



HARTMANN
France

Groupe Hartmann

Déclarations CE de conformité

et

Certificats CE de conformité

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Classes IIa et IIb**

ANNEXE 1

DECLARATION CE DE CONFORMITE

Laboratoires PAUL HARTMANN Sàrl

9 Route de Sélestat
Châtenois
67607 Sélestat Cedex
FRANCE

DECLARATION CE DE CONFORMITE CONFORMEMENT AU CODE DE LA SANTE PUBLIQUE :

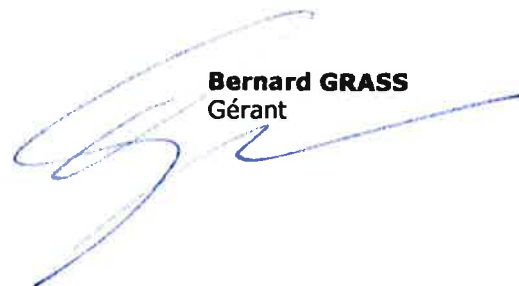
- **DECRET 2009-482**
 - **ORDONNANCE 2010-250**
 - **DECRET 2010-270**
- (DIRECTIVE 93/42/CEE AMENDEE 2007/47)**

Par la présente, nous déclarons que les dispositifs médicaux dont la liste est annexée, mis sur le marché par les Laboratoires Paul Hartmann Sàrl, appartiennent à la classe I. Ils satisfont aux exigences essentielles de la Directive Européenne 93/42/CEE du 14 juin 1993 amendée 2007/47 (Partie V Livre II Titre Ier du Code de la Santé Public). L'évaluation de la conformité a été réalisée conformément à l'Annexe VII de la directive.

Fait à Châtenois,
le 24 mai 2018



Sandrine VERLAINE
Pharmacien Responsable



Bernard GRASS
Gérant



Dispositifs médicaux de classe I des Laboratoires Paul Hartmann Sàrl

1. Dispositifs médicaux non actifs, non stériles

N° du groupe	Groupe de produits Nom des produits	Classification	Règle	UMDNS	1 ^{ère} date de déclaration
1.1	Bandes adhésives élastiques Ex. : Extensa Plus	I	1	10279	24 Novembre 1999
1.2	Bandes de compression Ex. : Idealflex elastic	I	1	10284	10 Octobre 2006
1.3	Bandes de crêpe Ex. : Hartmann, Stérilux, Idealcrepe E	I	1	10284	2 Septembre 1998
1.4	Bandes de gaze hydrophile Ex. : Hartmann, Stérilux	I	1	10281	3 Mars 1998
1.5	Bandes extensibles Ex. : Stérilux	I	1	15203	3 Mars 1998
1.7	Boules de coton Ex. : Hartmann	I	1	11028	3 Mars 1998
1.8	Coiffes chirurgicales Ex. : Medinette B rondo, Medinette B astro, Medinette B comfort, Medinette B apart, Medinette B universel	I	1	11901	20 Mai 1998
1.9	Coton hydrophile Ex. : Hartmann, Stérilux Ex. : Stérilux Pads	I	1	13981	3 Mars 1998 23 Décembre 2015
1.10	Dispositifs d'aide à l'incontinence urinaire masculine Ex. : Molifree étuis péniens Ex. : Molifree poches de recueil d'urine	I I	1 1	10765 14298	19 Juin 1998
1.11	Feuilles de stérilisation Ex. : Sterifeuilles, Sterichamps, Interfoliage, Sterifiltres, SteriGreen Ex. : Sterichamps Duo 1	I I	1 1	13735 13735	3 Mars 1998 3 Mars 2016
1.12	Filets tubulaires Ex. : Stérilux	I	1	10291	3 Mars 1998
1.13	Gants médicaux non stériles Ex. : Digitil S, Digitil V Ex. : Digitil PF	I	5 tiret 1	11882	3 Mars 1998 4 Octobre 2012
1.14	Gaze sous gaine Ex. : Stérilux	I	1	11859	5 Mars 2004
1.15	Petits instruments Ex. : pince clamp Ex. : rasoir	I I	1 1	11784 16580	20 Mai 1998
1.16	Sachets et gaines pour stérilisation Ex. : Sterilsop SX, Sterilsop SLX, Sterilsop SFT, Poupisop	I	1	13735	3 Mars 1998
1.17	Tenue de bloc Ex. : Foliodress suit Ex. : Foliodress suit Protect	I	1	13526	16 Mars 2006 1^{er} Mars 2012

1.18	Petits appareillages orthopédiques (ceintures lombaires, genouillères, chevillères...) Ex. : Colliers cervicaux Rhena Ex. : Orthèses d'immobilisation du membre supérieur Rhena (épaule / scapulo-humérale / claviculaire) Ex. : Orthèses d'immobilisation poignet/main, poignet/pouce, pouce Rhena Ex. : Coudières Rhena Ex. : Ceintures lombaires Rhena Ex. : Genouillères Rhena Ex. : Attelles d'immobilisation du genou Rhena Ex. : Chevillères Rhena Ex. : Ceintures abdominales Rhena	I	1	10938	10 Septembre 2003			
		I	1	12101				
		I	1	17911				
		I	1	17910				
		I	1	17909				
		I	1	17874				
		I	1	12099				
		I	1	17873				
		I	1	10003	29 Juin 2005			
1.19	Sous-vêtements de maintien pour protection absorbante urinaire Ex. : Molipants soft (par 3) Ex. : Molipants Comfort Plus	I	1	12111	30 Août 2010			
					03 Mai 2012			
1.20	Echantillons de produits d'incontinence Protèges-slips, petites protections anatomiques, coquilles péniennes et slips absorbants pour faiblesse urinaire Ex. : Confiance Sensitive Ex. : Confiance for men Ex. : Confiance Slip Ex. : Confiance Protège-slip Slips ou changes absorbants pour incontinence Ex. : MoliCare Ex. : MoliCare Mobile Ex. : Confiance Comfort Ex. : Confiance Mobile Grandes protections anatomiques pour incontinence Ex. : MoliForm Ex. : Confiance Secure Alèses Ex. : MoliNea Plus-E Ex. : Confiance Alèse Couches droites Ex. : MoliNea Pads Ex. : Confiance Protect D	I	1	16498	1^{er} Janvier 2011			
					I	1	16498	1^{er} Septembre 2011
					I	1	12111	1^{er} Janvier 2011
					I	1	12111	1^{er} Mars 2014
					I	1	16498	1^{er} Janvier 2011
					I	1	16498	1^{er} Janvier 2016
					I	1	16498	1^{er} Janvier 2011
					I	1	16498	1^{er} Janvier 2016
					I	1	16498	1^{er} Janvier 2016
							I	1
1.21	Surchaussures Ex. : Valachauss Simple Ex. : Valachauss Reinforced	I	1	13574	1^{er} Juin 2013			
1.22	Produits d'incontinence Ex. : MoliCare Plus	I	1	12111	30 Janvier 2014			

Fait à Châtenois,
le 24 mai 2018


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Pharmacien Responsable


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Gérant

ANNEXE 2

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89504 Heidenheim
Germany



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

Heidenheim, 2018-08-15

EC-Declaration of Conformity for Medical Devices class I

We herewith declare,

that the medical devices classified as class I, 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 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

A handwritten signature in black ink, appearing to be "R. Heinen".

Dr. R. Heinen
Chief Process Officer

ppa.

A handwritten signature in blue ink, appearing to be "S. Fischer".

S. Fischer
Head of Regulatory Affairs

This document is valid until: 2019-09-30.

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 for Medical Devices class I				
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
	Eycopad		4 (1 st)	11-661
1.03	Cellulose wadding products			
	Pur-Zellin		4 (1 st)	15-252
	Soft-Zellin		1	15-252
	Fil-Zellin		4 (1 st)	11-328
	Pehazell		1	15-216
	Celluron		5 (2 nd)	15-216
1.04	Absorbent dressing pads			
	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
	Samu plus		4 (1 st)	15-216
	Medicomp Höggradigt ren		4 (1 st)	15-216
	MoliMed Posparto		4 (1 st)	15-216
1.05	Adhesive wound plasters and plaster strips			
	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

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
	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
	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
	Lastocrêpe		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

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
	Sterilux cut gauze bandage roll	I	1	15-557
	Peha-Mullbinden	I	1	15-557
	Peha-Lastotel	I	1	15-557
	Dermaplast MEDICAL (Cohesive bandage)	I	1	15-557
1.07	Tubular and elastic net bandages			
	Stülpa	I	1	10-291
	Stülpa fix	I	1	10-291
	Lastogrip	I	1	10-291
	Coverflex	I	1	10-291
	Covertube tricot	I	1	10-291
	Coverflex fast	I	1	10-291
1.08	Adhesive tapes and straps			
	Omniplast	I	1	10-028
	Omnifilm	I	1	10-028
	Omnipor	I	1	10-028
	Omnisilk	I	1	10-028
	Omnifix elastic	I	1	10-028
	Omnifix E	I	1	10-028
	adhesive tapes Cosmos	I	1	10-028
	adhesive tapes Cosmoplast	I	1	10-028
	adhesive tapes DermaPlast	I	1	10-028
	Hydrofilm Roll	I	1	10-028
	DermaPlast Medical non-woven retention tape	I	1	10-028
	DermaPlast Medical film dressing	I	1	10-028
	Dermaplast MEDICAL (Elastic fixation dressing)	I	1	10-028
	Dermaplast MEDICAL (Waterproof fixation dressing)	I	1	10-028
	Tiritas MEDICAL (Waterproof fixation dressing)	I	1	10-028
1.09	Compression bandages			
	Idealbinde	I	1	15-557
	Idealflex	I	1	15-557
	Idealast	I	1	15-557
	Idealast haft	I	1	15-557
	Idealhaft	I	1	15-557

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
	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
	Safix plus		1	10-665
	Safix E		1	10-665
1.13	Padding and crêpe-paper bandages			
	Rolta		1	11-326
	Rolta soft		1	11-326
	Rolta pro		1	11-326
	Rolta strong		1	11-326
	Crêpe-paper bandages		1	15-557

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
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		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
	MoliCare Premium MEN Pad		1	12-111
	Confiance Lady (Pad)		1	12-111
Confiance MEN (Pad)		1	12-111	

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EC-Declaration of Conformity for Medical Devices class I				
Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
	MoliCare Pad	I	1	12-111
	Moliform range	I	1	16-498
	Molimed range	I	1	16-498
	Molinea range	I	1	16-498
	Moliflex range	I	1	16-498
	Confiance range	I	1	16-498
	NURSA Incontinence pads	I	1	16-498
	Strampelpeter Insert Pads	I	1	16-498
	Belted Product	I	1	16-498
	MoliCare Premium Form	I	1	16-498
	MoliCare Form	I	1	16-498
	LINDOR care AUSONIA	I	1	16-498
	Lindor AUSONIA	I	1	16-498
1.16	Incontinence underpads, not body-worn			
	Molinea range	I	1	16-498
	Molinea plus/plus-d	I	1	16-498
	NURSA underpads	I	1	16-498
	Lindor AUSONIA Salvacamas	I	1	16-498
1.17	Examination gloves Latex			
	Peha-soft	I	5 (1 st)	11-882
	Peha-soft powderfree	I	5 (1 st)	11-882
	Peha-soft satin powderfree	I	5 (1 st)	11-882
	Digitil PF	I	5 (1 st)	11-882
1.18	Examination gloves Non-latex			
	Peha-soft syntex (powderfree)	I	5 (1 st)	11-882
	Peha-soft vinyl (powderfree)	I	5 (1 st)	11-882
	Digitil V (powderfree)	I	5 (1 st)	11-882
	Peha-soft nitrile	I	5 (1 st)	11-882
	Peha-soft nitrile fino	I	5 (1 st)	11-882
	Peha-soft nitrile guard	I	5 (1 st)	11-882
	Peha-soft nitrile white	I	5 (1 st)	11-882
	Peha-soft nitrile WHITE SEMI-LONG	I	5 (1 st)	11-882
	Dermaplast MEDICAL GLOVES	I	5 (1 st)	11-882

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
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
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

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EC-Declaration of Conformity for Medical Devices class I

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
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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 st)	13-663

() 1st, 2nd bullet

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

ANNEXE 3



Product Service

CERTIFICAT CE**Systeme d'assurance qualite en production**

(Annexe V de la Directive 93/42/CEE relative aux dispositifs medicaux)

N° G2S 14 09 31924 016

Fabricant:**Laboratoires PAUL HARTMANN Sarl**9 route de Sélestat, Châtenois
67607 Sélestat Cedex
FRANCE**Site(s):**

PAUL HARTMANN S.A.

9 route de Sélestat, Châtenois, 67607 Sélestat Cedex, France

Laboratoires PAUL HARTMANN Sarl

9 route de Sélestat, Châtenois, 67607 Sélestat Cedex, France

PAUL HARTMANN S.A.

Z.I. Bois L'Abbesse, 68660 Lièpvre, FRANCE

Categorie(s) de produit:**Dispositifs medicaux de classe I sterile comme
decrits dans l'annexe jointe:****Dispositifs medicaux pour les soins generaux des
plaies, produits pour bloc operatoire, bandes et ban-
dages, produits pour le soin des patients, en milieu
hospitalier et en cabinet medical ou a domicile.****Systemes et sets de soins selon l'Article 12 de la
Directive 93/42/CEE**

L'Organisme de Certification du TÜV SÜD Product Service GmbH certifie par la presente que le fabricant designe ci-dessus met en oeuvre un systeme d'assurance qualite pour la fabrication conformement a l'Annexe V, paragraphe 3 de la Directive 93/42/CEE relative aux dispositifs medicaux. Ce systeme d'assurance qualite couvre les aspects de la fabrication ayant trait a l'obtention et au maintien de la sterilité des produits/categories de produits concernes et remplit les exigences stipulees par cette Directive. Ce systeme est soumis a une surveillance reguliere. Se rapporter egalement aux informations mentionnees au verso.

Rapport n°:

713048037

Valide depuis:

2014-12-01

Valide jusqu' au:

2019-11-30

Date, 2014-11-18

Hans-Heiner Junker



Conformement a la Directive du Conseil n° 93/42/CEE relative aux dispositifs medicaux, le TÜV SÜD Product Service GmbH est un Organisme Notifie enregistre sous le numero d'identification 0123.

Page 1 sur 2



Product Service

Annexe au Certificat CE N° G2S 14 09 31924 016
daté 2014-11-18

Dispositifs médicaux stériles de classe I

Categories de produits:	Classification	Règle
Compresses de gaze stériles pharmacie (par ex. Stérilux ES)	I	4 tiret 1
Gants d'examen stériles (par ex. Digitil Plus, Digitil Inter)	I	5 tiret 1
Sets de soins et accessoires à usage unique (Mediset)	I	1 ou 4 tiret 1 ou 5 tiret 1

Munich, CRT2, 2014-11-18

Hans-Heiner Junker



ANNEXE 4



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 11 11858 056

Manufacturer:

PAUL HARTMANN AG

Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY



**Product
Category(ies):**

Medical devices for general and special wound treatment, operating theatre products, bandages and tapes, patient care products for use on the ward and in general practice as well as products with special purposes.

(Class I sterile medical devices; for a complete list of product groups, see attachment)

Systems and procedure packs according to Article 12 of Directive 93/42/EEC

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 713093080

Valid from: 2017-01-21

Valid until: 2022-01-20

Date, 2016-11-16

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 3



Product Service

EC Certificate**Production Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 11 11858 056**Facility(ies):**

PAUL HARTMANN AG

Paul-Hartmann-Str. 12, 89522 Heidenheim, GERMANY



Product Service

Attachment for Certificate no G2S 16 11 11858 056
valid from 2017-01-21

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class I sterile medical devices

- First aid products
- Wound dressing pads
- Tamponades
- Swabs
- Adhesive dressings
- Bandages
- Sets for patient care
- Accessories / instruments for patient care
- Examination gloves latex
- Theatre clothing
- Theatre draping systems
- Wound management products based on absorbent cotton gauze
- Medical instruments

Munich, MHS-CRT, 2016-11-16

Stefan Preiß





Product Service

**Product Names to Attachment for Certificate No.
G2S 16 11 11858 056, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class I sterile medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
2.01	First aid products e. g. First aid sheets, Sterilux first aid packet	I sterile	4 (1 st bullet)
2.02	Wound dressing pads e. g. Zetuvit, Zetuvit E, Scrylin, Comprigel, Medicomp Drain, DermaPlast non- woven swabs, DermaPlast Medical swabs, Absoplaie, Samu steril, Peha slit dressings, Non-woven swabs, DermaPlast Medical non-woven swabs	I sterile	4 (1 st bullet)
2.03	Tamponades e. g. Tampogross, tamponing bandages	I sterile	5 (2 nd bullet)
2.04	Swabs e. g. Pur-Zellin, gauze swabs	I sterile	4 (1. bullet)
2.05	Adhesive dressings e. g. Cosmopor steril, Cosmopor E steril, 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, Dermaplast MEDICAL (Light bleeding wounds; breathable, sterile wound dressing)	I sterile	4 (1. bullet)
2.06	Bandages e. g. Conforming and compression bandages; padding bandages Rolta, Rolta soft, Sterilux cut gauze bandage roll, Sterilux Bulky Gauze Bandage	I sterile	1, 4 (1. bullet)



Product Service

**Product Names to Attachment for Certificate No.
G2S 16 11 11858 056, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class I sterile medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
2.07	Sets for patient care	I sterile	1 / 2 / 4 (1 st bullet) / 5 (1 st bullet)
e. g.	MediSet, Peha, Sterima		
	- Dental-Set, mouth care set		
	- Dialysis-Set, set for dent		
	- Wound treatment / dressing set		
	- Injection set		
	- Baby care set		
	- Anaesthesia set		
	- Catheterisation sets		
	- Suture removal set		
	- Maternity set		
	- Pose set for peripheral catheterization		
	- Suture set		
	- Surgical Preparation Kit		
	- Minor surgical set		
	- Set for central-venous catheterization		
2.08	Accessories / instruments for patient care	I sterile	1 / 4 (1 st bullet) / 5 (1 st bullet)
e. g.	MediSet, Peha, Sterima		
	- Applicator		
	- Non-woven balls		
	- Cotton buds		
	- Protective clothing		
	- Tongue depressor		
e. g.	Aqua dest. syringe		
e. g.	Tongue depressor		
e. g.	VivanoTec Port		
e. g.	VivanoTec Y-Connector		
e. g.	Foliodrape Comfort neonatal wrap		
e. g.	Peha-soft nitrile sterile		
e. g.	VivanoTec Exudate Canister		



Product Service

**Product Names to Attachment for Certificate No.
G2S 16 11 11858 056, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class I sterile medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
2.09	Examination gloves latex e. g. Peha-soft, Peha-soft powderfree	I sterile	5 (1 st bullet)
2.10	Theatre clothing e. g. Foliodress S, Foliodress protect, Foliodress comfort, Foliodress gown protect, Foliodress gown comfort, Foliodress S comfort	I sterile	1
2.11	Theatre draping systems e. g. Foliodrape comfort, Foliodrape protect, Foliodrape protect plus Foliodrape Accessories	I sterile	1
2.12	Wound care products based on absorbent cotton gauze e. g. CombiSet Eycopad, Gauze swabs, Cosmoplast Universal gauze swabs, ES-umbilical pads, Econolux, DermaPlast Faltkompressen, Sterilux cut gauze Sterilux gauze jacket, Dermoplast MEDICAL (Gauze Swab)	I sterile	e.g. 1, 4 or 5 1/ 4 (1 st bullet)



Product Service

**Product Names to Attachment for Certificate No.
G2S 16 11 11858 056, dated 2017-01-21**

2.13 Medical instruments

I sterile

1 / 4 (1st bullet) /
5 (1st bullet)

- e. g. Peha-instrument
 - Tubing clamp
 - Scissors
- e. g. MediSet, Peha, Sterima
 - Bandage scissors
 - Scissors
 - Forceps / clamp
 - Dental mirror
 - Curette
 - Disposable forceps, tweezers
 - Stitch cutter
 - Needle holder
 - Staple remover
 - Dental explorer

History of revisions:

Initial issue, project no. 71315089
Rev. 07-2007, project no. 71323866
Rev. 03-2009, project no. 71349669
Rev. 04-2009, project no. 71361439
Rev. 05-2010, project no. 71365837
Rev. 06-2011, project no. 71386881
Rev. 07-2011, project no. 71394684
Rev. 08-2012, project no. 713000943
Rev. 09-2012, project no. 713005130
Rev. 10-2013, project no. 713021659
Rev. 11-2014, project no. 713043904
Rev. 12-2015, project no. 713065782
Rev. 09-2016, project no. 713091054
Rev. 10-2016, project no. 713093080
Rev. 02-2017, project no. 713100768
Rev. 03-2017, project no. 713119437

Hamburg, 2017-11-06


Hendrik Schorler
AMP5, Department Manager



ANNEXE 5



Product Service

CERTIFICAT CE

Systeme Complet d'Assurance de la Qualite

Directive 93/42/CEE relative aux Dispositifs Medicaux (DDM), Annexe II à l'exclusion du paragraphe (4) (produits de la classe IIa, IIb ou III)

N° G1 17 04 31924 018

Fabricant:**Laboratoires PAUL HARTMANN S.à.r.l**

9 route de Sélestat, Châtenois

67607 Sélestat Cedex

FRANCE

Catégorie(s) de produit:

Dispositifs médicaux de classes IIa et IIb pour le traitement général ou spécial de plaies, pour le bloc opératoire, bandes et bandages, articles de soins en milieu hospitalier, en cabinet médical ou à domicile (liste des produits en annexe).

Par la présente, l'organisme de certification de TÜV SÜD Product Service GmbH certifie que le fabricant mentionné applique un système d'assurance de la qualité pour la conception, la fabrication et le contrôle final des produits / catégories de produits concernés conformément à l'Annexe II de la DDM. Ce système d'assurance de la qualité satisfait aux exigences de cette Directive et est soumis à une surveillance régulière. La mise sur le marché des produits de la classe III nécessite un certificat complémentaire de conformité aux exigences de l'Annexe II paragraphe (4). Les renseignements figurant au verso doivent être respectés.

Rapport n°:

713103505

Valide depuis:

2017-12-01

Valide jusqu' au :

2022-11-30

**Date, 2017-10-18****Stefan Preiß**

TÜV SÜD Product Service GmbH est un Organisme Notifié enregistré sous le numéro d'identification 0123.

Page 1 sur 3

Traduction à titre d'information. Seule la version anglaise est la référence légale



Product Service

CERTIFICAT CE

Systeme Complet d'Assurance de la Qualite

Directive 93/42/CEE relative aux Dispositifs Medicaux (DDM), Annexe II a l'exclusion du
pa-ragraphe (4) (produits de la classe IIa, IIb ou III)

N° G1 17 04 31924 018

Site(s):

Laboratoires PAUL HARTMANN S.à.r.l
9 route de Sélestat, Châtenois
67607 Sélestat Cedex
FRANCE

PAUL HARTMANN S.A.
9 route de Sélestat, Châtenois
67607 Sélestat Cedex
FRANCE

PAUL HARTMANN S.A.
Z.I. Bois L'Abbesse, 68660 Lièpvre
FRANCE



Product Service

Annexe au Certificat CE N° G1 17 04 31924 018
Valide depuis 2017-12-01

Dispositifs médicaux de classe IIa

Sets de soins (par ex. MediSet)

Dispositifs médicaux de classe IIb

Pansements absorbants hydroactifs (par ex. pansement absorbant avec interface siliconée)

Munich, MHS-CRT, 2017-10-18

Stefan Preiß



ANNEXE 6



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 11 11858 057

Manufacturer:

PAUL HARTMANN AG

Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY



**Product
Category(ies):**

**Medical devices for general and special wound treatment, operating theatre products, bandages and tapes, patient care products for use on the ward and in general practice as well as medical devices with a measuring function.
(Class IIa and IIb medical devices; for a complete list of product groups, see attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713093079

Valid from: 2017-01-21
Valid until: 2022-01-20

Date, 2016-11-16


Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 3



Product Service

EC Certificate**Full Quality Assurance System**Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)**No. G1 16 11 11858 057****Facility(ies):**PAUL HARTMANN AG
Paul-Hartmann-Str. 12, 89522 Heidenheim, GERMANY



Product Service

Attachment for Certificate No. G1 16 11 11858 057
valid from 2017-01-21

Medical Devices of the HARTMANN GROUP

Medical Devices of PAUL HARTMANN AG

Class II a medical devices

- Wound management products and dressings
- Special wound closure and covering products
- Sets for patient care
- Surgical wound management products
- Surgical gloves latex
- Surgical gloves non-latex
- Customised surgical procedure sets
- Electronic clinical thermometers
- Electronic blood pressure monitors
- Medical instruments
- Products for negative pressure wound therapy

Class II b medical devices

- Impregnated tulle dressings and special dressings
- Hydroactive dressings and accessories
- Products for negative pressure wound therapy
- Customized surgical procedure sets

Munich, CRT2, 2016-12-20

Stefan Preiß

Seite 3 von 3 / jdi





Product Service

**Product Names to the Attachment of Certificate
No. G1 16 11 11858 057, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with MDD93/42/EEC</i>	<i>Rule</i>
3.01	Wound management products and dressings	II a	7 / 4 (3rd bullet)
e. g.	ES gauze swabs, Sterilux ES, Sterilux gauze swabs, Standard gauze swabs, Mulpa swabs, Sterilux gauze sponges (USP), Lusan gauze swabs, Pagasling, Pagalong, Medicomp, Medicomp extra, Absorbent cotton gauze, Sterilux gauze swabs on a roll		
e.g.	Saline solution (0,9%), DermaPlast Clean, Dermaplast MEDICAL (Wound cleansing solution), Lusan Saline Solution		
3.02	Special wound closure and covering products	II a	4 (3rd bullet)
e. g.	Hydrofilm, Visulin, Hydrofilm plus, Omnistrip, Omnistrip reinforced, Dermaplast / Tiritas / Cosmos hydrocolloid plaster (e. g. for minor wounds, abrasions, blisters, cold sores and corns), Dermaplast / Tiritas / Cosmos burn plaster, DermaPlast Omnistrip, DermaActive burn plaster, DermaActive hydrocolloid plasters, DermaPlast Medical Transparent dressing, Dermaplast MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing), Dermaplast MEDICAL (Cuts and lacerations), Dermaplast MEDICAL (Burns)		



Product Service

**Product Names to the Attachment of Certificate
No. G1 16 11 11858 057, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with MDD93/42/EEC</i>	<i>Rule</i>
	Tiritas MEDICAL (Burns) DermaPlast EFFECT blister & 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 bullet)
3.03	Sets for patient care	II a	2 / 4 (3 rd bullet) 5 (2 nd bullet) 16 / 7
e.g.	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		
e.g.	Samu-med		
e.g.	DermaPlast / DermaActive wound treatment kits for the treatment of abrasion, burns, cuts and blisters		



Product Service

**Product Names to the Attachment of Certificate
No. G1 16 11 11858 057, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
3.04	Surgical wound management products	II a	7
e. g.	Telatrast surgical absorbents non-sterile: Telatex, Telasorb, Telasling, Telaprep, Telacomp		
e. g.	Telatrast-Module-System sterile: Telasorb, Telasorb E, Telasling, Telaprep, Telacomp, Telacomp E, Sterilux X-ray gauze sponges (USP), Telatrast non woven sponge, Telatrast non woven swab		
e. g.	Telaset steril		
3.05	Surgical gloves Latex	II a	7
e. g.	Peha-taft, Peha-taft classic (powder-free), Peha-micron plus powderfree, Peha-taft plus powderfree, Peha-profile plus powderfree, Peha-taft LATEX, Peha basic LATEX, Peha-micron LATEX, Peha-profile LATEX, Peha-taft classic POWDERED, Peha-taft classic POWDERFREE, Peha-underglove LATEX		
3.06	Surgical gloves non-Latex	II a	7
e. g.	Peha-neon plus powder-free, Peha-isoprene plus powderfree Peha-isoprene LATEXFREE, Peha-neon LATEXFREE, Peha-shield LATEXFREE, Peha-underglove LATEXFREE		



Product Service

**Product Names to the Attachment of Certificate
No. G1 16 11 11858 057, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
3.07	Customised surgical procedure sets e.g. Foliodrape Sets / Foliodrape CombiSets for indication-related surgical procedures e.g. for general surgery, ophthalmology, gynaecology, obstetrics, cardiosurgery, chest surgery, vascular surgery, ENT, oral and maxillofacial surgery, neurosurgery, orthopaedics, urology, CombiSet	II a	e.g. 2 / 6 / 7 / 11
3.08	Electronic clinical thermometers e. g. Thermoval basic / rapid / rapid flex / duo scan / standard / kids / kids flex, Cosmos thermometers electronic, Thermoval baby	II a	10 (3rd bullet)
3.09	Electronic blood pressure monitors e. g. Tensoval mobil, Tensoval comfort, Tensoval compact, Tensoval duo control, Tensoval mobil classic, Tensoval comfort classic	II a	10 (3rd bullet)
3.10	Medical instruments e. g. Peha-instrument - Scissors - Forceps - Needle holder - Wound hook - Sharp spoon - Basic Set e. g. MediSet, Sterima - Curette - Forceps - Grooved director - Stylet - Scissors	II a	4 (3rd bullet) / 6



Product Service

**Product Names to the Attachment of Certificate
No. G1 16 11 11858 057, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
3.11	Products for negative pressure wound therapy e.g. VivanoTec Pro	Ila	11



Product Service

**Product Names to the Attachment of Certificate
No. G1 16 11 11858 057, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II b medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
4.01	Impregnated tulle dressings and special dressings e. g. Grassolind neutral, Atrauman, Atrauman Ag, Branolind, Hydrotüll / Hydrotul, Syspur-derm, Interface Atrauman Silicone, Dermaplast MEDICAL (Wounds at risk of infection)	II b	4 (2 nd bullet)
4.02	Hydroactive dressings and accessories e. g. Hydrosorb, Hydrosorb plus, Hydrosorb comfort, Hydrosorb Gel, AquaClear, AquaClear adhesive, TenderWet, TenderWet 24, TenderWet 24 active, TenderWet active cavity, TenderWet Solution, TenderWet Duo, TenderWet plus, TenderWet plus cavity HydroClean, HydroClean cavité, HydroClean active, HydroClean active cavité, HydroClean Solution, HydroClean advance, HydroClean mini, HydroClean plus mini, HydroClean advance mini, Hydrocoll, Hydrocoll concave, Hydrocoll sacral, Hydrocoll thin, Sorbalgon, Sorbalgon T, Sorbalgon plus, PermaFoam, PermaFoam sacral, PermaFoam concave, PermaFoam cavity, PermaFoam comfort; PermaFoam tracheostomy, Zetuvit plus, Resposorb Super, Zetuvit Plus Silicone, RespSorb Silicone HydroTac, HydroTac comfort, HydroTac sacral, HydroTac transparent, HydroTac transparent comfort, HydroTac concave HydroClean cavity, HydroClean plus / HydroClean plus cavity	II b	4 (2 nd bullet)



Product Service

**Product Names to the Attachment of Certificate
No. G1 16 11 11858 057, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II b medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
4.03	Products for negative pressure wound therapy e.g. VivanoMed - Foam Kit, Foam Round Kit, Foam Thin Kit, - Foam - Silicone Layer - Abdominal Kit	II b	4 (2 nd bullet) / 8
4.04	Customised surgical procedure sets e.g. Foliodrape Sets / Foliodrape CombiSets for indication-related procedures e.g. for general surgery, ophthalmology, gynaecology, obstetrics, cardiosurgery, chest surgery, vascular surgery, ENT, oral and maxillofacial surgery, neurosurgery, orthopaedics, urology, CombiSet	II b	e.g. 5, 7, 9



Product Service

**Product Names to the Attachment of Certificate
No. G1 16 11 11858 057, dated 2017-01-21**

History of revisions:

Initial issue, project no. 71315089

Rev. 01-2007, project no. 71318435

Rev. 07-2007, project no. 71323864

Rev. 02-2008, project no. 71332843

Rev. 03-2009, project no. 71349669

Rev. 10-2009, project no. 71359891

Rev. 11-2009, project no. 71361438

Rev. 12-2010, project no. 71365835

Rev. 13-2010, project no. 71370423

Rev. 14-2010, project no. 71372243

Rev. 15-2011, project no. 71386881

Rev. 16-2011, project no. 71394684

Rev. 17-2012, project no. 713005130

Rev. 18-2012, project no. 713005934

Rev. 19-2013, project no. 713021659

Rev. 20-2013, project no. 713023609

Rev. 21-2014, project no. 713043904 and 713043905

Rev. 22-2015, project no. 713065784

Rev. 09-2016, project no. 713091055

Rev. 10-2016, project no. 713093079

Rev. 11-2016, project no. 713094281

Rev. 02-2017, project no. 713100768

Rev. 03-2017, project no. 713119437

Hamburg, 2017-11-06

**Hendrik Schorler
AMP5 – Department Manager**



