

PAUL HARTMANN AG
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P.O. Box 1420
89504 Heidenheim
Germany



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PAUL HARTMANN AG, P.O. Box 1420, 89522 Heidenheim, Germany

EC-Declaration of Conformity for Medical Devices Class I sterile

Heidenheim, 2019-09-24

We herewith declare,

that the medical devices classified as class I sterile, which are first 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

ppa.

Dr. Raymund Heinen
Chief Process Officer

Stefan Fischer
Senior Vice President Regulatory Affairs

This document is valid until: 2023-09-30

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IILN 040 9500 00000 0

Vorstand/ Management Board: Britta Fünfstück
(Vorstandsvorsitzende/ 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



EC-Declaration of Conformity for Medical Devices Class I sterile				
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	I sterile	4 (1 st)	15-216
	First aid sheets	I sterile	4 (1 st)	13-561
2.02	Wound dressing pads			
	Zetuvit	I sterile	4 (1 st)	15-216
	Zetuvit E	I sterile	4 (1 st)	15-216
	Scrylin	I sterile	4 (1 st)	15-216
	Comprigel	I sterile	4 (1 st)	15-216
	Medicomp Drain	I sterile	4 (1 st)	15-216
	DermaPlast non-woven swabs	I sterile	4 (1 st)	15-216
	DermaPlast medical swabs	I sterile	4 (1 st)	15-216
	Absoplaie	I sterile	4 (1 st)	15-216
	Samu sterile	I sterile	4 (1 st)	15-216
	Non-woven swabs	I sterile	4 (1 st)	15-216
	DermaPlast Medical non-woven swabs	I sterile	4 (1 st)	15-216
	PeHa slit dressings	I sterile	4 (1 st)	10-966
2.03	Tamponades			
	Tampograss	I sterile	5 (2 nd)	11-325
	Tamponing bandages	I sterile	5 (2 nd)	15-557
2.04	Swabs			
	Pur-Zellin	I sterile	4 (1 st)	15-252
	Gauze swabs	I sterile	4 (1 st)	13-700
2.05	Adhesive dressings			
	Cosmopor sterile	I sterile	4 (1 st)	10-288
	Cosmopor E sterile	I sterile	4 (1 st)	10-288
	Cosmopor I.V.	I sterile	4 (1 st)	10-288
	Sterifix	I sterile	4 (1 st)	10-288
	DermaPlast sensitive sterile	I sterile	4 (1 st)	10-288
	Hydrofilm I.V.	I sterile	4 (1 st)	10-288
	Hydrofilm I.V. control	I sterile	4 (1 st)	10-288
	Cosmopor antibacterial	I sterile	4 (1 st)	10-288
	Cosmopor advance	I sterile	4 (1 st)	10-288
	Cosmopor waterproof	I sterile	4 (1 st)	10-288
Cosmopor skin color	I sterile	4 (1 st)	10-288	



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	DermaPlast Medical non-woven dressing	I sterile	4 (1 st)	10-288
	Dermaplast MEDICAL (Light bleeding wounds; breathable, sterile wound dressing)	I sterile	4 (1 st)	10-288
	Cosmopor Entry	I sterile	4 (1 st)	10-288
2.06	Bandages			
	Conforming bandages	I sterile	1	15-557
	Compression bandages	I sterile	1	15-557
	Sterilux cut gauze bandage roll	I sterile	1	15-557
	Sterilux Bulky Gauze Bandage	I sterile	4 (1 st)	15-557
	Padding bandages	I sterile	1	11-326
	Rolta	I sterile	1	11-326
	Rolta soft	I sterile	1	11-326
2.07	Sets for patient care			
	MediSet			
	Dental-Set	I sterile	5 (1 st)	15-896 11-160
	Dialysis-Set	I sterile	1	15-896
		I sterile	4 (1 st)	16-615
	Wound treatment/ dressing set	I sterile	1	11-314
		I sterile	4 (1 st)	11-314
	Injection set	I sterile	1	12-161
		I sterile	4 (1 st)	15-252
		I sterile	4 (1 st)	15-896
		I sterile	4 (1 st)	12-161
	Baby care set	I sterile	1	10-243
		I sterile	4 (1 st)	10-243
	Anesthesia set	I sterile	1	15-202
		I sterile	4 (1 st)	15-202
		I sterile		10-127
		I sterile	5 (1 st)	15-664
	Catheterisation sets	I sterile	1	15-564
		I sterile	4 (1 st)	15-564
	Suture removal set	I sterile	1	15-896
		I sterile	4 (1 st)	15-896
	Maternity set	I sterile	1	10-243
		I sterile	1	12-463
	Pose set for peripheral catheterisation	I sterile	4 (1 st)	12-161
	Suture set	I sterile	4 (1 st)	13-892
	Surgical preparation kit	I sterile	1	15-896
		I sterile	1	13-097
		I sterile	4 (1 st)	13-097



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	Set for central-venous catheterization	I sterile	1	16-615
		I sterile	4 (1 st)	16-615
	Minor surgical set	I sterile	4 (1 st)	15-896
Peha				
	Dental-Set	I sterile	5 (1 st)	15-896 11-160
	Dialysis-Set	I sterile	1 4 (1 st)	15-896 16-615
	Wound treatment/ dressing set	I sterile	1 4 (1 st)	11-314 11-314
	Injection set	I sterile	1 4 (1 st) 4 (1 st) 4 (1 st)	12-161 15-252 15-896 12-161
	Baby care set	I sterile	1 4 (1 st)	10-243 10-243
	Anesthesia set	I sterile	1 4 (1 st)	15-202 15-202 10-127 15-664
	Catheterisation sets	I sterile	1 4 (1 st)	15-564 15-564
	Suture removal set	I sterile	1 4 (1 st)	15-896 15-896
	Maternity set	I sterile	1 1	10-243 12-463
	Pose set for peripheral catheterisation	I sterile	4 (1 st)	12-161
	Suture set	I sterile	4 (1 st)	13-892
	Surgical preparation kit	I sterile	1 1 4 (1 st)	15-896 13-097 13-097
	Set for central-venous catheterization	I sterile	1 4 (1 st)	16-615 16-615
	Minor surgical set	I sterile	4 (1 st)	15-896
Sterima				
	Dental-Set	I sterile	5 (1 st)	15-896 11-160
	Dialysis-Set	I sterile	1 4 (1 st)	15-896 16-615
	Wound treatment/ dressing set	I sterile	1 4 (1 st)	11-314 11-314
	Injection set	I sterile	1 4 (1 st) 4 (1 st)	12-161 15-252 15-896

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Management Board: Britta Fünfstick
(Chairman/ CEO), Dr. Raymund Heinen,
Thomas Schulz.
Chairman of the Supervisory Board:
Thomas Heinen

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			4 (1 st)	12-161
	Baby care set	I sterile	1	10-243
			4 (1 st)	10-243
	Anesthesia set	I sterile	1	15-202
			4 (1 st)	15-202
				10-127
	Catheterisation sets	I sterile	5 (1 st)	15-664
			1	15-564
			4 (1 st)	15-564
	Suture removal set	I sterile	1	15-896
			4 (1 st)	15-896
	Maternity set	I sterile	1	10-243
			1	12-463
	Pose set for peripheral catheterisation	I sterile	4 (1 st)	12-161
	Suture set	I sterile	4 (1 st)	13-892
	Surgical preparation kit	I sterile	1	15-896
			1	13-097
			4 (1 st)	13-097
	Set for central-venous catheterization	I sterile	1	16-615
			4 (1 st)	16-615
	Minor surgical set	I sterile	4 (1 st)	15-896
2.08	Accessories/ instruments for patient care			
	MediSet			
	Applicator	I sterile	5 (1 st)	15-066
	Cotton buds	I sterile	5 (1 st)	15-689
	Sponge stick	I sterile	1	15-689
	Protective clothing	I sterile	1	15-037
	Tongue depressor	I sterile	5 (1 st)	15-249
	Peha			
	Applicator	I sterile	5 (1 st)	15-066
	Cotton buds	I sterile	5 (1 st)	15-689
	Sponge stick	I sterile	1	15-689
	Protective clothing	I sterile	1	15-037
	Tongue depressor	I sterile	5 (1 st)	15-249
	Sterima			
	Applicator	I sterile	5 (1 st)	15-066
	Cotton buds	I sterile	5 (1 st)	15-689
	Sponge stick	I sterile	1	15-689
	Protective clothing	I sterile	1	15-037
	Tongue depressor	I sterile	5 (1 st)	15-249
	Aqua dest. syringe	I sterile	1	13-936



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	Tongue depressor	I sterile	5 (1 st)	15-249
	VivanoTec Port	I sterile	1	11-305
	VivanoTec Y-Connector	I sterile	1	11-305
	VivanoTec Exudate Canister	I sterile	1	15-270
	Foliodrape Comfort neonatal wrap	I sterile	1	10-417
	Peha-soft nitrile sterile	I sterile	5 (1 st)	11-882
2.09	Examination Gloves Latex			
	Peha-soft	I sterile	5 (1 st)	11-882
	Peha-soft powderfree	I sterile	5 (1 st)	11-882
2.10	Theatre clothing			
	Foliodress comfort	I sterile	1	11-901
	Foliodress gown comfort	I sterile	1	11-901
	Foliodress protect	I sterile	1	11-901
	Foliodress gown protect	I sterile	1	11-901
	Foliodress S	I sterile	1	15-037
	Foliodress S comfort	I sterile	1	15-037
2.11	Theatre draping systems			
	Foliodrape comfort	I sterile	1	15-646
	Foliodrape protect	I sterile	1	15-646
	Foliodrape protect plus	I sterile	1	15-646
	Foliodrape Accessories	I sterile	1	15-646
	CombiSet	I sterile	1	15-646
		I sterile	4	15-646
		I sterile	5	15-646
2.12	Wound care products based on absorbent cotton gauze			
	Eycopad	I sterile	4 (1 st)	11-661
	Gauze swabs	I sterile	4 (1 st)	10-966
	Cosmoplast Universal gauze swabs	I sterile	4 (1 st)	10-966
	ES-umbilical pads	I sterile	4 (1 st)	10-966
	Econolux	I sterile	4 (1 st)	10-966
	DermaPlast Faltkompressen	I sterile	4 (1 st)	10-966
	Sterilux cut gauze	I sterile	4 (1 st)	10-966
	Dermaplast MEDICAL (Gauze Swab)	I sterile	1	10-281
	Sterilux gauze jacket	I sterile	1	10-281
2.13	Medical instruments			
	Peha-instrument			
	Tubing clamp	I sterile	1	10-875
	Scissors	I sterile	1	12-695
			1	13-481
	MediSet			



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	Scissors	I sterile	1	13-480
			1	13-502
			1	13-481
	Forceps / clamp	I sterile	1	11-774
			1	11-777
			1	14-257
	Dental mirror	I sterile	5 (1 st)	12-547
	Needle holder	I sterile	1	12-726
	Staple remover	I sterile	1	16-787
	Dental explorer	I sterile	5 (1 st)	16-482
Peha				
	Scissors	I sterile	1	13-480
			1	13-502
			1	13-481
	Forceps / clamp	I sterile	1	11-774
			1	11-777
			1	14-257
	Dental mirror	I sterile	5 (1 st)	12-547
	Needle holder	I sterile	1	12-726
	Staple remover	I sterile	1	16-787
	Dental explorer	I sterile	5 (1 st)	16-482
Sterima				
	Scissors	I sterile	1	13-480
			1	13-502
			1	13-481
	Forceps / clamp	I sterile	1	11-774
			1	11-777
			1	14-257
	Dental mirror	I sterile	5 (1 st)	12-547
	Needle holder	I sterile	1	12-726
	Staple remover	I sterile	1	16-787
	Dental explorer	I sterile	5 (1 st)	16-482

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