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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.

Dr. Raymund Heinen
CPO

Stefan Fischer
Head of Regulatory Affairs

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

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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	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
3.02	**Special wound closure and covering products**			
	Hydrofilm	IIa	4 (3rd)	17-428
	Hydrofilm non-sterile for Kit Packagers	IIa	4 (3rd)	17-428
	Visulin	IIa	4 (3rd)	17-428
	Hydrofilm plus	IIa	4 (3rd)	10-288
	Tiritas MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing)	IIa	4 (3rd)	10-288
	Omnistrip	IIa	4 (3rd)	10-288
	Omnistrip reinforced	IIa	4 (3rd)	10-288
	Dermaplast Omnistrip	IIa	4 (3rd)	10-288
	Dermaplast MEDICAL (Wound closure strips, sterile)	IIa	4 (3rd)	10-288
	Dermaplast hydrocolloid plaster for:			
	minor wounds	IIa	4 (3rd)	10-288
	abrasions	IIa	4 (3rd)	10-288
	Blisters	IIa	4 (3rd)	10-288
	cold sores	IIa	4 (3rd)	10-288
	corns	IIa	4 (3rd)	10-288
	Tiritas hydrocolloid plaster for:			
	minor wounds	IIa	4 (3rd)	10-288

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

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

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

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

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	Telacomp	IIa	7	10-966
	Telacomp E	IIa	7	10-966
	Sterilux X-ray Gauze Sponges (USP)	IIa	7	10-966
	Telaset sterile	IIa	7	11-314
3.05	**Surgical gloves Latex**			
	Peha-taft	IIa	7	11-883
	Peha-taft classic (powderfree)	IIa	7	11-883
	Peha-micron plus powderfree	IIa	7	11-883
	Peha-taft plus powderfree	IIa	7	11-883
	Peha-profile plus powderfree	IIa	7	11-883
	Peha-basic LATEX	IIa	7	11-883
	Peha-micron LATEX	IIa	7	11-883
	Peha-profile LATEX	IIa	7	11-883
	Peha-taft classic POWDERED	IIa	7	11-883
	Peha-taft classic POWDERFREE	IIa	7	11-883
	Peha-taft LATEX	IIa	7	11-883
	Peha-underglove LATEX	IIa	7	11-883
3.06	**Surgical gloves non-Latex**			
	Peha-neon plus powderfree	IIa	7	11-884
	Peha-isoprene plus powderfree	IIa	7	11-884
	Peha-isoprene LATEXFREE	IIa	7	11-884
	Peha-neon LATEXFREE	IIa	7	11-884
	Peha-shield LATEXFREE	IIa	7	11-884
	Peha-underglove LATEXFREE	IIa	7	11-884
3.07	**Customised surgical procedure sets**			
	Foliodrape Sets/Foliodrape for indication-related procedures:	IIa IIa IIa IIa	2 6 7 11	15-896 15-896 15-896 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: General surgery ophthalmology gynaecology obstetrics cardiosurgery chest surgery vascular surgery ENT oral surgery maxillofacial surgery neurosurgery orthopaedics urology	IIa IIa IIa IIa	2 6 7 11	15-896 15-896 15-896 15-896
3.08	**Electronic clinical thermometers**			
	Thermoval basic	IIa	10 (3rd)	14-032
	Thermoval Rapid	IIa	10 (3rd)	14-032
	Thermoval rapid flex	IIa	10 (3rd)	14-032
	Thermoval standard	IIa	10 (3rd)	14-032
	Thermoval kids	IIa	10 (3rd)	14-032
	Thermoval kids flex	IIa	10 (3rd)	14-032
	Cosmos thermometers electronic	IIa	10 (3rd)	14-032
	Thermoval duo scan	IIa	10 (3rd)	14-036
	Thermoval baby	IIa	10 (3rd)	14-036
3.09	**Electronic blood pressure monitors**			
	Tensoval mobile	IIa	10 (3rd)	16-173
	Tensoval comfort	IIa	10 (3rd)	16-173
	Tensoval compact	IIa	10 (3rd)	16-173
	Tensoval duo control	IIa	10 (3rd)	16-173
	Tensoval mobil classic	IIa	10 (3rd)	16-173
	Tensoval comfort classic	IIa	10 (3rd)	16-173
	Veroval duo control	IIa	10 (3rd)	16-173
3.10	**Medical instruments**			
	Peha-instrument			
	Scissors	IIa	6 6 6 6	13-493 13-480 13-488 13-492
	Forceps	IIa	6 6 6	14-257 11-791 11-797

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

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4.01	**Impregnated tulle and special dressings**			
	Grassolind neutral	IIb	4 (2nd)	11-325
	Atrauman	IIb	4 (2nd)	11-325
	Branolind	IIb	4 (2nd)	11-325
	Hydrotüll / Hydrotul	IIb	4 (2nd)	11-325
	Atrauman Silicone	IIb	4 (2nd)	11-325
	Interface	IIb	4 (2nd)	15-216
4.02	**Hydroactive dressings and accessories**			
	Hydrosorb	IIb	4 (2nd)	15-216
	Hydrosorb comfort	IIb	4 (2nd)	15-216
	Hydrosorb Gel	IIb	4 (2nd)	15-216
	HydroClean	IIb	4 (2nd)	15-216
	HydroClean cavité	IIb	4 (2nd)	15-216
	HydroClean cavity	IIb	4 (2nd)	15-216
	HydroClean active	IIb	4 (2nd)	15-216
	HydroClean active cavité	IIb	4 (2nd)	15-216
	HydroClean plus	IIb	4 (2nd)	15-216
	HydroClean plus cavity	IIb	4 (2nd)	15-216
	HydroClean mini	IIb	4 (2nd)	15-216
	HydroClean advance	IIb	4 (2nd)	15-216
	HydroClean advance mini	IIb	4 (2nd)	15-216
	HydroClean plus mini	IIb	4 (2nd)	15-216
	HydroClean advance cavity	IIb	4 (2nd)	15-216
	Hydrocoll	IIb	4 (2nd)	15-216
	Hydrocoll concave	IIb	4 (2nd)	15-216
	Hydrocoll sacral	IIb	4 (2nd)	15-216
	Hydrocoll thin	IIb	4 (2nd)	15-216
	Sorbalgon	IIb	4 (2nd)	15-216
	Sorbalgon T	IIb	4 (2nd)	15-216
	Zetuvit plus	IIb	4 (2nd)	15-216
	Resposorb Super	IIb	4 (2nd)	15-216
	Zetuvit Plus Silicone	IIb	4 (2nd)	15-216
	RespoSorb Silicone	IIb	4 (2nd)	15-216
	HydroTac	IIb	4 (2nd)	15-216
	HydroTac comfort	IIb	4 (2nd)	15-216
	HydroTac concave	IIb	4 (2nd)	15-216

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

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

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Going further for health

	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

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