

EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	3522
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	40495003522KQ	
EMDN	Code	Term
	M040406	POLYURETHANE DRESSINGS
GMDN	34864	Adhesive bandage
UMDNS	10-288	Bandages, Self-Adherent

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



PAUL HARTMANN AG

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
901050	Cosmopor transparent 5x7,2cm steril P5
901051	Cosmopor transparent 5x7,2cm sterile P50 Cosmopor transparent 5x7,2cm steril P50
901052	Cosmopor transparent 9x10cm steril P5
901053	Cosmopor transparent 9x10cm steril P50
901054	Cosmopor transparent 9x15cm steril P5
901055	Cosmopor transparent 9x15cm steril P25
901056	Cosmopor transparent 10x12cm steril P25
901057	Cosmopor transparent 10x20cm steril P5 Cosmopor transparent 10x20cm steril P5
901058	Cosmopor transparent 10x20cm steril P25
901059	Cosmopor transparent 10x25cm steril P25
901060	Cosmopor transparent 10x30cm steril P25

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, P.O. Box 1420, 89522 Heidenheim, Germany
For submission at competent authorities / institutions
in Australia

Heidenheim, 2023-05-30

MANUFACTURER'S DECLARATION OF CONFORMITY

**AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
FULL QUALITY ASSURANCE PROCEDURE**

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian
Therapeutic Goods (Medical Devices) Regulations 2002

Reference:	Australian Product List
Manufacturer's Name:	PAUL HARTMANN AG
Business Address:	Paul-Hartmann-Straße, 89522 Heidenheim, Germany
Medical Devices:	See attached schedule for multiple products
Classification:	Class II a and II b medical devices
GMDN Code and Term:	See attached schedule for GMDN codes
Scope of Application:	All batches to which the Full Quality Assurance Procedures have been applied.

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Management System Certificate:

TÜV SÜD Product Service GmbH, notified body no.0123:
European Medical Devices Regulation (EU) 2017/745 Annex
IX Chapters I and III certificate
No: G10 011858 0065 Rev. 02

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller
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



Helps. Cares. Protects.

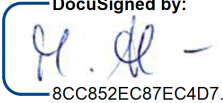
Standard Applied:

EN ISO 13485:2016: Medical Devices – Quality management
Systems – Requirements for regulatory purposes

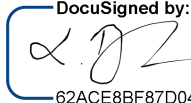
Yours sincerely

According to the internal guidelines of PAUL HARTMANN AG, the following persons are allowed to sign jointly on behalf of PAUL HARTMANN AG.

Signature:

i.V. 
8CC852EC87EC4D7...

Dr. Michaela Akermann
Director Regulatory Affairs Submission

i.A. 
62ACE8BF87D040F...

Lea Dudziak
Manager Regulatory Affairs Submission

DocuSigned by:


ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller
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



Attachment to the Manufacturer's Declaration of Conformity for class II a and II b medical devices according to Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 – Australian Product List

Note: For Detailed product range and code numbers refer to Paul Hartmann Catalogues

GMDN Code	Products	Class / Rule
32207 - Adhesive strip, skin-closure	Omnistrip	Class IIa Clause 2.4(1)
34864 – Bandage, adhesive	Hydrofilm plus, Cosmopor Transparent	Class IIa Clause 2.4(1)
58301 - Synthetic polymer semi-permeable film dressing, adhesive, sterile	Hydrofilm	Class IIa Clause 2.4(1)
44970 - Exudate-absorbent dressing, non-gel	PermaFoam, PermaFoam comfort, PermaFoam concave	Class IIb Clause 2.4(4)
	PermaFoam sacral, PermaFoam cavity	
	HydroTac, HydroTac comfort	
47764 - Wound hydrogel dressing, sterile	Hydrosorb, Hydrosorb comfort, Hydrosorb Gel	Class IIb Clause 2.4(4)
	HydroTac transparent, HydroTac transparent comfort	
43186 - Exudate-absorbent dressing, hydrophilic-gel	Hydrocoll range	Class IIb Clause 2.4(4)
	Sorbalgon, Sorbalgon T	
46854 - Dressing, wound-nonadherent, absorbent	Zetuvit plus, Zetuvit plus Silicone, Zetuvit plus Silicone Border	Class IIb Clause 2.4(4)
46855 - Dressing, wound-nonadherent, permeable	Atrauman, Atrauman Silicone	Class IIb Clause 2.4(4)
	Grassolind neutral	
	Hydrotul	
	HydroClean, HydroClean Plus	Class IIb

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller
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



58475 - Sodium chloride dressing	HydroClean Cavity, HydroClean Plus Cavity	Clause 2.4(4)
15624 – Dressing, tracheostomy tube	PermaFoam tracheostomy	Class IIb Clause 2.4(4)

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller
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