PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	3397
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 IIa	Rule 7 | main paragraph
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: M020201 - NON-WOVEN FOLDED GAUZES	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003397LD	
	Code	Term
EMDN	M020201	NON-WOVEN FOLDED GAUZES
GMDN	48131	Non-woven gauze pad
UMDNS	15-216	Verband, sonstige (dressings, other)

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ppa.

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

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid from: 2025-05-06
Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
411076	Medicomp Extra Bl st 7,5x7,5 6fS30 P25x2
411077	Medicomp Extra Bl st 10x10 6f S30 P25x2
411078	Medicomp Extra Bl st 5x5 6f S30 P25x2
411079	Medicomp Extra st 10x20 6f S30 P25x2

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