

PAUL HARTMANN AG  
Paul-Hartmann-Strasse 12  
89522 Heidenheim

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[www.hartmann.info](http://www.hartmann.info)

P.O. Box 1420  
89504 Heidenheim  
Germany



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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*

<b>Reference:</b>	Australian Product List
<b>Manufacturer's Name:</b>	PAUL HARTMANN AG
<b>Business Address:</b>	Paul-Hartmann-Straße, 89522 Heidenheim, Germany
<b>Medical Devices:</b>	See attached schedule for multiple products
<b>Classification:</b>	Class II a and II b medical devices
<b>GMDN Code and Term:</b>	See attached schedule for GMDN codes
<b>Scope of Application:</b>	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  
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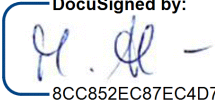
**Standard Applied:**

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

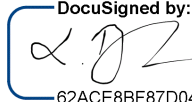
Yours sincerely

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.   
8CC852EC87EC4D7...

Dr. Michaela Akermann  
Director Regulatory Affairs Submission

i.A.   
62ACE8BF87D040F...

Lea Dudziak  
Manager Regulatory Affairs Submission

DocuSigned by:  


ILN 040 9500 00000 0

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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

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

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

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