

EU Declaration of Conformity

Heidenheim, 2026-01-13

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 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	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	

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

EU Certificates	EU Quality Management System Certificate (MDR) No. G12 011858 0076 Rev.00 and Class III devices certificate No. G70 011858 0073 Rev.01, Device Group: M040408 – SILVER DRESSINGS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001386KS	
	Code	Term
EMDN	M040408	SILVER DRESSINGS
GMDN	46855	Wound non-adherent dressing, permeable
UMDNS	11-325	Dressings, other

PAUL HARTMANN AG

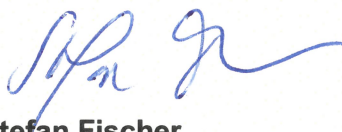
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Jochen Bauer

Vice President R&D Wound Care & Consumer Health



Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2029-08-22

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PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

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

P.O. Box 1420
89504 Heidenheim
Germany



Helps. Cares. Protects.

List of products falling under the respective Product Group Number:

REF	Name - Description
499600	Atrauman Ag st 5x5cm P3
499601	Atrauman Ag st 5x5cm P10
499602	Atrauman Ag st 10x10cm P3
499603	Atrauman Ag st 10x10cm P10
499604	Atrauman Ag st 10x20cm P3
499605	Atrauman Ag st 10x20cm P10
499609	Atrauman Ag st 5x5cm P10
499610	Atrauman Ag st 10x10cm P10
499611	Atrauman Ag st 10x20cm P10

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