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EC-Declaration of Conformity for Medical Devices Class I

Heidenheim, 11. January 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 I and meet the applicable provisions, especially the Essential Requirements of the Council Directive 93/42/EEC of 14th June 1993.

The conformity assessment procedure according to Annex VII of the Council Directive 93/42/EEC 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 2021.

PAUL HARTMANN AG

ppa.

A handwritten signature in blue 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

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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Running No.	Product Groups / Product Names	Classification in accordance with Directive 93/42/EEC	Rule	UMDNS
1.01	Absorbent cotton gauze			
	ZZ-Gauze		4 (1 st)	10-281
	Absorbent cotton gauze		4 (1 st)	10-281
	Mullix		4 (1 st)	11-327
	Mullro		4 (1 st)	11-327
	Mullro extra		4 (1 st)	11-327
	Sterilux höggradigt ren		4 (1 st)	10-966
	Econolux		4 (1 st)	10-966
1.02	Medical wadding			
	Hartmann Wadding		1	15-216
	Absorbent cotton wool		1	15-216
1.03	Cellulose wadding products			
	Eycopad		4 (1 st)	11-661
	Pur-Zellin		4 (1 st)	15-252
	Soft-Zellin		1	15-252
	Fil-Zellin		4 (1 st)	11-328
1.04	Absorbent dressing pads			
	Pehazell		1	15-216
	Celluron		5 (2 nd)	15-216
	Zetuvit		4 (1 st)	15-216
	Zetuvit E		4 (1 st)	15-216
	Scrylin		4 (1 st)	15-216
	Samu-Pads		4 (1 st)	15-216
	Samu classic		4 (1 st)	15-216
1.05	Adhesive wound plasters and plaster strips			
	Samu plus		4 (1 st)	15-216
	Medicomp Höggradigt ren		4 (1 st)	15-216
	MoliMed Posparto		4 (1 st)	15-216
	Cosmoplast		4 (1 st)	10-288
	Cosmomed		4 (1 st)	10-288
	DermaPlast Hydro-(Active) blister plaster		4 (1 st)	10-288
	DermaPlast Hydro-(Active) corn plaster		4 (1 st)	10-288
	Tiritas Hydro-(Active) blister plaster		4 (1 st)	10-288
	Tiritas Hydro-(Active) corn plaster		4 (1 st)	10-288
	Cosmos range		4 (1 st)	10-288
	DermaPlast range		4 (1 st)	10-288
	DermaPlast TEXTILE		4 (1 st)	10-288
	DermaPlast SENSITIVE		4 (1 st)	10-288
	DermaPlast PROTECT PLUS		4 (1 st)	10-288
DermaPlast KIDS		4 (1 st)	10-288	
DermaPlast comfort		4 (1 st)	10-288	
DermaPlast SPOTS		4 (1 st)	10-288	
Tiritas range		4 (1 st)	10-288	



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	M-Plast wound dressings		4 (1 st)	10-288
	DermaPlast SOFT SILICONE		4 (1 st)	10-288
	Cosmos ULTRA SENSITIVE		4 (1 st)	11-321
	DermaPlast range		4 (1 st)	11-321
	Tiritas range		4 (1 st)	11-321
	Cosmos range		4 (1 st)	11-321
	DermaActive Protect Spray		4 (1 st)	11-321
	Tiritas EFFECT Protect Spray		4 (1 st)	11-321
1.06	Conforming bandages			
	Gauze Bandages		1	15-557
	Pehalast		1	15-557
	Lastotel		1	15-557
	Peha-crepp		1	15-557
	Peha-haft / color		1	15-557
	Peha-fix		1	15-557
	Telelast		1	15-557
	Lastocrepe		1	15-557
	Conforming bandages Cosmos		1	15-557
	Conforming bandages DermaPlast		1	15-557
	Tensocrepe		1	15-557
	Idealfix color cohesive		1	15-557
	Cosmoplast elastic		1	15-557
	Hospilux		1	15-557
	Hospiform		1	15-557
	Hospifix K		1	15-557
	Idealcrepe		1	15-557
	Idealcrepe Hospital Weight		1	15-557
	Crepe bandages		1	15-557
	Hospicrepe		1	15-557
	Haco-crepe		1	15-557
	Hospilite		1	15-557
	Lastoban		1	15-557
	Elastocrepe		1	15-557
	Sterilux cut gauze bandage roll		1	15-557
	Peha-Mullbinden		1	15-557
	Peha-Lastotel		1	15-557
	Dermaplast MEDICAL (Cohesive bandage)		1	15-557
1.07	Tubular and elastic net bandages			
	Stülpa		1	10-291
	Stülpa fix		1	10-291
	Lastogrip		1	10-291
	Coverflex		1	10-291
	Covertube tricot		1	10-291
	Coverflex fast		1	10-291
1.08	Adhesive tapes and straps			
	Omniplast		1	10-028
	Omnifilm		1	10-028
	Omnipor		1	10-028



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	Omnisilk		1	10-028
	Omnifix elastic		1	10-028
	Omnifix E		1	10-028
	Adhesive tapes Cosmos		1	10-028
	Adhesive tapes Cosmoplast		1	10-028
	Adhesive tapes DermaPlast		1	10-028
	Hydrofilm Roll		1	10-028
	DermaPlast Medical non-woven retention tape		1	10-028
	DermaPlast Medical film dressing		1	10-028
	DermaPlast MEDICAL (Elastic fixation dressing)		1	10-028
	DermaPlast MEDICAL (Waterproof fixation dressing)		1	10-028
	Tiritas MEDICAL (Waterproof fixation dressing)		1	10-028
1.09	Compression bandages			
	Idealbinde		1	15-557
	Idealflex		1	15-557
	Idealast		1	15-557
	Idealast haft		1	15-557
	Idealhaft		1	15-557
	Idealcool		1	15-557
	Lastopress		1	15-557
	Lastodur		1	15-557
	Lastohaft		1	15-557
	Lastocomp		1	15-557
	Lastolan		1	15-557
	Pütterbinde		1	15-557
	Pütter-Bandage		1	15-557
	Veno 4		1	15-557
	Cosmoplast Sport Bandage		1	15-557
	PütterFlex		1	15-557
	Pütter-haft		1	15-557
	PütterPro 2		1	15-557
	TwoPress 2		1	15-557
1.10	Zinc paste bandages			
	Varix		1	15-557
	Ideal-Varix		1	15-557
	Varolast		1	15-557
	Varolast plus		1	15-557
1.11	Functional bandages and accessories			
	Omnitape		1	10-288
	DermaPlast ACTIVE Sport Tape		1	10-288
	Cosmos ACTIVE Sport Tape		1	10-288
	Hypolastic		1	10-288
	Idealplast		1	10-288
1.12	Plaster of paris and rigid plastic bandages plus accessories			
	Platrix		1	10-665



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	Safix plus		1	10-665
	Safix E		1	10-665
1.13	Padding and crepe-paper bandages			
	Rolta		1	11-326
	Rolta soft		1	11-326
	Rolta pro		1	11-326
	Rolta strong		1	11-326
	Crepe-paper bandages		1	15-557
1.14	Medical stockings and support bandages			
	Verba		1	10-279
	Verba E		1	10-279
1.15	Incontinence products body-worn and accessories			
	MoliCare range		1	12-111
	NURSA Incontinence slips		1	12-111
	NURSA pants		1	12-111
	MoliBelt		1	12-111
	Dignity range		1	12-111
	Confiance slip		1	12-111
	Confiance Mobile		1	12-111
	MoliCare Premium Fixpants long leg		1	12-111
	MoliCare Premium Fixpants short leg		1	12-111
	Confiance Fixpants long leg		1	12-111
	Confiance Fixpants short leg		1	12-111
	MoliCare Premium Mobile		1	12-111
	MoliCare Fixpants long leg		1	12-111
	MoliCare Fixpants short leg		1	12-111
	Molipants range		1	12-111
	Molimed pants		1	12-111
	LINDOR care AUSONIA elasticos		1	12-111
	LINDOR care AUSONIA anatomicos		1	12-111
	Lindor fit Pants		1	12-111
	Lindor AUSONIA Pants		1	12-111
	Lindor AUSONIA elasticos / Elásticos		1	12-111
	Lindor AUSONIA anatomicos		1	12-111
	MoliCare Premium Elastic		1	12-111
	MoliCare Premium Slip		1	12-111
	MoliCare Slip		1	12-111
	MoliCare Premium lady pants		1	12-111
	MoliCare Premium MEN PANTS		1	12-111
	Confiance Lady Pants		1	12-111
	Confiance MEN Pants		1	12-111
	MoliCare Premium lady pad		1	12-111
	MoliDare Premium MEN pad		1	12-111
	Confiance Lady (Pad)		1	12-111
	Confiance MEN (Pad)		1	12-111
	MoliCare Pad		1	12-111
	MoliCare Pants		1	12-111
	Secure Slip		1	12-111
	Lindor AUSONIA Rectangular		1	12-111



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	Moliform range		1	16-498
	Molimed range		1	16-498
	Molinea range		1	16-498
	Moliflex range		1	16-498
	Confiance range		1	16-498
	NURSA Incontinence pads		1	16-498
	Strampelpeter Insert Pads		1	16-498
	Belted Product		1	16-498
	MoliCare Premium Form		1	16-498
	MoliCare Form		1	16-498
	LINDOR care AUSONIA		1	16-498
	Lindor AUSONIA		1	16-498
	Lindor CARE Empapador		1	16-498
1.16	Incontinence underpads, not body-worn			
	Molinea range		1	16-498
	Molinea plus/plus-d		1	16-498
	NURSA underpads		1	16-498
	Lindor AUSONIA Salvacamas		1	16-498
1.17	Examination gloves Latex			
	Peha-soft		5 (1 st)	11-882
	Peha-soft powderfree		5 (1 st)	11-882
	Peha-soft satin powderfree		5 (1 st)	11-882
	Digitil PF		5 (1 st)	11-882
1.18	Examination gloves Non-latex			
	Peha-soft syntax (powderfree)		5 (1 st)	11-882
	Peha-soft vinyl (powderfree)		5 (1 st)	11-882
	Digitil V (powderfree)		5 (1 st)	11-882
	Peha-soft nitrile		5 (1 st)	11-882
	Peha-soft nitrile fino		5 (1 st)	11-882
	Peha-soft nitrile guard		5 (1 st)	11-882
	Peha-soft nitrile white		5 (1 st)	11-882
	Peha-soft nitrile WHITE SEMI-LONG		5 (1 st)	11-882
	Dermaplast MEDICAL GLOVES		5 (1 st)	11-882
1.19	OR-clothing			
	Medimask range		1	12-458
	Foliodress mask		1	12-458
	Medinette range		1	11-901
	Foliodress cap		1	11-901
	Foliodress comfort (scrub clothing)		1	11-901
	Foliodress gown comfort		1	11-901
	Foliodress gown protect		1	11-901
	Foliodress S		1	15-037
	Foliodress Suit		1	15-037
	Foliodress Suit Comfort		1	15-037
	Foliodress Suit Comfort Extra		1	15-037
	Foliodress Suit jacket Comfort		1	15-037
	Foliodress Suit warming colla		1	15-037
	Foliodress jacket Comfort		1	15-037
	Foliodress warming collar		1	15-037



1.20	Tamponades			
	Absorbent ribbon gauze		5 (2 nd)	15-557
1.21	First aid products			
	Rescue blanket		1	10-416
	Triangular cloth		1	13-561
	Finger bandages		4 (1 st)	10-288
	First aid scissors		1	13-481
	Elastic conforming bandage		1	15-557
	First aid glove		5 (1 st)	15-222
	Adhesive tape		1	16-769
1.22	Products for patient care and examination			
	Medical cotton buds		1	15-066
	Valamask		1	15-230
	ValaComfort mask		1	15-230
	Tongue depressor		5 (1 st)	15-249
	Protective covers for thermometers		5 (1 st)	13-116
	Pagavit		5 (1 st)	16-619
	Arm cuff (for blood pressure monitor)		1	11-073
	Hand pump ball for Tensoval compact		1	11-071
	Pur-Zellin Box		1	11-313
	Veroval DUO CONTROL Draw-clamp cuff		1	11-073
	1.23	Mains adapter (for blood pressure monitor)		
Tensoval main adapter			12	16-935
1.24	Medical instruments			
	Peha-instrument Eye retractor		5 (1 st)	13-663
1.25	Surgical drapes			
	HARTMANN patient drapes and covers		1	15-646
	HARTMANN equipment covers		1	15-646
	HARTMANN collection products		1	15-646
	HARTMANN fixation products		1	15-646