

Heidenheim, 2017-09-25

EC-Declaration of Conformity for Medical Devices class I

We herewith declare,

that the **medical devices classified as class I**, which are manufactured and/or 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 14th June, 1993.

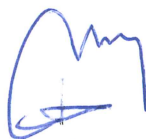
The required conformity assessment procedure acc. to Annex VII has been performed and the technical documentation is kept available.

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

PAUL HARTMANN AG



Dr. R. Heinen
Chief Process Officer



M. Kuehn
Chief Commercial Officer

This document is valid until: 2018-09-30.

IILN 040 9500 00000 0 Vorstand/ Management Board: Andreas Joehle (Vorstandsvorsitzender/ 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
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EC-Declaration of Conformity as well as manufacturers declaration according to article 12 MDD of PAUL HARTMANN AG

Doc.-No./-Name: 2017_09_25_EC_Declaration_of_Conformity_MD_class_I
Version/Date: 2.0
Unit/Dept.: PHAG / CPO-RA
Issued by: CPO-RAO/
Manager Regulatory Affairs



Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
1.01	Absorbent cotton gauze ZZ-Gauze and layered, absorbent cotton gauze Mullix, Mullro, Mullro extra Sterilux höggradigt ren, Econolux	I	4 (1 st)	10-281 11-327 10-966
1.02	Medical wadding Hartmann Wadding, absorbent cotton wool Eycopad	I	1 4 (1 st)	15-216 11-661
1.03	Cellulose wadding products Pur-Zellin, Soft-Zellin Fil-Zellin Pehazell Celluron	I	4 (1 st) 1 4 (1 st) 1 5 (2 nd)	15-252 15-252 11-328 15-216 15-216
1.04	Absorbent dressing pads Zetuvit, Zetuvit E, Scrylin, Samu-Pads, Samu classic/ plus, Medicomp Höggradigt ren, MoliMed Posparto	I	4 (1 st)	15-216
1.05	Adhesive wound plasters and plaster strips Cosmopor strip, Cosmoplast, Cosmomed, DermaPlast Hydro-(Active) blister and corn plaster, Tiritas Hydro-(Active) blister and corn plaster, Cosmos, DermaPlast, Tiritas, Primapore DermaPlast/ Tiritas/ Cosmos/ DermaActive Protect Spray Tiritas EFFECT Protect Spray+	I	4 (1 st) 4 (1 st) 4 (1 st)	10-288 11-321 11-321

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1.06	Conforming bandages Gauze Bandages, Pehalast, Lastotel, Peha-crepp, Peha-haft, Peha-haft color, Telelast, Lastocrêpe, conforming bandages Cosmos and DermaPlast, Tensocrepe, Idealfix color cohesive, Cosmoplast elastic, Hospilux, Hospiform, Hospifix K, Idealcrepe, Idealcrepe Hospital Weight, Crepe bandages, Hospicrepe, Haco-crepe, Hospilite, Lastoban, Elastocrepe, Sterilux cut gauze bandage roll, Peha-Mullbinden, Peha-Lastotel, Dermoplast MEDICAL (Cohesive bandage)	I	1	15-557
1.07	Tubular and elastic net bandages Stülpa, Stülpa fix, Lastogrip, Coverflex, Covertube tricot	I	1	10-291
1.08	Adhesive tapes and straps Omniplast, Omnifilm, Omnipor, Omnisilk, Omnifix elastic, Omnifix E, Tarofilm, Taropor, Tarosilk, adhesive tapes Cosmos, Cosmoplast and DermaPlast, Hydrofilm Roll, DermaPlast Medical non-woven retention tape, DermaPlast Medical film dressing, Dermoplast MEDICAL (Elastic fixation dressing), Dermoplast MEDICAL (Waterproof fixation dressing) Taroplast	I	1	10-028 16-769
1.09	Compression bandages Idealbinde, Idealflex, Idealast (-haft), Idealhaft, Idealcool, Lastopress, Lastodur, Lastohaft, Lastocomp, Lastolan, Pütterbinde, Pütter-Bandage, Veno 4, Cosmoplast Sport Bandage, PütterFlex, Pütter-haft, PütterPro 2, TwoPress 2 Cover Care-Lymphset	I	1	15-557 10-284

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1.10	Zinc paste bandages Varix, Ideal-Varix, Varolast, Varolast plus	I	1	15-557
1.11	Functional bandages and accessories Omnitape, DermaPlast ACTIVE Sport Tape (Omnitape), Hypolastic, Idealplast Cathofix compression bandage, Cathofix compressories	I	1	10-288 10-279
1.12	Plaster of paris and rigid plastic bandages plus accessories Plastrona, Platrix, Safix plus, Safix E, Rhena therm, Rhena cast, Rhena cast splint Plastrona step Plastrona step Fixing Strip Rhena cast boot Rhena supercut	I	1	10-665 10-672 13-368 10-667 13-481
1.13	Padding and crêpe-paper bandages Rolta, Rolta soft, Rolta pro, Rolta strong Crêpe-paper bandages	I	1	11-326 15-557
1.14	Medical stockings and support bandages Verba, Verba E Cambren C, VitaSan classic/ fine/ satinell/ chic, Saphenamed ucv and post op	I	1	10-279 13-789
1.15	Incontinence products body-worn and accessories Molicare-range, NURSA Incontinence slips, MoliBelt, Dignity-range Moliform-, Molimed-, Molinea- Moliflex-range, Confiance-range, NURSA Incontinence pads, Strampelpeter Insert Pads, Belted Product Molipants-range, Molimed pants, Confiance slip, NURSA pants MoliCare Premium Fixpants long leg, MoliCare Premium Fixpants short leg	I	1	12-111 16-498 12-111 12-111

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	MoliCare Premium Form, MoliCare Form			16-498
1.16	Incontinence underpads, not body-worn Underpads like Molinea, Molinea plus/plus-d, NURSA underpads	I	1	16-498
1.17	Examination gloves Latex PeHa-soft, PeHa-soft powderfree, PeHa-soft satin powderfree, Digitil PF	I	5 (1 st)	11-882
1.18	Examination gloves Non-latex PeHa-soft syntex (powderfree), PeHa-soft vinyl (powderfree), Digitil V (powderfree), PeHa-soft nitrile, PeHa-soft nitrile fino, PeHa-soft nitrile guard, PeHa-soft nitrile white, Dermoplast MEDICAL GLOVES	I	5 (1 st)	11-882
1.19	OR-clothing Medimask-range, Foliodress mask Medinette-range, Foliodress cap, Foliodress comfort (scrub clothing), Foliodress gown comfort and protect Foliodress S	I	1	12-458 11-901 15-037
1.20	Tamponades Absorbent ribbon gauze	I	5 (2 nd)	15-557
1.21	First aid products Rescue blanket Triangular cloth Finger bandages First aid scissors Elastic conforming bandage First aid glove Adhesive tape	I	1 1 4 (1.) 1 1 5 (1.) 1	10-416 13-561 10-288 13-481 15-557 15-222 16-769
1.22	Products for patient care and examination Medical cotton buds Clips for bandages Valamask, ValaComfort mask Tongue depressor Protective covers for thermometers Pagavit Arm cuff (for blood pressure)	I	1 1 1 5 (1 st) 5 (1 st) 5 (1 st) 1	15-066 16-771 15-230 15-249 13-116 16-619 11-073

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	monitor) Hand pump ball for Tensoval compact Pur-Zellin Box		1 1	11-071 11-313
1.23	Mains adapter (for blood pressure monitor) Tensoval main adapter	I	12	16-935
1.24	Medical instruments Peha-instrument - Eye retractor	I	5 (1.)	13-663

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