



EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	1805
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 1
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: A0699 - DRAINAGE AND FLUID COLLECTION DEVICES - OTHER, Device Properties: MDS 1005.3 - Sterilization by moist heat	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001805KR	
EMDN	Code	Term
	A0699	DRAINAGE AND FLUID COLLECTION DEVICES - OTHER
GMDN	47409	Negative-pressure wound therapy tubing set
UMDNS	11-307	Drains

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



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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
409557	VivanoTec Y-Konnektor P3

GLN 404 9500 00000 0

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Stefan Grote, Oliver Neubrand
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