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

Heidenheim, 25. February 2021

We herewith declare,

that the medical devices, listed in the appendix, which are first placed on the market by PAUL HARTMANN AG, are classified as class IIa, IIb and III and meet the applicable provisions, especially the Essential Requirements of the Council Directive 93/42/EEC of 14th June 1993.

The conformity assessment procedure for the IIa and IIb products according to Annex II excluding 4 of the Council Directive 93/42/EEC has been performed and the technical documentation is kept available. For the class III products the required conformity assessment procedure according to Council Directive 93/42/EEC Annex II including Section 4 has been performed and the technical documentation is kept available.

This EC Declaration of Conformity is issued under the sole responsibility of PAUL HARTMANN AG and is valid until 25th May 2024.

The conformity assessment procedure is under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany, Identification No. 0123.

PAUL HARTMANN AG

ppa.

A handwritten signature in black ink, appearing to be "Dr. Heinen".

Dr. Raymund Heinen
CPO

A handwritten signature in blue ink, appearing to be "Stefan Fischer".

Stefan Fischer
Head of Regulatory Affairs

IILN 040 9500 00000 0

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Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Dr. Raymund Heinen, Michel Kuehn, 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



Running No.	Product Groups / Product Names	Classification in accordance with Directive 93/42/EEC	Rule	UMDNS
3.01	Wound management products and dressings			
	ES gauze swabs	Ila	7	10-966
	Sterilux ES	Ila	7	10-966
	Sterilux gauze swabs	Ila	7	10-966
	Standard gauze swabs	Ila	7	10-966
	Mulpa swabs	Ila	7	10-966
	Sterilux gauze sponges (USP)	Ila	7	10-966
	Lusan gauze swabs	Ila	7	10-966
	Sterilux gauze swabs on a roll	Ila	7	10-966
	Pagasling	Ila	7	13-700
	Pagalong	Ila	7	13-700
	Medicomp	Ila	7	15-216
	Medicomp extra	Ila	7	15-216
	Absorbent cotton gauze	Ila	7	10-281
3.02	Special wound closure and covering products			
	Hydrofilm	Ila	4 (3 rd)	17-428
	Hydrofilm non-sterile for Kit Packagers	Ila	4 (3 rd)	17-428
	Visulin	Ila	4 (3 rd)	17-428
	Hydrofilm plus	Ila	4 (3 rd)	10-288
	Tiritas MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing)	Ila	4 (3 rd)	10-288
	Omnistrip	Ila	4 (3 rd)	10-288
	Omnistrip reinforced	Ila	4 (3 rd)	10-288
	Dermaplast Omnistrip	Ila	4 (3 rd)	10-288
	Dermaplast MEDICAL (Wound closure strips, sterile)	Ila	4 (3 rd)	10-288
	Dermaplast hydrocolloid plaster for:			
	minor wounds	Ila	4 (3 rd)	10-288
	abrasions	Ila	4 (3 rd)	10-288
	Blisters	Ila	4 (3 rd)	10-288
	cold sores	Ila	4 (3 rd)	10-288
	corns	Ila	4 (3 rd)	10-288
	Tiritas hydrocolloid plaster for:			
minor wounds	Ila	4 (3 rd)	10-288	



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



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MediSet				
	Catheterisation sets	Ila	2	15-564
			5 (2 nd)	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
	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 nd)	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 nd)	12-463
			6	12-463
			7	12-463
	Surgical set	Ila	2	15-896
			5 (2 nd)	15-896
			6	15-896
			7	15-896
	Birth set	Ila	7	10-243
	Arthrography set	Ila	6	15-316
			7	15-316
	Peha			
	Catheterisation sets	Ila	2	15-564
			5 (2 nd)	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



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			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 nd)	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 nd)	12-463
			6	12-463
			7	12-463
	Surgical set	Ila	2	15-896
			5 (2 nd)	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 nd)	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
	Injection set	Ila	6	12-157
			7	12-157
	Set for central-venous catheterisation	Ila	2	16-615
			6	16-615



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			7	16-615
	Suture set	Ila	5 (2 nd)	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 nd)	12-463
			6	12-463
			7	12-463
	Surgical set	Ila	2	15-896
			5 (2 nd)	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 nd)	16-164
	DermaPlast wound treatment kits for the treatment of:			
	abrasions	Ila	4 (3 rd)	11-314
	burns	Ila	4 (3 rd)	11-314
	cuts	Ila	4 (3 rd)	11-314
	blisters	Ila	4 (3 rd)	11-314
	DermaActive wound treatment kits for the treatment of:			
	abrasions	Ila	4 (3 rd)	11-314
	burns	Ila	4 (3 rd)	11-314
	cuts	Ila	4 (3 rd)	11-314
	blisters	Ila	4 (3 rd)	11-314
3.04	Surgical wound management products			
	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
	Telasling	Ila	7	13-705
	Telaprep	Ila	7	13-705



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	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
3.05	Surgical gloves Latex			
	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
3.06	Surgical gloves non-Latex			
	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
3.07	Customised surgical procedure sets			
	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			
	orthopaedics			
	urology			



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	CombiSets/CombiSet 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				
orthopaedics				
urology				
3.08	Electronic clinical thermometers			
	Themoval basic	Ila	10 (3 rd)	14-032
	Themoval Rapid	Ila	10 (3 rd)	14-032
	Themoval rapid flex	Ila	10 (3 rd)	14-032
	Themoval standard	Ila	10 (3 rd)	14-032
	Themoval kids	Ila	10 (3 rd)	14-032
	Themoval kids flex	Ila	10 (3 rd)	14-032
	Cosmos thermometers electronic	Ila	10 (3 rd)	14-032
	Themoval duo scan	Ila	10 (3 rd)	14-036
	Themoval baby	Ila	10 (3 rd)	14-036
3.09	Electronic blood pressure monitors			
	Tensoval mobile	Ila	10 (3 rd)	16-173
	Tensoval comfort	Ila	10 (3 rd)	16-173
	Tensoval compact	Ila	10 (3 rd)	16-173
	Tensoval duo control	Ila	10 (3 rd)	16-173
	Tensoval mobil classic	Ila	10 (3 rd)	16-173
	Tensoval comfort classic	Ila	10 (3 rd)	16-173
	Veroval duo control	Ila	10 (3 rd)	16-173
3.10	Medical instruments			
	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



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			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 rd)	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 rd)	11-084
	Forceps	Ila	6	11-797
	Grooved director	Ila	6	13-117
	Stylet	Ila	6	13-833
	Scissors	Ila	6	13-480
3.11	Products for negative pressure wound therapy			
	VivanoTec Pro	Ila	11	10-223



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Running No.	Product Groups / Product Names	Classification in accordance with Directive 93/42/EEC	Rule	UMDNS
4.01	Impregnated tulle and special dressings			
	Grassolind neutral	IIb	4 (2 nd)	11-325
	Atrauman	IIb	4 (2 nd)	11-325
	Branolind	IIb	4 (2 nd)	11-325
	Hydrotüll / Hydrotul	IIb	4 (2 nd)	11-325
	Atrauman Silicone	IIb	4 (2 nd)	11-325
	Interface	IIb	4 (2 nd)	15-216
4.02	Hydroactive dressings and accessories			
	Hydosorb	IIb	4 (2 nd)	15-216
	Hydosorb comfort	IIb	4 (2 nd)	15-216
	Hydosorb Gel	IIb	4 (2 nd)	15-216
	HydroClean	IIb	4 (2 nd)	15-216
	HydroClean cavité	IIb	4 (2 nd)	15-216
	HydroClean cavity	IIb	4 (2 nd)	15-216
	HydroClean active	IIb	4 (2 nd)	15-216
	HydroClean active cavité	IIb	4 (2 nd)	15-216
	HydroClean plus	IIb	4 (2 nd)	15-216
	HydroClean plus cavity	IIb	4 (2 nd)	15-216
	HydroClean mini	IIb	4 (2 nd)	15-216
	HydroClean advance	IIb	4 (2 nd)	15-216
	HydroClean advance mini	IIb	4 (2 nd)	15-216
	HydroClean plus mini	IIb	4 (2 nd)	15-216
	HydroClean advance cavity	IIb	4 (2 nd)	15-216
	Hydrocoll	IIb	4 (2 nd)	15-216
	Hydrocoll concave	IIb	4 (2 nd)	15-216
	Hydrocoll sacral	IIb	4 (2 nd)	15-216
	Hydrocoll thin	IIb	4 (2 nd)	15-216
	Sorbalgon	IIb	4 (2 nd)	15-216
	Sorbalgon T	IIb	4 (2 nd)	15-216
	Zetuvit plus	IIb	4 (2 nd)	15-216
	Resposorb Super	IIb	4 (2 nd)	15-216
	Zetuvit Plus Silicone	IIb	4 (2 nd)	15-216
	RespoSorb Silicone	IIb	4 (2 nd)	15-216
	HydroTac	IIb	4 (2 nd)	15-216
HydroTac comfort	IIb	4 (2 nd)	15-216	
HydroTac concave	IIb	4 (2 nd)	15-216	



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	HydroTac sacral	IIb	4 (2 nd)	15-216
	HydroTac transparent	IIb	4 (2 nd)	15-216
	HydroTac transparent comfort	IIb	4 (2 nd)	15-216
	PermaFoam	IIb	4 (2 nd)	11-323
	PermaFoam sacral	IIb	4 (2 nd)	11-323
	PermaFoam concave	IIb	4 (2 nd)	11-323
	PermaFoam cavity	IIb	4 (2 nd)	11-323
	PermaFoam comfort	IIb	4 (2 nd)	11-323
	PermaFoam tracheostomy	IIb	4 (2 nd)	15-624
	Zetuvit Plus Silicone Border /	IIb	4 (2 nd)	15-216
	RespoSorb Silicone Border			
	HydroTac Border Multisite	IIb	4 (2 nd)	15-216
4.03	Products for negative pressure wound therapy			
	VivanoMed Foam Kit	IIb	4 (2 nd)	11-314
	VivanoMed Foam Round Kit	IIb	4 (2 nd)	11-314
	VivanoMed Foam Thin Kit	IIb	4 (2 nd)	11-314
	VivanoMed Abdominal Kit	IIb	8	11-314
	VivanoMed Foam	IIb	4 (2 nd)	11-323
	VivanoMed Silicone Layer	IIb	4 (2 nd)	11-325
4.04	Customised surgical procedure sets			
	Foliodrape Sets/Foliodrape for	IIb	5	15-896
	indication-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			
	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			

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	vascular surgery ENT oral surgery maxillofacial surgery neurosurgery orthopaedics urology			
5.01	Wound dressings (class III)			
	Atrauman Ag (EC Design Examination Certificate No. G7 011858 0068 Rev. 00)	III	13	11-325

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
 (Vorsitzende des Vorstands/CEO), François Georgelin,
 Dr. Raymund Heinen, Michel Kuehn, 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