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PAUL HARTMANN AG, P.O. Box 1420, 89522 Heidenheim, Germany

**EC-Declaration of Conformity for Medical Devices Class IIa and IIb**

Heidenheim, 2019-09-24

We herewith declare,

that the medical devices classified as class IIa and class IIb, which are first placed on the market by PAUL HARTMANN AG (the valid list of product categories is enclosed), meet the applicable provisions, especially the Essential Requirements of the following EC-Directive:

Council Directive 93/42/EEC of 14<sup>th</sup> June 1993.

The required conformity assessment procedure acc. to Annex II excluding (4) has been performed and the technical documentation is kept available.

This EC-Declaration of conformity is issued under the sole responsibility of the PAUL HARTMANN AG.

The sterilization processes are under the supervision of the Notified Body:  
**TÜV SÜD Product Service GmbH, DE-80339 München, Ridlerstr. 65, Identification No. 0123.**

PAUL HARTMANN AG

ppa.

Dr. Raymund Heinen  
Chief Process Officer

Stefan Fischer  
Senior Vice President Regulatory Affairs

This document is valid until: 2023-09-30

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IILN 040 9500 00000 0

Vorstand/ Management Board: Britta Fünfstück  
(Vorstandsvorsitzende/ CEO). Dr. Raymund Heinen.  
Michel Kuehn. Stephan Schulz.

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



EC-Declaration of Conformity for Medical Devices Class IIa				
Running No.	Product Groups / Product Names	Classification in accordance with Directive 93/42/EEC	Rule	UMDNS
3.01	<b>Wound management products and dressings</b>			
	ES gauze swabs	IIa	7	10-966
	Sterilux ES	IIa	7	10-966
	Sterilux gauze swabs	IIa	7	10-966
	Standard gauze swabs	IIa	7	10-966
	Mulpa swabs	IIa	7	10-966
	Sterilux gauze sponges (USP)	IIa	7	10-966
	Lusan gauze swabs	IIa	7	10-966
	Sterilux gauze swabs on a roll	IIa	7	10-966
	Pagasling	IIa	7	13-700
	Pagalong	IIa	7	13-700
	Medicomp	IIa	7	15-216
	Medicomp extra	IIa	7	15-216
	Absorbent cotton gauze	IIa	7	10-281
	Saline solution (0,9%)			
	DermaPlast Clean	IIa	4 (3 <sup>rd</sup> )	12-300
Dermaplast MEDICAL (Wound cleansing solution)	IIa	4 (3 <sup>rd</sup> )	12-300	
Lusan Saline Solution	IIa	4 (3 <sup>rd</sup> )	12-300	
3.02	<b>Special wound closure and covering products</b>			
	Hydrofilm	IIa	4 (3 <sup>rd</sup> )	17-428
	Hydrofilm non-sterile for Kit	IIa	4 (3 <sup>rd</sup> )	17-428
	Packagers			
	Visulin	IIa	4 (3 <sup>rd</sup> )	17-428
	Hydrofilm plus	IIa	4 (3 <sup>rd</sup> )	10-288
	Tiritas MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing)	IIa	4 (3 <sup>rd</sup> )	10-288
	Omnistrip	IIa	4 (3 <sup>rd</sup> )	10-288
	Omnistrip reinforced	IIa	4 (3 <sup>rd</sup> )	10-288
	Dermaplast Omnistrip	IIa	4 (3 <sup>rd</sup> )	10-288
	Dermaplast MEDICAL (Wound closure strips, sterile)	IIa	4 (3 <sup>rd</sup> )	10-288
	Dermaplast hydrocolloid plaster for:			
	minor wounds	IIa	4 (3 <sup>rd</sup> )	10-288
abrasions	IIa	4 (3 <sup>rd</sup> )	10-288	



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Blisters	Ila	4 (3 <sup>rd</sup> )	10-288
cold sores	Ila	4 (3 <sup>rd</sup> )	10-288
corns	Ila	4 (3 <sup>rd</sup> )	10-288
Tiritas hydrocolloid plaster for:			
minor wounds	Ila	4 (3 <sup>rd</sup> )	10-288
abrasions	Ila	4 (3 <sup>rd</sup> )	10-288
Blisters	Ila	4 (3 <sup>rd</sup> )	10-288
cold sores	Ila	4 (3 <sup>rd</sup> )	10-288
corns	Ila	4 (3 <sup>rd</sup> )	10-288
Cosmos hydrocolloid plaster for:			
minor wounds	Ila	4 (3 <sup>rd</sup> )	10-288
abrasions	Ila	4 (3 <sup>rd</sup> )	10-288
Blisters	Ila	4 (3 <sup>rd</sup> )	10-288
cold sores	Ila	4 (3 <sup>rd</sup> )	10-288
corns	Ila	4 (3 <sup>rd</sup> )	10-288
DermaActive hydrocolloid plaster for:			
minor wounds	Ila	4 (3 <sup>rd</sup> )	10-288
abrasions	Ila	4 (3 <sup>rd</sup> )	10-288
Blisters	Ila	4 (3 <sup>rd</sup> )	10-288
cold sores	Ila	4 (3 <sup>rd</sup> )	10-288
corns	Ila	4 (3 <sup>rd</sup> )	10-288
DermaPlast EFFECT Abrasion	Ila	4 (3 <sup>rd</sup> )	10-288
Dermaplast Medical Transparent dressing	Ila	4 (3 <sup>rd</sup> )	10-288
Dermaplast MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing)	Ila	4 (3 <sup>rd</sup> )	10-288
Dermaplast MEDICAL (Cuts and lacerations)	Ila	4 (3 <sup>rd</sup> )	10-288
DermaPlast EFFECT To cut blisters & minor wounds	Ila	4 (3 <sup>rd</sup> )	10-288
DermaPlast EFFECT blister large	Ila	4 (3 <sup>rd</sup> )	10-288
DermaPlast EFFECT blister heel	Ila	4 (3 <sup>rd</sup> )	10-288
DermaPlast EFFECT blister small	Ila	4 (3 <sup>rd</sup> )	10-288
DermaPlast EFFECT corns	Ila	4 (3 <sup>rd</sup> )	10-288
DermaPlast EFFECT minor wounds	Ila	4 (3 <sup>rd</sup> )	10-288
DermaPlast EFFECT cold sores	Ila	4 (3 <sup>rd</sup> )	10-288
Dermaplast burn plaster	Ila	4 (3 <sup>rd</sup> )	10-288
Tiritas burn plaster	Ila	4 (3 <sup>rd</sup> )	11-322
Cosmos burn plaster	Ila	4 (3 <sup>rd</sup> )	11-322
DermaActive burn plaster	Ila	4 (3 <sup>rd</sup> )	11-322



	Dermaplast MEDICAL (Burns)	Ila	4 (3 <sup>rd</sup> )	11-322
	Tiritas MEDICAL (Burns)	Ila	4 (3 <sup>rd</sup> )	11-322
	DermaPlast EFFECT Burns	Ila	4 (3 <sup>rd</sup> )	11-322
<b>3.03</b>	<b>Sets for patient care</b>			
	MediSet			
	Catheterisation sets	Ila	2 5 (2 <sup>nd</sup> ) 6 7	15-564 15-564 15-564 15-564
	Set for anaesthesia	Ila	2 6 7	15-202 15-202 15-202
	Set for anaesthesia	Ila	2 6 7	10-127 10-127 10-127
	Wound treatment sets/wound dressing sets	Ila	2 6 7	11-314 11-314 11-314
	Infusion set	Ila	2 7	12-157 12-157
	Injection set	Ila	6 7	12-157 12-157
	Set for central-venous catheterisation	Ila	2 6 7	16-615 16-615 16-615
	Suture set	Ila	5 (2 <sup>nd</sup> ) 6 7	13-892 13-892 13-892
	Dialysis set	Ila	2 6 7	15-896 15-896 15-896
	Surgical set	Ila	2 5 (2 <sup>nd</sup> ) 6 7	12-463 12-463 12-463 12-463
	Surgical set	Ila	2 5 (2 <sup>nd</sup> ) 6 7	15-896 15-896 15-896 15-896
	Birth set	Ila	7	10-243
	Arthrography set	Ila	6 7	15-316 15-316
	Peha			
	Catheterisation sets	Ila	2 5 (2 <sup>nd</sup> ) 6 7	15-564 15-564 15-564 15-564



	Set for anaesthesia	Ila	2	15-202
			6	15-202
			7	15-202
	Set for anaesthesia	Ila	2	10-127
			6	10-127
			7	10-127
	Wound treatment sets/wound dressing sets	Ila	2	11-314
			6	11-314
			7	11-314
	Infusion set	Ila	2	12-157
			7	12-157
	Injection set	Ila	6	12-157
			7	12-157
	Set for central-venous catheterisation	Ila	2	16-615
			6	16-615
			7	16-615
	Suture set	Ila	5 (2 <sup>nd</sup> )	13-892
			6	13-892
			7	13-892
	Dialysis set	Ila	2	15-896
			6	15-896
			7	15-896
	Surgical set	Ila	2	12-463
			5 (2 <sup>nd</sup> )	12-463
			6	12-463
			7	12-463
	Surgical set	Ila	2	15-896
			5 (2 <sup>nd</sup> )	15-896
			6	15-896
			7	15-896
	Birth set	Ila	7	10-243
	Arthrography set	Ila	6	15-316
			7	15-316
	Sterima			
	Catheterisation sets	Ila	2	15-564
			5 (2 <sup>nd</sup> )	15-564
			6	15-564
			7	15-564
	Set for anaesthesia	Ila	2	15-202
			6	15-202
			7	15-202
	Set for anaesthesia	Ila	2	10-127
			6	10-127
			7	10-127
	Wound treatment sets/wound dressing sets	Ila	2	11-314
			6	11-314
			7	11-314
	Infusion set	Ila	2	12-157
			7	12-157



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	Injection set	Ila	6	12-157
			7	12-157
	Set for central-venous catheterisation	Ila	2	16-615
			6	16-615
			7	16-615
	Suture set	Ila	5 (2 <sup>nd</sup> )	13-892
			6	13-892
			7	13-892
	Dialysis set	Ila	2	15-896
			6	15-896
			7	15-896
	Surgical set	Ila	2	12-463
			5 (2 <sup>nd</sup> )	12-463
			6	12-463
			7	12-463
	Surgical set	Ila	2	15-896
			5 (2 <sup>nd</sup> )	15-896
			6	15-896
			7	15-896
	Birth set	Ila	7	10-243
	Arthrography set	Ila	6	15-316
			7	15-316
	Samu-med	Ila	5 (2 <sup>nd</sup> )	16-164
	DermaPlast wound treatment kits for the treatment of:			
	abrasions	Ila	4 (3 <sup>rd</sup> )	11-314
	burns	Ila	4 (3 <sup>rd</sup> )	11-314
	cuts	Ila	4 (3 <sup>rd</sup> )	11-314
	blisters	Ila	4 (3 <sup>rd</sup> )	11-314
	DermaActive wound treatment kits for the treatment of:			
	abrasions	Ila	4 (3 <sup>rd</sup> )	11-314
	burns	Ila	4 (3 <sup>rd</sup> )	11-314
	cuts	Ila	4 (3 <sup>rd</sup> )	11-314
	blisters	Ila	4 (3 <sup>rd</sup> )	11-314
<b>3.04</b>	<b>Surgical wound management products</b>			
	Telatrast surgical absorbents non-sterile:			
	Telasorb	Ila	7	10-281
	Telasling	Ila	7	13-705
	Telaprep	Ila	7	13-705
	Telacomp	Ila	7	10-966
	Telatrast-module-system sterile:			
	Telasorb	Ila	7	10-281
	Telasorb E	Ila	7	10-281

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10 0

Management Board: Britta Fünfstück  
(Chairman/ CEO), Dr. Raymund Heinen,  
Thomas Schulz,  
Ulrich Schneider/ Chairman of the Supervisory Board:  
Ulrich Schneider

Sitz Heidenheim  
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	Telasling	Ila	7	13-705
	Telaprep	Ila	7	13-705
	Telacomp	Ila	7	10-966
	Telacomp E	Ila	7	10-966
	Sterilux X-ray Gauze Sponges (USP)	Ila	7	10-966
	Telaset sterile	Ila	7	11-314
<b>3.05</b>	<b>Surgical gloves Latex</b>			
	Peha-taft	Ila	7	11-883
	Peha-taft classic (powderfree)	Ila	7	11-883
	Peha-micron plus powderfree	Ila	7	11-883
	Peha-taft plus powderfree	Ila	7	11-883
	Peha-profile plus powderfree	Ila	7	11-883
	Peha-basic LATEX	Ila	7	11-883
	Peha-micron LATEX	Ila	7	11-883
	Peha-profile LATEX	Ila	7	11-883
	Peha-taft classic POWDERED	Ila	7	11-883
	Peha-taft classic POWDERFREE	Ila	7	11-883
	Peha-taft LATEX	Ila	7	11-883
	Peha-underglove LATEX	Ila	7	11-883
<b>3.06</b>	<b>Surgical gloves non-Latex</b>			
	Peha-neon plus powderfree	Ila	7	11-884
	Peha-isoprene plus powderfree	Ila	7	11-884
	Peha-isoprene LATEXFREE	Ila	7	11-884
	Peha-neon LATEXFREE	Ila	7	11-884
	Peha-shield LATEXFREE	Ila	7	11-884
	Peha-underglove LATEXFREE	Ila	7	11-884
<b>3.07</b>	<b>Customised surgical procedure sets</b>			
	Foliodrape Sets/Foliodrape for indication-related procedures:	Ila	2	15-896
		Ila	6	15-896
		Ila	7	15-896
		Ila	11	15-896
	General surgery			
	ophthalmology			
	gynaecology			
	obstetrics			
	cardiosurgery			
	chest surgery			
	vascular surgery			
	ENT			
	oral surgery			
	maxillofacial surgery			
	neurosurgery			



	<p>orthopaedics urology CombiSets/CombiSet for indication- related procedures:</p> <p>General surgery ophthalmology gynaecology obstetrics cardiosurgery chest surgery vascular surgery ENT oral surgery maxillofacial surgery neurosurgery orthopaedics urology</p>	<p>Ila Ila Ila Ila</p>	<p>2 6 7 11</p>	<p>15-896 15-896 15-896 15-896</p>
<b>3.08</b>	<b>Electronic clinical thermometers</b>			
	Therموال basic	Ila	10 (3 <sup>rd</sup> )	14-032
	Therموال Rapid	Ila	10 (3 <sup>rd</sup> )	14-032
	Therموال rapid flex	Ila	10 (3 <sup>rd</sup> )	14-032
	Therموال standard	Ila	10 (3 <sup>rd</sup> )	14-032
	Therموال kids	Ila	10 (3 <sup>rd</sup> )	14-032
	Therموال kids flex	Ila	10 (3 <sup>rd</sup> )	14-032
	Cosmos thermometers electronic	Ila	10 (3 <sup>rd</sup> )	14-032
	Therموال duo scan	Ila	10 (3 <sup>rd</sup> )	14-036
	Therموال baby	Ila	10 (3 <sup>rd</sup> )	14-036
<b>3.09</b>	<b>Electronic blood pressure monitors</b>			
	Tensoval mobile	Ila	10 (3 <sup>rd</sup> )	16-173
	Tensoval comfort	Ila	10 (3 <sup>rd</sup> )	16-173
	Tensoval compact	Ila	10 (3 <sup>rd</sup> )	16-173
	Tensoval duo control	Ila	10 (3 <sup>rd</sup> )	16-173
	Tensoval mobil classic	Ila	10 (3 <sup>rd</sup> )	16-173
	Tensoval comfort classic	Ila	10 (3 <sup>rd</sup> )	16-173
	Veroval duo control	Ila	10 (3 <sup>rd</sup> )	16-173
<b>3.10</b>	<b>Medical instruments</b>			
	Peha-instrument			
	Scissors	Ila	6	13-493
			6	13-480
			6	13-488
			6	13-492
	Forceps	Ila	6	14-257





			6	11-791
			6	11-797
			6	10-865
	Needle holder	Ila	6	12-726
	Wound hook	Ila	6	13-373
	Sharp spoon	Ila	6	11-084
	Basic Set	Ila	6	17-168
	MediSet			
	Curette	Ila	4 (3 <sup>rd</sup> )	11-084
	Forceps	Ila	6	11-797
	Grooved director	Ila	6	13-117
	Stylet	Ila	6	13-833
	Scissors	Ila	6	13-480
	Sterima			
	Curette	Ila	4 (3 <sup>rd</sup> )	11-084
	Forceps	Ila	6	11-797
	Grooved director	Ila	6	13-117
	Stylet	Ila	6	13-833
	Scissors	Ila	6	13-480
<b>3.11</b>	<b>Products for negative pressure wound therapy</b>			
	VivanoTec Pro	Ila	11	10-223

( ) 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, bullet



EC-Declaration of Conformity for Medical Devices Class IIb				
Running No.	Product Groups / Product Names	Classification in accordance with Directive 93/42/EEC	Rule	UMDNS
4.01	<b>Impregnated tulle and special dressings</b>			
	Grassolind neutral	IIb	4 (2 <sup>nd</sup> )	11-325
	Atrauman	IIb	4 (2 <sup>nd</sup> )	11-325
	Branolind	IIb	4 (2 <sup>nd</sup> )	11-325
	Hydrotüll / Hydrotul	IIb	4 (2 <sup>nd</sup> )	11-325
	Atrauman Silicone	IIb	4 (2 <sup>nd</sup> )	11-325
	Atrauman Ag	IIb	4 (2 <sup>nd</sup> )	11-325
	Syspur-derm	IIb	4 (2 <sup>nd</sup> )	11-323
	Interface	IIb	4 (2 <sup>nd</sup> )	15-216
4.02	<b>Hydroactive dressings and accessories</b>			
	Hydrosorb	IIb	4 (2 <sup>nd</sup> )	15-216
	Hydrosorb comfort	IIb	4 (2 <sup>nd</sup> )	15-216
	Hydrosorb Gel	IIb	4 (2 <sup>nd</sup> )	15-216
	TenderWet	IIb	4 (2 <sup>nd</sup> )	15-216
	TenderWet 24	IIb	4 (2 <sup>nd</sup> )	15-216
	TenderWet 24 active	IIb	4 (2 <sup>nd</sup> )	15-216
	TenderWet active cavity	IIb	4 (2 <sup>nd</sup> )	15-216
	TenderWet Duo	IIb	4 (2 <sup>nd</sup> )	15-216
	TenderWet plus	IIb	4 (2 <sup>nd</sup> )	15-216
	TenderWet plus cavity	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean cavité	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean cavity	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean active	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean active cavité	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean plus	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean plus cavity	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean mini	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean advance	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean advance mini	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean plus mini	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroClean advance cavity	IIb	4 (2 <sup>nd</sup> )	15-216
Hydrocoll	IIb	4 (2 <sup>nd</sup> )	15-216	
Hydrocoll concave	IIb	4 (2 <sup>nd</sup> )	15-216	
	Hydrocoll sacral	IIb	4 (2 <sup>nd</sup> )	15-216



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	Hydrocoll thin	IIb	4 (2 <sup>nd</sup> )	15-216
	Sorbalgon	IIb	4 (2 <sup>nd</sup> )	15-216
	Sorbalgon T	IIb	4 (2 <sup>nd</sup> )	15-216
	Zetuvit plus	IIb	4 (2 <sup>nd</sup> )	15-216
	Resposorb Super	IIb	4 (2 <sup>nd</sup> )	15-216
	Zetuvit Plus Silicone	IIb	4 (2 <sup>nd</sup> )	15-216
	RespoSorb Silicone	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroTac	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroTac comfort	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroTac concave	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroTac sacral	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroTac transparent	IIb	4 (2 <sup>nd</sup> )	15-216
	HydroTac transparent comfort	IIb	4 (2 <sup>nd</sup> )	15-216
	PermaFoam	IIb	4 (2 <sup>nd</sup> )	11-323
	PermaFoam sacral	IIb	4 (2 <sup>nd</sup> )	11-323
	PermaFoam concave	IIb	4 (2 <sup>nd</sup> )	11-323
	PermaFoam cavity	IIb	4 (2 <sup>nd</sup> )	11-323
	PermaFoam comfort	IIb	4 (2 <sup>nd</sup> )	11-323
	PermaFoam tracheostomy	IIb	4 (2 <sup>nd</sup> )	15-624
	Zetuvit Plus Silicone Border / RespoSorb Silicone Border	IIb	4 (2 <sup>nd</sup> )	15-216
<b>4.03</b>	<b>Products for negative pressure wound therapy</b>			
	VivanoMed Foam Kit	IIb	4 (2 <sup>nd</sup> )	11-314
	VivanoMed Foam Round Kit	IIb	4 (2 <sup>nd</sup> )	11-314
	VivanoMed Foam Thin Kit	IIb	4 (2 <sup>nd</sup> )	11-314
	VivanoMed Abdominal Kit	IIb	8	11-314
	VivanoMed Foam	IIb	4 (2 <sup>nd</sup> )	11-323
	VivanoMed Silicone Layer	IIb	4 (2 <sup>nd</sup> )	11-325
<b>4.04</b>	<b>Customised surgical procedure sets</b>			
	Foliodrape Sets/Foliodrape for indication-related procedures:	IIb	5	15-896
		IIb	7	15-896
		IIb	9	15-896
	General surgery			
	ophthalmology			
	gynaecology			
	obstetrics			
	cardiosurgery			
	chest surgery			
	vascular surgery			
	ENT			
	oral surgery			
	maxillofacial surgery			
	neurosurgery			



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orthopaedics			
urology			
CombiSets/CombiSet for indication-	IIb	5	15-896
related procedures:	IIb	7	15-896
	IIb	9	15-896
General surgery			
ophthalmology			
gynaecology			
obstetrics			
cardiosurgery			
chest surgery			
vascular surgery			
ENT			
oral surgery			
maxillofacial surgery			
neurosurgery			
orthopaedics			
urology			

( ) 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, bullet