



EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	2378
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 1st indent
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	40495002378L2	
EMDN	Code	Term
	M020201	NON-WOVEN FOLDED GAUZES
GMDN	48131	Non-woven gauze pad,
UMDNS	15-216	Verband, sonstige (dressings, other)

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

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0dddd
Fax: +49 (0) 7321 36-3636
www.hartmann.info



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
421831	Medicomp Extr VL-Kompr 5x5 6f S30 P100 Medicomp Extr VL-Kpr 5x5 6F S30 P100
421833	Medicomp Extr VL-Kompr 7,5x7,5 6f30P100BCH Medicomp Extr VL-Kpr 7,5x7,5 6F S30 P100
421835	Medicomp Extr VL-Kpr 10x10 6F S30 P100
421837	Medicomp Extr VL-Kpr 10x20 6F S30 P100

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