



HARTMANN  
France

**Groupe Hartmann**

**Déclarations CE de conformité**

**et**

**Certificats CE de conformité**



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# 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 19 septembre 2016



**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 <sup>ère</sup> date de déclaration
1.1	<b>Bandes adhésives élastiques</b> Ex. : Extensa Plus	I	1	10279	24 Novembre 1999
1.2	<b>Bandes de compression</b> Ex. : Idealflex elastic	I	1	10284	10 Octobre 2006
1.3	<b>Bandes de crêpe</b> Ex. : Hartmann, Stérilux, Idealcrepe E	I	1	10284	2 Septembre 1998
1.4	<b>Bandes de gaze hydrophile</b> Ex. : Hartmann, Stérilux	I	1	10281	3 Mars 1998
1.5	<b>Bandes extensibles</b> Ex. : Stérilux	I	1	15203	3 Mars 1998
1.7	<b>Boules de coton</b> Ex. : Hartmann	I	1	11028	3 Mars 1998
1.8	<b>Coiffes chirurgicales</b> Ex. : Medinette B rondo, Medinette B astro, Medinette B comfort, Medinette B apart, Medinette B universel	I	1	11901	20 Mai 1998
1.9	<b>Coton hydrophile</b> Ex. : Hartmann, Stérilux	I	1	13981	3 Mars 1998
1.10	<b>Dispositifs d'aide à l'incontinence urinaire masculine</b> Ex. : Molifree étuis péniens Ex. : Molifree poches de recueil d'urine	I I	1 1	10765 14298	19 Juin 1998
1.11	<b>Feuilles de stérilisation</b> Ex. : Sterifeuilles, Sterichamps, Interfoliage, Sterifiltres, SteriGreen	I	1	13735	3 Mars 1998
	Ex. : Sterichamps Duo 1	I	1	13735	3 Mars 2016
1.12	<b>Filets tubulaires</b> Ex. : Stérilux	I	1	10291	3 Mars 1998
1.13	<b>Gants médicaux non stériles</b> Ex. : Digitil S, Digitil V, Digitil N, Ex. : Digitil PF	I	5 turet 1	11882	3 Mars 1998
					4 Octobre 2012
1.14	<b>Gaze sous gaine</b> Ex. : Stérilux	I	1	11859	5 Mars 2004
1.15	<b>Petits instruments</b> Ex. : pince clamp Ex. : rasoir	I	1	11784	20 Mai 1998
		I	1	16580	
1.16	<b>Sachets et gaines pour stérilisation</b> Ex. : Sterilsop SX, Sterilsop SLX, Sterilsop SFT, Poupisop	I	1	13735	3 Mars 1998
1.17	<b>Tenue de bloc</b> Ex. : Foliadress suit Ex. : Foliadress suit Protect	I	1	13526	16 Mars 2006
					1 <sup>er</sup> Mars 2012
1.18	<b>Petits appareillages orthopédiques (ceintures lombaires, genouillères, chevillères...)</b> 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	<b>Sous-vêtements de maintien pour protection absorbante urinaire</b> Ex. : Molipants soft (par 3) Ex. : Molipants Comfort Plus	I	1	12111	<b>30 Août 2010</b> <b>03 Mai 2012</b>
1.20	<b>Echantillons de produits d'incontinence</b> 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	<b>1<sup>er</sup> Janvier 2011</b>
		I	1	16498	<b>1<sup>er</sup> Septembre 2011</b>
		I	1	12111	<b>1<sup>er</sup> Janvier 2011</b>
		I	1	12111	<b>1<sup>er</sup> Mars 2014</b>
		I	1	16498	<b>1<sup>er</sup> Janvier 2011</b>
		I	1	16498	<b>1<sup>er</sup> Janvier 2016</b>
		I	1	16498	<b>1<sup>er</sup> Janvier 2011</b>
		I	1	16498	<b>1<sup>er</sup> Janvier 2016</b>
1.21	<b>Surchaussures</b> Ex. : Valachauss Simple Ex. : Valachauss Reinforced	I	1	13574	<b>1<sup>er</sup> Juin 2013</b>
1.22	<b>Produits d'incontinence</b> Ex. : MoliCare Plus	I	1	12111	<b>30 Janvier 2014</b>

Fait à Châteinois,  
le 19 septembre 2016

  
**Sandrine VERLAINE**  
Pharmacien Responsable

**Bernard GRASS**  
Gérant





## **ANNEXE 2**



PAUL HARTMANN AG  
Paul-Hartmann-Strasse 12  
89522 Heidenheim  
  
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Germany

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hartmann.info



Going further  
for health

Heidenheim, 2016-06-06

## EC-Declaration of Conformity for Medical Devices

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.

PAUL HARTMANN AG

A blue ink signature of Dr. Heinen, consisting of a stylized, cursive script.

Dr. Heinen  
Chief Process Officer

ppa.

A blue ink signature of Dr. Menzl, consisting of a stylized, cursive script.

Dr. Menzl  
Vice President Quality & Regulatory

ILN 040 9500 00000 0

Vorstand/ Management Board: Andreas Joehle  
(Vorstandsvorsitzender/ CEO). Dr. Raymund Heinen.  
Michel Kuehn. Dr. Wolfgang Neumann. 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**

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11.05.2015

**Annex 9.2: Class I Medical Devices of PAUL HARTMANN AG**

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

 ( ) 1<sup>st</sup>, 2<sup>nd</sup> bullet

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
1.06	<b>Conforming bandages</b> e.g. 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	<b>Tubular and elastic net bandages</b> e.g. Stülpa, Stülpa fix, Lastogrip, Coverflex, Covertube tricot	I	1	10-291
1.08	<b>Adhesive tapes and straps</b> e.g. 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) e.g. Taroplast	I	1	10-028  16-769

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Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
1.09	<b>Compression bandages</b> e.g. Idealbinde, Idealflex, Idealast (-haft), Idealhaft, Idealcool, Idealast color cohesive, Lastopress, Lastodur, Lastohaft, Lastocomp, Lastobind, Lastolan, Pütterbinde, Pütter-Bandage, Veno 4, Cosmoplast Sport Bandage, Elasticon, PütterFlex, Pütter-haft, PütterPro 2 e.g. Cover Care-Lymphset	I	1	15-557  10-284
1.10	<b>Zinc paste bandages</b> e.g. Varix, Ideal-Varix, Varolast, Varolast plus	I	1	15-557
1.11	<b>Functional bandages and accessories</b> e.g. Omnitape, Hypolastic, Idealplast e.g. Cathofix compression bandage, Cathofix compressories	I	1	10-288 10-279
1.12	<b>Orthosis and bandages</b> e.g. Rhena abdominal e.g. Rhena achillo e.g. Rhena cervical e.g. Rhena clavícula e.g. Rhena epi e.g. Rhena genu e.g. Rhena gilchrist e.g. Rhena lumbal e.g. Rhena malleo e.g. Rhena manu, Rhena rhizo e.g. Rhena scapulo e.g. Rhena ulna	I	1	10-003 17-873 10-938 12-101 17-910 17-874 12-101 17-909 17-873 17-911 12-101 12-096



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**Annex 9.2: Class I Medical Devices of PAUL HARTMANN AG**

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
1.13	<b>Plaster of paris and rigid plastic bandages plus accessories</b> e.g. Plastrona, Platrix, Safix plus, Safix E, Rhena therm, Rhena cast, Rhena cast splint e.g. Plastrona step e.g. Plastrona step Fixing Strip e.g. Rhena cast boot e.g. Rhena supercut	I	1	10-665  10-672 13-368 10-667 13-481
1.14	<b>Padding and crêpe-paper bandages</b> e.g. Rolta, Rolta soft, Rolta pro, Rolta strong e.g. Crêpe-paper bandages	I	1	11-326  15-557
1.15	<b>Medical stockings and support bandages</b> e.g. Verba, Verba E e.g. Cambren C, VitaSan classic/ fine/ satinell/ chic, Saphenamed ucv and post op	I	1	10-279 13-789
1.16	<b>Incontinence products body-worn and accessories</b> e.g. Molicare-range, NURSA Incontinence slips, MoliBelt, Dignity-range e.g. Moliform-, Molimed-, Molinea-Moliflex-range, Confiance-range, NURSA Incontinence pads, Strampelpeter Insert Pads, Belted Product e.g. Molipants-range, Molimed pants, Confiance slip, NURSA pants	I	1	12-111  16-498  12-111
1.17	<b>Incontinence underpads, not body-worn</b> e.g. Underpads like Molinea, Molinea plus/plus-d, NURSA underpads	I	1	16-498

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**Annex 9.2: Class I Medical Devices of PAUL HARTMANN AG**

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
1.18	<b>Examination gloves Latex</b> e.g. Peha-soft, Peha-soft powderfree, Peha-soft satin powderfree, Digitil PF	I	5 (1 <sup>st</sup> )	11-882
1.19	<b>Examination gloves Non-latex</b> e.g. Peha-soft syntex (powderfree), Peha-soft vinyl (powderfree), Digitil V (powderfree), Peha-soft nitrile, Peha-soft nitrile fino, Peha-soft ni- trile guard, Peha-soft nitrile white, Dermaplast MEDICAL GLOVES	I	5 (1 <sup>st</sup> )	11-882
1.20	<b>OR-clothing</b> e.g. Medimask-range, Folidress mask e.g. Medinette-range, Folidress cap, Folidress comfort (scrub clothing), Folidress gown comfort and pro- tect e.g. Foliadress S	I	1	12-458 11-901  15-037
1.21	<b>Tamponades</b> e.g. Absorbent ribbon gauze	I	5 (2 <sup>nd</sup> )	15-557
1.22	<b>First aid products</b> e.g. Rescue blanket e.g. Triangular cloth e.g. Finger bandages e.g. First aid scissors e.g. Elastic conforming bandage e.g. First aid glove e.g. 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

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**Annex 9.2: Class I Medical Devices of PAUL HARTMANN AG**

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
1.23	<b>Products for patient care and examination</b> e.g. Medical cotton buds e.g. Clips for bandages e.g. Valamask, ValaComfort mask e.g. Tongue depressor e.g. Protective covers for thermometers e.g. Pagavit e.g. Arm cuff (for blood pressure monitor) e.g. Hand pump ball for Tensoval compact	I	1 1 1 5 (1 <sup>st</sup> ) 5 (1 <sup>st</sup> ) 5 (1 <sup>st</sup> ) 1 1	15-066 16-771 15-230 15-249 13-116 16-619 11-073 11-071
1.24	<b>Mains adapter (for blood pressure monitor)</b> e.g. Tensoval main adapter	I	12	16-935
1.25	<b>Medical instruments</b> e.g. Peha-instrument - Eye retractor	I	5 (1.)	13-663



# ANNEXE 3





Product Service

# CERTIFICAT CE

## Système d'assurance qualité en production

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

N° G2S 14 09 31924 016

### Fabricant:

**Laboratoires PAUL HARTMANN Sàrl**

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 Sàrl

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

PAUL HARTMANN S.A.

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

### Catégorie(s) de produit:

**Dispositifs médicaux de classe I stérile comme décrits dans l'annexe jointe:**

**Dispositifs médicaux pour les soins généraux des plaies, produits pour bloc opératoire, bandes et bandages, produits pour le soin des patients, en milieu hospitalier et en cabinet médical ou à 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 présente que le fabricant désigné ci-dessus met en œuvre un système d'assurance qualité pour la fabrication conformément à l'Annexe V, paragraphe 3 de la Directive 93/42/CEE relative aux dispositifs médicaux. Ce système d'assurance qualité couvre les aspects de la fabrication ayant trait à l'obtention et au maintien de la stérilité des produits/catégories de produits concernés et remplit les exigences stipulées par cette Directive. Ce système est soumis à une surveillance régulière. Se rapporter également aux informations mentionnées au verso.

**Rapport n°:**

713048037

**Valide depuis:**

2014-12-01

**Valide jusqu' au:**

2019-11-30

**Date, 2014-11-18**

Hans-Heiner Junker



Conformément à la Directive du Conseil n° 93/42/CEE relative aux dispositifs médicaux, le TÜV SÜD Product Service GmbH est un Organisme Notifié enregistré sous le numéro d'identification 0123.

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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



Heidenheim, 2015-05-11

**EC-Declaration of Conformity for Medical Devices**

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.

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. Fremerey  
Chief Process Officer

ppa.  


Fischer  
Head of Corporate Quality

PAUL HARTMANN AG  
Paul-Hartmann-Strasse 12  
89527 Heidenheim

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89504 Heidenheim

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[www.hartmann.info](http://www.hartmann.info)

Management Board  
Andreas Joehle (CEO)  
Dr. Felix Fremerey  
Michel Kueln  
Dr. Wolfgang Neumann  
Stephan Schulz

Chairman of the Supervisory Board  
Fritz-Jürgen Heckmann

Registered Office Heidenheim  
Commercial Register of the  
District Court of Ulm  
file no. HRB 661090

HARTMANN helps healing.



EC-Declaration of Conformity  
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Annex 9.3: Class I sterile Medical Devices of PAUL HARTMANN AG

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
2.01	<b>First aid products</b> e.g. Standard dressings, Sterilux first aid packet e.g. First aid sheets	I sterile	4 (1 <sup>st</sup> )	15-216 13-561
2.02	<b>Wound dressing pads</b> e.g. 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 e.g. Peha slit dressings	I sterile	4 (1 <sup>st</sup> )	15-216 10-966
2.03	<b>Tamponades</b> e.g. Tampogross e.g. Tamponing bandages	I sterile	5 (2 <sup>nd</sup> )	11-325 15-557
2.04	<b>Swabs</b> e.g. Pur-Zellin, e.g. Gauze swabs	I sterile	4 (1 <sup>st</sup> )	15-252 13-700
2.05	<b>Adhesive dressings</b> e.g. 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, DermaPlast Medical non-woven dressing	I sterile	4 (1 <sup>st</sup> )	10-288
2.06	<b>Bandages</b> e.g. Conforming bandages e.g. Compression bandages e.g. Padding bandages Rolta, Rolta soft e.g. Sterilux cut gauze bandage roll e.g. Sterilux Bulky Gauze Bandage	I sterile	1 4 (1 <sup>st</sup> )	15-557 15-557 11-326 15-557 15-557

( ) 1<sup>st</sup>, 2<sup>nd</sup> bullet



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Annex 9.3: Class I sterile Medical Devices of PAUL HARTMANN AG

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
2.07	<b>Sets for patient care</b> e.g. 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 <sup>st</sup> ) 1, 2, 4 (1 <sup>st</sup> ) or 5 (1 <sup>st</sup> ) 1 or 4 (1 <sup>st</sup> )  1 or 4 (1 <sup>st</sup> )  1 or 4 (1 <sup>st</sup> ) 1, 2 or 4(1 <sup>st</sup> ) 1, 2, 4(1 <sup>st</sup> ) or 5(1 <sup>st</sup> ) 4 (1 <sup>st</sup> ) or 5(1 <sup>st</sup> ) 1, 4 (1 <sup>st</sup> ) or 5(1 <sup>st</sup> ) 1 or 4(1 <sup>st</sup> )  4 (1 <sup>st</sup> ) 1 or 4 (1 <sup>st</sup> ) 1, 2 or 4 (1 <sup>st</sup> ) 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



EC-Declaration of Conformity  
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Annex 9.3: Class I sterile Medical Devices of PAUL HARTMANN AG

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
2.08	<b>Accessories/ instruments for patient care</b> 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. VivanoTec Exudate Canister e.g. Foliodrape Comfort neonatal wrap e.g. Peha-soft nitrile sterile	I sterile	1 or 5(1 <sup>st</sup> ) 4 (1 <sup>st</sup> ) 1 or 5(1 <sup>st</sup> ) 1 5 (1 <sup>st</sup> ) 1 5 (1 <sup>st</sup> ) 1 1 1 1 5 (1 <sup>st</sup> )	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	<b>Examination Gloves Latex</b> e.g. Peha-soft, Peha-soft powderfree	I sterile	5 (1 <sup>st</sup> )	11-882
2.10	<b>Theatre clothing</b> e.g. Foliodress comfort, Foliodress gown comfort, Foliodress protect, Foliodress gown protect e.g. Foliodress S, Foliodress S comfort	I sterile	1	11-901 15-037
2.11	<b>Theatre draping systems</b> e.g. Foliodrape comfort, Foliodrape protect, Foliodrape protect plus e.g. CombiSet	I sterile	1 e.g. 1, 4 or 5	15-646
2.12	<b>Wound care products based on absorbent cotton gauze</b> e.g. Eycopad e.g. Gauze swabs, Cosmoplast Universal gauze swabs, ES-umbilical pads, Econolux, DermaPlast Faltkompressen, Sterilux cut gauze e.g. Sterilux gauze jacket	I sterile	4 (1 <sup>st</sup> ) 1	11-661 10-966 10-281



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Annex 9.3: Class I sterile Medical Devices of PAUL HARTMANN AG

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS	
2.13	<b>Medical instruments</b>	I sterile	1	10-875	
	e.g. Peha-instrument			12-695	
	- Tubing clamp			13-481	
	- Scissors				
	e.g. MediSet, Peha, Sterima				
	- Bandage scissors		1	13-481	
	- Scissors		1	13-480	
					13-502
	- Forceps / clamp		1	11-777	
					15-212
					11-774
	- Dental mirror		5 (1 <sup>st</sup> )	12-547	
	- Curette		4 (1 <sup>st</sup> )	11-084	
	- Disposable forceps, tweezers		1	14-257	
- Stitch cutter	1	15-226			
- Needle holder	1	12-726			
- Staple remover	1	16-787			





# ANNEXE 5





Product Service

# CERTIFICAT CE

**Système Complet d'Assurance de la Qualité**

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

**N° G1 12 10 31924 014**

**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 des 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°:**

713013211

**Valide depuis:**

2012-12-12

**Valide jusqu' au:**

2017-11-30

**Date,** 2012-12-13

Hans-Heiner Junker



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

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Product Service

## CERTIFICAT CE

**Système Complet d'Assurance de la Qualité**

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

**N° G1 12 10 31924 014**

### 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

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Product Service

Annexe au Certificat CE N° G1 12 10 31924 014  
daté 2012-12-13

ZERTIFIKAT ♦ CERTIFICATE ♦ 認 証 証 書 ♦ CERTIFICADO ♦ CERTIFICAT

**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, CRT2, 2012-12-13

Hans-Heiner Junker





# ANNEXE 6







Heidenheim, 2015-05-11

**EC-Declaration of Conformity for Medical Devices**

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.3 has been performed and the technical documentation is kept available.

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. Fremerey  
Chief Process Officer

ppa

Fischer  
Head of Corporate Quality

PAUL HARTMANN AG  
Paul-Hartmann-Strasse 12  
89522 Heidenheim

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Management Board  
Andreas Joehle (CEO)  
Dr. Felix Fremerey  
Michel Kuehn  
Dr. Wolfgang Neumann  
Stephan Schulz

Chairman of the Supervisory Board  
Fritz Jürgen Heckmann

Registered Office Heidenheim  
Commercial Register of the  
District Court of Ulm  
file no. HRB 661090

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## Annex 9.4: 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	<b>Wound management products and dressings</b> e.g. 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 e.g. Pagasling, Pagalong e.g. Medicomp, Medicomp extra e.g. Absorbent cotton gauze e.g. Saline solution (0,9%)	II a	7          4 (3 <sup>rd</sup> )	10-966    13-700 15-216 10-281 12-300
3.02	<b>Special wound closure and covering products</b> e.g. Hydrofilm, Visulin e.g. Hydrofilm plus, Omnistrip, Omnistrip reinforced, Dermoplast Omnistrip, Dermoplast/ Tiritas/ Cosmos/ DermaActive hydrocolloid plaster (e.g. for minor wounds, abrasions, blisters, cold sores and corns), Dermoplast Medical Transparent dressing e.g. Dermoplast/ Tiritas/ Cosmos/ DermaActive burn plaster	II a	4 (3 <sup>rd</sup> )	17-428 10-288      11-322

() 1<sup>st</sup>, 2<sup>nd</sup> bullet



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Annex 9.4: 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		
3.03	Sets for patient care	II a				
	e.g. MediSet, Peha, Sterima					
	- Catheterisation sets				2, 5 (2 <sup>nd</sup> ) 6 or 7	15-564
	- Set for anaesthesia				2, 6 or 7	15-202
	- Wound treatment sets/ wound dressing sets				2, 6 or 7	10-127 11-314
	- Infusion set				2 or 7	12-157
	- Injection set				6 or 7	12-157
	- Set for central-venous catheterisation				2, 6 or 7	16-615
	- Suture set				5 (2 <sup>nd</sup> ), 6 or 7	13-892
	- Dialysis set				2, 6 or 7	15-896
	- Surgical set				2, 5 (2 <sup>nd</sup> ), 6 or 7	12-463 15-896
	- Birth set				7	10-243
	- Arthrography set				6 or 7	15-316
	e.g. Samu-med				5 (2 <sup>nd</sup> )	16-164
	e.g. DermaPlast/ DermaActive wound treatment kits for the treatment of				4 (3 <sup>rd</sup> )	11-314
- abrasions						
- burns						
- cuts						
- blisters						



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Annex 9.4: 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
3.04	<p><b>Surgical wound management products</b></p> <p>e.g. Telatrast surgical absorbents non-sterile: Telatex, Telasorb, Telasling, Telaprep, Telacomp</p> <p>e.g. 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</p> <p>e.g. Telaset sterile</p>	II a	7	10-281 13-705 10-966  10-281 13-705  10-966  15-216 11-314
3.05	<p><b>Surgical gloves Latex</b></p> <p>e.g. 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</p>	II a	7	11-883
3.06	<p><b>Surgical gloves non-Latex</b></p> <p>e.g. Peha-neon plus powderfree, Peha-isoprene plus powderfree, Peha-isoprene LATEXFREE, Peha-neon LATEXFREE, Peha-shield LATEXFREE, Peha-underglove LATEXFREE</p>	II a	7	11-884



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Annex 9.4: Class II a Medical Devices of PAUL HARTMANN AG

Table with 5 columns: Running No., Product Groups/Product Names, Classification in Accordance with Directive 93/42 EEC, Rule, UMDNS. Rows include Customised surgical procedure sets, Electronic clinical thermometers, and Electronic blood pressure monitors.



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**Annex 9.4: 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
3.10	<b>Medical instruments</b> 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	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 <sup>rd</sup> ) 6 6 6 6



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## Annex 9.4: Class II b Medical Devices of PAUL HARTMANN AG

Running No.	Product Groups/Product Names	Classification in Accordance with Directive 93/42 EEC	Rule	UMDNS
4.03	<b>Products for negative pressure wound therapy</b> e.g. VivanoMed - Foam Kit, Foam Round Kit, Foam Thin Kit, - Foam - Silicone Layer - Abdominal Kit	II b	4 (2 <sup>nd</sup> )  8	11-314  11-323 11-325 11-314
4.04	<b>Customised surgical procedure sets</b> e.g. Foliodrape Sets/ Foliodrape CombiSets / CombiSet  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	II b	e.g. 5, 7, 9	15-896