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www.hartmann.info

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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

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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. DocuSigned by: 8CC852EC87EC4D7...

Dr. Michaela Akermann

Director Regulatory Affairs Submission

i.A. DocuSigned by: 62ACE8BF87D040F...

Lea Dudziak

Manager Regulatory Affairs Submission

DocuSigned by:

PAUL HARTMANN AG HEIDENHEIM DEUTSCHLAND

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

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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 Sorbalgon, Sorbalgon T	**Class IIb** Clause 2.4(4)
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**

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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

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EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	2502
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 + 4th 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: H900102 - BANDAGES FOR SUTURES	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002502KB	
	Code	Term
EMDN	H900102	BANDAGES FOR SUTURES
GMDN	32207	Skin-closure adhesive strip
UMDNS	10-288	Verbandmaterial, selbstklebend (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

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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: 2025-05-06
Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
540010	Omnistrip 6x38mm st 1x6ST DE,FR,IT,NL P2
540020	Omnistrip 6x76mm st 1x3St DE,FR,IT,NL P2
540030	Omnistrip 6x38mm st 1x6St EN,ES,PT,GR P2
540040	Omnistrip 6x76mm st 1x3St EN,ES,PT,GR P2
540681	Omnistrip 3x76mm st, 1x5St, P50
540682	Omnistrip 6x38mm st, 1x6St, P50
540683	Omnistrip 6x76mm st, 1x3St, P50
540684	Omnistrip 6x101mm st, 2x5St, P50
540685	Omnistrip 12x101mm st, 2x3St, P50
540686	Omnistrip 25x127mm st, 2x2St, P50

GLN 404 9500 00000 0

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Declaration of Conformity

PPWR

EU DECLARATION NO.*... **100728774** Date: **10.08.2026**

Product Identification	
Unique identification of the packaging	RL_PEP_FB_FB
Manufacturer name and address	Paul Hartmann AG Paul-Hartmann-Straße 12 89522 Heidenheim Germany
Sole responsibility statement	This declaration of conformity is issued under the sole responsibility of the manufacturer.
Identification enabling traceability	Applies to all products packaged using this packaging model
Object of the Declaration	
Description of packaging	Product with release liner in a peel pouch, packed in a folding box, packed in a second folding box (dispenser)
Relevant Union Legislation	
Reference to Regulation (EU) 2025/40 and applicable articles	Regulation (EU) 2025/40 of the European Parliament and of the Council, Article 5
Harmonized Standards	
Harmonised standards applied	Not applicable
References to common specifications used	Not applicable
Additional Information	
Heidenheim, 10.08.2026	Heidenheim, 10.08.2026
(Place and Date of Issue)	(Place and Date of Issue)
i.V. Rüdiger Kliewer Rüdiger Kliewer Director Packaging/Materials Handling	i.V. Georgina Bischur Georgina Bischur Teamlead Packaging Development
(Name, Function) (Signature)	(Name, Function) (Signature)

Declaration of Conformity

PPWR

EU DECLARATION NO.* **100742561** Date: **11.08.2026**

Product Identification	
Unique identification of the packaging	LOAD
Manufacturer name and address	Paul Hartmann AG Paul-Hartmann-Straße 12 89522 Heidenheim Germany
Sole responsibility statement	This declaration of conformity is issued under the sole responsibility of the manufacturer.
Identification enabling traceability	Applies for all packaging materials used for load securing of shipping units
Object of the Declaration	
Description of packaging	Pallet cover layers, intermediate layers, and trays made from cardboard or corrugated board; edge protection, stretch film, honeycomb segments, PE film sheets, strapping, pallet stretch band
Relevant Union Legislation	
Reference to Regulation (EU) 2025/40 and applicable articles	Regulation (EU) 2025/40 of the European Parliament and of the Council, Article 5
Harmonized Standards	
Harmonised standards applied	Not applicable
References to common specifications used	Not applicable
Additional Information	
Heidenheim, 11.08.2026	Heidenheim, 11.08.2026
(Place and Date of Issue)	(Place and Date of Issue)
i.V. Rüdiger Kliewer Rüdiger Kliewer Director Packaging/Materials Handling	i.V. Georgina Bischur Georgina Bischur Teamlead Packaging Development
(Name, Function) (Signature)	(Name, Function) (Signature)