

EU Declaration of Conformity

Heidenheim, 2024-10-23

Product Group Number	1386
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 legislations. 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	Atrauman Ag is a non-adherent wound contact layer suitable during the treatment of chronic wounds and of acute burns up to 2nd degree. The dressing is a single-use, sterile, non-invasive medical device to be used by healthcare professionals on human skin. Atrauman Ag needs to be combined with a suitable, sterile, absorbent, secondary dressing. The total treatment time of Atrauman Ag can exceed 30 days; however, the wear time of one single dressing shall not exceed seven days.	
Classification	Risk Class	Rule
	Class III	Rule 14
Conformity Assessment Procedure	Article 52 (3) 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) G12 011858 0076 Rev. 00 and Class III devices certificate No.: G70 011858 0073 Rev.00, Device Group: M040408 – SILVER DRESSINGS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001386KS	

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
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Helps. Cares. Protects.

	Code	Term
EMDN	M040408	SILVER DRESSINGS
GMDN	46855	Wound non-adherent dressing, permeable
UMDNS	11-325	Dressings, other

PAUL HARTMANN AG

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François Georgelin

Member of the Management Board

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2029-08-22

List of products falling under the respective Product Group Number:

REF	Name - Description
499600	Atrauman® Ag
499601	Atrauman® Ag
499602	Atrauman® Ag
499603	Atrauman® Ag
499604	Atrauman® Ag
499605	Atrauman® Ag

GLN 404 9500 00000 0

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