

Heidenheim, 2017-09-25

EC-Declaration of Conformity for Medical Devices class IIa and IIb

We herewith declare,

that the **medical devices classified as class IIa and class IIb**, 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 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 conformity assessment procedure is under the supervision of the Notified Body:
TÜV SÜD Product Service GmbH, DE-80339 München, Ridlerstr. 65, Identification No. 0123.

PAUL HARTMANN AG



Dr. R. Heinen
Chief Process Officer



M. Kuehn
Chief Commercial Officer

This document is valid until: 30.09.2018.

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_Ila_Ilb
Version/Date: 2.0
Unit/Dept.: PHAG / CPO-RA
Issued by: CPO-RAO/
Manager Regulatory Affairs



Class II a Medical Devices of PAUL HARTMANN AG

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, Sterilux ES, Sterilux gauze swabs, Standard gauze swabs, Mulpa swabs, Sterilux gauze sponges (USP), Lusan gauze swabs, Sterilux gauze swabs on a roll Pagasling, Pagalong Medicomp, Medicomp extra Absorbent cotton gauze Saline solution (0,9%), DermaPlast Clean, Dermaplast MEDICAL (Wound cleansing solution), Lusan Saline Solution	II a	7 4 (3 rd)	10-966 13-700 15-216 10-281 12-300
3.02	Special wound closure and covering products Hydrofilm, Visulin Hydrofilm plus, Omnistrip, Omnistrip reinforced, Dermaplast Omnistrip, Dermaplast/ Tiritas/ Cosmos/ DermaActive hydrocolloid plaster (e.g. for minor wounds, abrasions, blisters, cold sores and corns), Dermaplast Medical Transparent dressing, Dermaplast MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing), Dermaplast MEDICAL (Cuts and lacerations) Dermaplast/ Tiritas/ Cosmos/ DermaActive burn plaster, Dermaplast MEDICAL (Burns) Tiritas MEDICAL (Burns), DermaPlast EFFECT blisters & minor wounds, DermaPlast EFFECT blister large, DermaPlast EFFECT blister heel, DermaPlast EFFECT blister small, DermaPlast EFFECT corns, DermaPlast EFFECT minor wounds, DermaPlast EFFECT cold sores	II a	4 (3 rd)	17-428 10-288 11-322 10-288

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
3.03	Sets for patient care MediSet, Peha, Sterima - Catheterisation sets - Set for anaesthesia - Wound treatment sets/ wound dressing sets - Infusion set - Injection set - Set for central-venous catheterisation - Suture set - Dialysis set - Surgical set - Birth set - Arthrography set Samu-med DermaPlast/ DermaActive wound treatment kits for the treatment of - abrasions - burns - cuts - blisters	II a	2, 5 (2 nd) 6 or 7 2, 6 or 7 2, 6 or 7 2 or 7 6 or 7 2, 6 or 7 5 (2 nd), 6 or 7 2, 6 or 7 2, 5 (2 nd), 6 or 7 7 6 or 7 5 (2 nd) 4 (3 rd)	15-564 15-202 10-127 11-314 12-157 12-157 16-615 13-892 15-896 12-463 15-896 10-243 15-316 16-164 11-314
3.04	Surgical wound management products Telatrast surgical absorbents non-sterile: Telatex, Telasorb, Telasling, Telaprep, Telacomp Telatrast-module-system sterile: Telasorb, Telasorb E Telasling, Telaprep, Telatrast non woven sponge Telacomp , Telacomp E, Sterilux X-ray Gauze Sponges (USP) Telatrast non woven swab Telaset sterile	II a	7	10-281 13-705 10-966 10-281 13-705 10-966 15-216 11-314

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3.05	Surgical gloves Latex Peha-taft, Peha-taft classic (powderfree), Peha-micron plus powderfree, Peha-taft plus powderfree, Peha-profile plus powderfree, Peha-basic LATEX, Peha-micron LATEX, Peha-profile LATEX, Peha-taft classic POWDERED, Peha-taft classic POWDERFREE, Peha-taft LATEX, Peha-underglove LATEX	II a	7	11-883
3.06	Surgical gloves non-Latex Peha-neon plus powderfree, Peha-isoprene plus powderfree, Peha-isoprene LATEXFREE, Peha-neon LATEXFREE, Peha-shield LATEXFREE, Peha-underglove LATEXFREE	II a	7	11-884
3.07	Customised surgical procedure sets Foliodrape Sets/ Foliodrape CombiSets / CombiSet for indication-related procedures: for general surgery, ophthalmology, gynaecology, obstetrics, cardiosurgery, chest surgery, vascular surgery, ENT, oral and maxillofacial surgery, neurosurgery , orthopaedics, urology	II a	2, 6, 7, 11	15-896
3.08	Electronic clinical thermometers Thermal basic/ rapid/ rapid flex/ standard / kids/ kids flex, Cosmos thermometers electronic Thermal duo scan, Thermal baby	II a	10 (3 rd)	14-032 14-036
3.09	Electronic blood pressure monitors Tensoval mobile, Tensoval comfort, Tensoval compact, Tensoval duo control, Tensoval mobil classic, Tensoval comfort classic	II a	10 (3 rd)	16-173

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3.10	Medical instruments Peha-instrument - Scissors - Forceps - Needle holder - Wound hook - Sharp spoon - Basic Set MediSet, Sterima - Curette - Forceps - Grooved director - Stylet - Scissors	II a	6	13-493 13-480 13-488 13-492 14-257 11-791 11-797 10-865 12-726 13-373 11-084 17-168 4 (3 rd) 6 6 6 6 11-084 11-797 13-117 13-833 13-480
3.11	Products for negative pressure wound therapy VivanoTec Pro	II a	11	10-223

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
4.03	Products for negative pressure wound therapy VivanoMed - Foam Kit, Foam Round Kit, Foam Thin Kit, - Foam - Silicone Layer - Abdominal Kit	II b	4 (2nd) 8	11-314 11-323 11-325 11-314
4.04	Customised surgical procedure sets Foliodrape Sets/ Foliodrape CombiSets / CombiSet for indication-related procedures for general surgery, ophthalmology, gynaecology, obstetrics, cardiosurgery, chest surgery, vascular surgery, ENT, oral and maxillofacial surgery, neurosurgery, orthopaedics, urology	II b	5, 7, 9	15-896

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