



EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	1809
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	Sterile, non-medicated, products for negative pressure wound therapy	
Classification	Risk Class	Rule
	Class IIb	Rule 8 main paragraph
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: Sterile, non-medicated, products for negative pressure wound therapy	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001809KZ	
EMDN	Code	Term
	M040499	DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
GMDN	47956	Negative-pressure wound therapy system dressing set
UMDNS	11-314	Dressing kits

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

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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
409720	VivanoMed Foam Kit Abdominal st P1 VivanoMed Foam Abdominal Kit st P1
409721	VivanoMed Foam Kit Abdominal st P3 VivanoMed Foam Abdominal Kit st P3

GLN 404 9500 00000 0

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