

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	4103
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 IIa	Rule 4 main paragraph + 3rd indent
Conformity Assessment Procedure	Article 52 (6) 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: M040406 - POLYURETHANE DRESSINGS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495004103K7	
EMDN	Code	Term
	M040406	POLYURETHANE DRESSINGS
GMDN	47771	Scar management dressing, single-use, non-sterile
UMDNS	13-598	Silicone Rubber Sheeting

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

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

P.O. Box 1420
89504 Heidenheim
Germany



PAUL HARTMANN AG

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
535009	Cosmos Scar Plaster 7,2x5cm P5
535010	Cosmos Scar Plaster 4x30cm P5
535015	Cosmos Scar plaster LG2 7,2x5cm P5
535016	Cosmos Scar Plaster LG2 4x30cm P5

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