PAUL HARTMANN AG
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Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	3199
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, sterile, non-medicated dressings suitable for the treatment of wounds	
Classification	Risk Class	Rule
	Class IIb	Rule 4 | main paragraph + 2nd indent
Conformity Assessment Procedure	Article 52 (4) 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: M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER, Intended Purpose: Single-use, sterile, non-medicated dressings suitable for the treatment of wounds	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003199L7	
EMDN	Code	Term
	M040499	DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
GMDN	58475	Sodium chloride dressing
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

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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
609002	HydroClean cavity 4cm P10 K6
609004	HydroClean cavity 4x8cm P10 K6
609006	HydroClean cavity 5,5cm P10 K6
609008	HydroClean cavity 7,5x7,5cm P10 K6
609012	HydroClean cavity 10x10cm P10 K6

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
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