winner
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EU Declaration of Conformity
Packaging and Packaging Waste Regulation (PPWR)

EU DECLARATION NO.20260727

Date: 20260729

Product Identification

Customer code	Product Description
5361100	Hydrocoll Classic, 5x5 cm, P10
5361110	Hydrocoll Classic, 7.5x7.5 cm, P10
5361120	Hydrocoll Classic, 10x10 cm, P3
5361130	Hydrocoll Classic, 10x10 cm, P10
5361140	Hydrocoll Classic (DE), 10x10 cm, P10
5361150	Hydrocoll Classic, 15x15 cm, P3
5361160	Hydrocoll Classic, 15x15 cm, P5
5361170	Hydrocoll Classic, 20x20 cm, P5
5361180	Hydrocoll Classic (Thin), 7.5x7.5 cm, P10
5361190	Hydrocoll Classic (Thin), 10x10 cm, P3
5361200	Hydrocoll Classic (Thin), 10x10 cm, P10
5361210	Hydrocoll Classic (Thin), 15x15 cm, P3
5361220	Hydrocoll Classic (Thin), 15x15 cm, P5
5361230	Hydrocoll Classic (Sacral), 12x18 cm, P3
5361240	Hydrocoll Classic (Sacral), 12x18 cm, P5
5361250	Hydrocoll Classic (Concave), 8x12 cm, P10
5002011	DermaPlast protect spray plaster 30ml LG1
5002020	DermaPlast protect spray plaster 30ml LG2
5002030	Tiritas protect spray plaster 30ml LG3
5002040	Cosmos protect spray plaster 30ml LG4
3000840	Peha-haft Easy 6cm x 4m White P1
3000850	Peha-haft Easy 8cmx4m White P1
3000860	Peha-haft Easy 6cmx4m White P1

3000870	Peha-haft Easy 8cmx4m White P1
3000880	Peha-haft Easy 6cmx4m White P1
3000890	Peha-haft Easy 8cmx4m White P1
3000900	DermaPlast easy-rip 2.5cmx4m White P1
3000910	Dermaplast easy-rip 4cmx4m White P1
3000920	Dermaplast easy-rip 6cmx4m White P1
3100800	Peha-haft Easy 6cmx4m Blue P1
3100810	Peha-haft Easy 8cmx4m Blue P1
3001400	Dermaplast easy-rip 8cmx4m White P1 CH
3001410	Dermaplast easy-rip 6cmx4m Blue P1 CH
3001420	Dermaplast easy-rip 8cmx4m Blue P1 CH
4090000	VivanoMed Hydrofilm 20x30cm st P20
910660	VivanoMed Hydrofilm 15x20 cm non-sterile
910670	VivanoMed Hydrofilm 20x30 cm non-sterile
9012110	Cosmopor Kids 7.5 x 5 cm P5 LG1
9012120	Cosmopor Kids 10 x 6 cm P5 LG1
9012130	Cosmopor Kids 7.5 x 5 cm P5 LG2
9012140	Cosmopor Kids 10 x 6 cm P5 LG2
9012150	Cosmopor Kids 7.5 x 5 cm P5 LG3
9012160	Cosmopor Kids 10 x 6 cm P5 LG3
9012170	Cosmopor Kids MIX Sachet P2 LG1
9012180	Cosmopor Kids MIX Sachet P2 LG2
9012190	Cosmopor Kids MIX Sachet P2 LG3

Manufacturer name and address

Winner Medical Co., Ltd.

Winner Industrial Park, No.660 Bulong , Road, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Sole responsibility statement

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Object of the Declaration

Description of packaging

Customer code	Product Description	Primary		Secondary		Tertiary		Others
		Type	material	Type	material	Type	material	
5361100	Hydrocoll Classic, 5x5 cm, P10	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361110	Hydrocoll Classic, 7.5x7.5 cm, P10	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361120	Hydrocoll Classic, 10x10 cm, P3	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361130	Hydrocoll Classic, 10x10 cm, P10	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361140	Hydrocoll Classic (DE), 10x10 cm, P10	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361150	Hydrocoll Classic, 15x15 cm, P3	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361160	Hydrocoll Classic, 15x15 cm, P5	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361170	Hydrocoll Classic, 20x20 cm, P5	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361180	Hydrocoll Classic (Thin), 7.5x7.5 cm, P10	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361190	Hydrocoll Classic (Thin), 10x10 cm, P3	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361200	Hydrocoll Classic (Thin), 10x10 cm, P10	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361210	Hydrocoll Classic (Thin), 15x15 cm, P3	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet

5361220	Hydrocoll Classic (Thin), 15x15 cm, P5	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361230	Hydrocoll Classic (Sacral), 12x18 cm, P3	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361240	Hydrocoll Classic (Sacral), 12x18 cm, P5	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5361250	Hydrocoll Classic (Concave), 8x12 cm, P10	Pouch	FSC paper & film (PET12 PE45)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
5002011	DermaPlast protect spray plaster 30ml LG1	Bottle & Pump /Cap	HDPE & PP	Unit box & Box	White cardboard	Carton with label	Corrugated board	PE bag Wood pallet
5002020	DermaPlast protect spray plaster 30ml LG2	Bottle & Pump /Cap	HDPE & PP	Unit Box & Box	White cardboard	Carton with label	Corrugated board	PE bag Wood pallet
5002030	Tiritas protect spray plaster 30ml LG3	Bottle & Pump /Cap	HDPE & PP	Unit Box & Box	White cardboard	Carton with label	Corrugated board	PE bag Wood pallet
5002040	Cosmos protect spray plaster 30ml LG4	Bottle & Pump /Cap	HDPE & PP	Unit Box & Box	White cardboard	Carton with label	Corrugated board	PE bag Wood pallet
3000840	Peha-haft Easy 6cm x 4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3000850	Peha-haft Easy 8cmx4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3000860	Peha-haft Easy 6cmx4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3000870	Peha-haft Easy 8cmx4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3000880	Peha-haft Easy 6cmx4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet

3000890	Peha-haft Easy 8cmx4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3000900	DermaPlast easy-rip 2.5cmx4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3000910	Dermaplast easy-rip 4cmx4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3000920	Dermaplast easy-rip 6cmx4m White P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3100800	Peha-haft Easy 6cmx4m Blue P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3100810	Peha-haft Easy 8cmx4m Blue P1	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3001400	Dermaplast easy-rip 8cmx4m White P1 CH	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3001410	Dermaplast easy-rip 6cmx4m Blue P1 CH	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
3001420	Dermaplast easy-rip 8cmx4m Blue P1 CH	Box	White cardboard	/	/	Carton	Corrugated board	Kraft paper band, PE bag , Wood pallet
4090000	VivanoMed Hydrofilm 20x30cm st P20	Pouch	Paper & film (PET12 PE47)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
910660	VivanoMed Hydrofilm 15x20 cm non-sterile	Pouch	Paper & film (PET12 PE47)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
910670	VivanoMed Hydrofilm 20x30 cm non-sterile	Pouch	Paper & film (PET12 PE47)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet
9012110	Cosmopor Kids 7.5 x 5 cm P5 LG1	Pouch	Paper & film (PET12 PE47)	Box	White cardboard	Carton with label	Corrugated board	Seal sticker PE bag Wood pallet

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Hydrocoll
Pansament hidrocoloidal

Instrucțiuni de utilizare
Hydrocoll este un pansament hidrocoloidal, absorbant, autoadeziv, cu un strat extern din poliuretan care este permeabil pentru gaze şi impermeabil pentru lichide şi bacterii.

Proprietăți și mod de acțiune
Hidrocoloidul absoarbe exsudatul din plagă (rană) transformând-ul în gel, astfel asigurând un mediu umed ce stimulează procesele de vindecare. Stratul de gel previne aderarea pansamentului de plagă. Schimbul pansamentului nu afectează țesutul de granulație sau țesutul epitelial şi nu creează disconfort pentru pacient.
Marginile autoadezive ale Hydrocoll asigură o fixare bună pe orice tip de suprafață. Hydrocoll permite igiena personală zilnică.

Indicații
Hydrocoll este indicat în tratamentul plăgilor cu exsudat minim până la moderat.

Mod de aplicare
Alegeți dimensiunea şi forma corectă de Hydrocoll. Pansamentul trebuie să depăşească cu câțiva centimetri marginile plăgii pentru a se fixa sigur pe plagă.

Hydrocoll/ Hydrocoll thin: îndepărtați hârtia protectoare, aplicați Hydrocoll pe plagă, potriviți marginile şi presați-le pentru o fixare bună.

Hydrocoll trebuie schimbat la decolorarea vizibilă a pansamentului şi formarea unei vezicule de mărimea suprafeței plăgii. Pentru a schimba pansamentul, dezlipiți marginile Hydrocoll şi îndepărtați cu grijă întregul pansament. Pe plagă rămâne un strat de gel hidrocoloidal ce nu trebuie confundat cu puroiul. În acest caz, vindecarea plăgii nu este afectată, stratul de gel putând fi îndepărtat, dacă este necesar.
În cazul plăgilor necomplicate, Hydrocoll poate fi lăsat pe plagă până la 7 zile.

Contraindicații
Nu utilizați Hydrocoll în escarele profunde cu extindere musculară, tendinoasă sau osoasă, pe plăgi infectate sau în cazul arsurilor de gradul III.

Precauţii speciale
Hydrocoll poate fi eficient numai după o evaluare medicală a pacientului şi a stării plăgii. Tratamentul cu Hydrocoll nu poate înlocui tratamentul afecţiunii de bază care a condus la cronicizarea plăgii.

Instrucţiuni generale
A se depozita la temperaturi sub 30° C. Conţinut steril - dacă ambalajul nu este deteriorat. A nu se resteriliza. A nu se lăsa la îndemâna copiilor!

Forme de prezentare
Ambalat steril, individual.

Hydrocoll	
5 x 5cm	cutii cu 10 pansamente
7,5 x 7,5cm	cutii cu 10 pansamente
10 x 10cm	cutii cu 10 pansamente
15 x 15cm	cutii cu 5 pansamente
20 x 20cm	cutii cu 5 pansamente
Concave, 8 x 12 cm	cutii cu 10 pansamente
Hydrocoll thin	
10 x 10cm	cutii cu 10 pansamente

Producător
PAUL HARTMANN AG
89522 — Heidenheim
Germania

Importator
SC PAUL HARTMANN SRL
Str. Arany Janos nr 46, etaj 1
RO-540 045 Târgu Mureş
România

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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

DocuSign Envelope ID: 52FD3985-EFEA-4DB0-A946-D58EC9E903C3

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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

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

EU Declaration of Conformity

Hydrocolloid Dressing

This Declaration of Conformity is issued under the sole responsibility of Winner Medical Co., Ltd.

We hereby declare that the mentioned product/ attached list of products with CE marking comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745. And the CE marking is subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Legal Manufacturer:	Winner Medical Co., Ltd. Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000005692
Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
SRN:	DE-AR-000000001
Product Name:	Refer to Appendix A
EMDN Code and Term Description:	Refer to Appendix A
Basic UDI-DI:	Refer to Appendix A
Intended Purpose:	Refer to Appendix A
Risk Classification:	Class IIb as per Rule 4 in Annex VIII of EU Medical Device Regulation (EU) 2017/745
Conformity Assessment Route:	Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIb Devices)
Applicable Standards:	EN ISO 13485: 2016/A11:2021 EN ISO 14971: 2019/A11:2021 EN ISO 20417: 2021 EN ISO 15223-1: 2021 EN ISO 10993-1: 2020 EN ISO 11137-1:2015/A2:2019

Confidential and Proprietary

	EN ISO 11737-1: 2018/A1:2021 EN ISO 11737-2:2020 EN ISO 11607-1:2020/A1:2023 EN 13726: 2023
References to any CS:	Not Applicable
Identification of Notified Body:	TÜV SÜD Product Service GmbH 0123 Zertifizierstelle, Ridlerstraße 65, 80339 München, GERMANY
Identification of the Certificate(s):	EU Quality Management System Certificate (MDR) No. G10 046241 0073 Rev.02 , issued by TÜV SÜD Valid from: 2025-06-24 Valid until: 2028-07-09
Identification of the person authorized to sign on behalf of Legal Manufacturer:	**Name:** Xiaomeng Yang **Signature:** Xiaomeng Yang Management Representative Place of Issue: Shenzhen, China Date: 2025-06-24

Appendix A: List of Product Range Covered under this Declaration of Conformity

General Device Group	Product	Classification	EMDN Code	Basic UDI-DI
Hydrocolloid Dressing	Hydrocolloid Dressing Standard	Class Ⅱb Rule 4	M04040301	694109403536EU
	Hydrocolloid Dressing Thin			
	Hydrocolloid Dressing with Tapered Edges			

Intended purpose:

- Hydrocolloid Dressing Standard/Hydrocolloid Dressing Thin

Hydrocolloid Dressing Standard/Thin is intended for management of non- to low-exuding wounds that the injuries to skin have breached epidermis or dermis, such as donor sites, postoperative wounds and skin abrasions. This dressing is for short-term use (single use time≤7days and accumulated use time≤28 days). This is a professional use only and single use device.

- Hydrocolloid Dressing with Tapered Edges

Hydrocolloid Dressing with Tapered Edges is intended for management of non- to moderate-exuding wounds that the injuries to skin have breached epidermis or dermis, such as pressure ulcers, leg ulcers, donor sites, postoperative wounds and skin abrasions. This dressing is for short-term use (single use time≤7days and accumulated use time≤28 days). This is a professional use only and single use device.

Revision History

Rev No.	Date	Comment	Author
A/0	2024-06-11	Initial Release of Technical Documentation under the Medical Device Regulation (EU) 2017/745	Jinling Luo
A/1	2025-06-24	Standards &CE certificate No. updates	Jinling Luo

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Annex to EU Declaration of Conformity

(Doc No.: WN-CE(MDR)62-10 A/1)

The following Product names and Article codes are covered by the EU Declaration of Conformity (Doc No.: WN-CE(MDR)62-10 A/1, CE certificate No. G10 046241 0073 Rev.02).

Winner Product	GMDN Code	EMDN Code	Ref Code	Product description
Hydrocolloid Dressing	43186	M04040301	5361100	Hydrocoll Classic, 5x5 cm, P10
			5361110	Hydrocoll Classic, 7.5x7.5 cm, P10
			5361120	Hydrocoll Classic, 10x10 cm, P3
			5361130	Hydrocoll Classic, 10x10 cm, P10
			5361140	Hydrocoll Classic (DE), 10x10 cm, P10
			5361150	Hydrocoll Classic, 15x15 cm, P3
			5361160	Hydrocoll Classic, 15x15 cm, P5
			5361170	Hydrocoll Classic, 20x20 cm, P5
			5361180	Hydrocoll Classic (Thin), 7.5x7.5 cm, P10
			5361190	Hydrocoll Classic (Thin), 10x10 cm, P3
			5361200	Hydrocoll Classic (Thin), 10x10 cm, P10
			5361210	Hydrocoll Classic (Thin), 15x15 cm, P3
			5361220	Hydrocoll Classic (Thin), 15x15 cm, P5
			5361230	Hydrocoll Classic (Sacral), 12x18 cm, P3
			5361240	Hydrocoll Classic (Sacral), 12x18 cm, P5
			5361250	Hydrocoll Classic (Concave), 8x12 cm, P10

Issued in Shenzhen, China

Quality Management Department

Winner Medical Co., Ltd.

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EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	1815
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, sterile, non-medicated dressings suitable for the treatment of wounds	
Classification	Risk Class	Rule
	Class IIb	Rule 4 | main paragraph + 2nd indent
Conformity Assessment Procedure	Article 52 (4) 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: M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER, Intended Purpose: Single-use, sterile, non-medicated dressings suitable for the treatment of wounds	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001815KU	
EMDN	Code	Term
	M040499	DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
GMDN	43186	Exudate-absorbent dressing, hydrophilic-gel, non-antimicrobial
UMDNS	15-216	Verband, sonstige (dressings, other)

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

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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
900740	HydrocollVerband Z-fold 5x5cm P10
900742	HydrocollVerband Z-fold 7,5x7,5cm P10
900744	HydrocollVerb. Z-fold st 10x10cm P10 int
900746	Hydrocoll HydrokVerb II st 10x10cm P10
900747	Hydrocoll 10x10 P3
900748	Hydrocoll 15x15cm P5
900749	Hydrocoll 20x20cm P5
900755	HydrocollVerb. sacral Z-fold 12x18cm P5
900756	Hydrocoll concave 8x12cm P10
900757	Hydrocoll Thin 7,5x7,5cm P10
900758	HydrocollVerb. thin Z-fold 10x10cm P10
900759	HydrocollVerb. thin 10x10cm P3
900760	HydrocollVerband thin Z-fold 15x15cm P5
900761	HydrocollVerb. basic Z-fold 10x10cm P10
900931	HydrocollVerb. sacral Z-fold 12x18cm P3
900933	Hydrocoll thin 15x15cm P3
900935	Hydrocoll Verband z-falt. st 15x15cm P3

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Declaration of Conformity

PPWR

EU DECLARATION NO.*.. **100729076** Date: **10.08.2026**

Product Identification	
Unique identification of the packaging	RL_PEP_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 a release liner in a peel pouch inside a folding box
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.* **100742560** Date: **11.08.2026**

Product Identification	
Unique identification of the packaging	LABEL
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 to label packaging
Object of the Declaration	
Description of packaging	Self-adhesive labels (pre-printed, neutral, and/or with sterile indicator), papers, inkjet inks and thermal transfer ribbons, documents enclosed envelopes
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)

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)