 12f P2X50
401505	Peha-Slit Dressing 10x10 17fd 12f P2X50
481001	Peha-Slit Dressing 7,5x7,5 17fd 8f P2x50
481002	Peha Slit Dressing 10x10 17fd 8f P2X50

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