

Heidenheim, 2017-09-25

EC-Declaration of Conformity for Medical Devices class I sterile

We herewith declare,

that the **medical devices classified as class I sterile**, 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 in connection with Annex V 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 sterilization processes are 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: 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_sterile
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
2.01	First aid products Sterilux first aid packet First aid sheets	I sterile	4 (1 st)	15-216 13-561
2.02	Wound dressing pads Zetuvit, Zetuvit E, Scrylin, Comprigel, Medicomp Drain, DermaPlast non-woven swabs, DermaPlast medical swabs, Absoplaie, Samu sterile, Non-woven swabs, DermaPlast Medical non-woven swabs Peha slit dressings	I sterile	4 (1 st)	15-216 10-966
2.03	Tamponades Tampogross Tamponing bandages	I sterile	5 (2 nd)	11-325 15-557
2.04	Swabs Pur-Zellin, Gauze swabs	I sterile	4 (1 st)	15-252 13-700
2.05	Adhesive dressings Cosmopor sterile, Cosmopor E sterile, Cosmopor I.V., Sterifix, DermaPlast sensitive sterile, Hydrofilm I.V., Hydrofilm I.V. control, Cosmopor antibacterial, Cosmopor advance, Cosmopor waterproof, Cosmopor skin color, DermaPlast Medical non-woven dressing, Dermoplast MEDICAL (Light bleeding wounds; breathable, sterile wound dressing)	I sterile	4 (1 st)	10-288
2.06	Bandages Conforming bandages Compression bandages Padding bandages Rolta, Rolta soft Sterilux cut gauze bandage roll Sterilux Bulky Gauze Bandage	I sterile	1 4 (1 st)	15-557 15-557 11-326 15-557 15-557

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Running No.	Product Groups/Product Names	Classification in accordance with Directive 93/42 EEC	Rule	UMDNS
2.07	Sets for patient care MediSet, Peha, Sterima - Dental-Set, mouth care set - Dialysis-Set, set for dent - Wound treatment/ dressing set - Injection set - Baby care set - Anesthesia set - Catheterisation sets - Suture removal set - Maternity set - Pose set for peripheral catheterisation - Suture set - Surgical preparation kit - Set for central-venous catheterization - Minor surgical set	I sterile	5 (1 st) 1, 2, 4 (1 st) or 5 (1 st) 1 or 4 (1 st) 1 or 4 (1 st) 1 or 4 (1 st) 1, 2 or 4(1 st) 1, 2, 4(1 st) or 5(1 st) 4 (1 st) or 5(1 st) 1, 4 (1 st) or 5(1 st) 1 or 4(1 st) 4 (1 st) 1 or 4 (1 st) 1, 2 or 4 (1 st) 1, 2 or 4(1.)	15-896 15-896 16-992 11-314 13-700 15-216 15-252 15-896 10-243 15-202 16-321 15-564 15-896 12-463 12-161 13-892 13-097 16-615 15-896
2.08	Accessories/ instruments for patient care MediSet, Peha, Sterima - Applicator - Non-woven balls - Cotton buds - Protective clothing - Tongue depressor Aqua dest. syringe Tongue depressor VivanoTec Port VivanoTec Y-Connector VivanoTec Exudate Canister Foliodrape Comfort neonatal wrap Peha-soft nitrile sterile	I sterile	1 or 5(1 st) 4 (1 st) 1 or 5(1 st) 1 5 (1 st) 1 5 (1 st) 1 1 1 1 1 5 (1 st)	15-689 13-703 15-066 15-037 15-249 13-936 15-249 11-305 11-307 15-270 10-417 11-882
2.09	Examination Gloves Latex Peha-soft, Peha-soft powderfree	I sterile	5 (1 st)	11-882

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2.10	Theatre clothing Foliodress comfort, Foliodress gown comfort, Foliodress protect, Foliodress gown protect Foliodress S, Foliodress S comfort	I sterile	1	11-901 15-037
2.11	Theatre draping systems Foliodrape comfort, Foliodrape protect, Foliodrape protect plus, Foliodrape Accessories CombiSet	I sterile	1 1, 4 or 5	15-646
2.12	Wound care products based on absorbent cotton gauze Eycopad Gauze swabs, Cosmoplast Univesal gauze swabs, ES-umbilical pads, Econolux, DermaPlast Faltkompressen, Sterilux cut gauze, Dermoplast MEDICAL (Gauze Swab) Sterilux gauze jacket	I sterile	4 (1 st) 1	11-661 10-966 10-281
2.13	Medical instruments Peha-instrument - Tubing clamp - Scissors MediSet, Peha, Sterima - Bandage scissors - Scissors - Forceps / clamp - Dental mirror - Curette - Disposable forceps, tweezers - Stitch cutter - Needle holder - Staple remover - Dental explorer	I sterile	1 1 1 1 5 (1 st) 4 (1 st) 1 1 1 1 5 (1 st)	10-875 12-695 13-481 13-481 13-480 13-502 11-777 15-212 11-774 12-547 11-084 14-257 15-226 12-726 16-787 16-482

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