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Groupe HARTMANN

Déclarations de conformité

Certificats de conformité

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Annexe 1 – Classe I non stérile - Laboratoires PAUL HARTMANN Sàrl

Déclaration UE de conformité

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DECLARATION UE DE CONFORMITE CONSOLIDEE POUR DISPOSITIFS MEDICAUX DE CLASSE I NON STERILES

Consolidated EU-Declaration of Conformity for Class I unsterile medical devices

Laboratoires PAUL HARTMANN Sàrl
9 Route de Sélestat - Châtenois
67607 Sélestat Cedex
FRANCE

Châtenois, le 1er juin 2021

Nous déclarons par la présente sous notre seule responsabilité, que les dispositifs médicaux de Classe I listés ci-dessous, mis sur le marché pour la première fois par les Laboratoires PAUL HARTMANN S.à.r.l, satisfont aux obligations applicables, en particulier aux Exigences Générales de Sécurité et de Performances du Règlement (EU) 2017/745 du Parlement Européen et du Conseil Européen du 05 avril 2017 sur les dispositifs médicaux.
We herewith declare under our sole responsibility, that the Class I medical devices listed below, first placed on the market by Laboratoires PAUL HARTMANN S.à.r.l, *satisfy the applicable provisions, in particular the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices*

La procédure d'évaluation de la conformité selon l'Article 52 (7) a été réalisée et la documentation technique est disponible.
The conformity assessment procedure according to Article 52 (7) has been performed and the technical documentation is available.

Single Registration Number: FR-MF-000004029

Sandrine VERLAINE
Pharmacien Responsable

Christophe GEHL
Gérant

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Usage revendiqué ***Intended Purpose***	Vêtements non actifs non implantables à usage unique pour la prévention des infections *Non-active, non-implantable single use clothing for prevention of infection*		
Nom du produit ***Product Name***	**Groupe produit** ***Product Group Number***	**Règle de classification** ***Classification Rule*** **(suivant, *according to* Annex VIII MDR (EU) 2017/745)**	**Basic-UDI-DI**
Foliodress Suit	1266	1	32614812664Q
Foliodress Suit Protect	1271	1	32614812714H

Usage revendiqué ***Intended Purpose***	Dispositifs non actifs non implantables à usage unique pour la stérilisation de dispositifs médicaux *Non-active, non-implantable single use devices for sterilization of medical devices*		
Nom du produit ***Product Name***	**Groupe produit** ***Product Group Number***	**Règle de classification** ***Classification Rule*** **(suivant, *according to* Annex VIII MDR (EU) 2017/745)**	**Basic-UDI-DI**
Sterilsop SX	1958	1	32614819585U

Annexe 2 – Classe I non stérile - PAUL HARTMANN AG

Déclaration UE de conformité

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Consolidated EU Declaration of Conformity for Medical Devices in Class I

Heidenheim, 01. March 2021

We herewith declare under our sole responsibility that the Class I medical devices listed below, first placed on the market by PAUL HARTMANN AG (Registration Number DE/0000007683 [BfArM]), satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (7) have been performed and the Technical Documentation is kept available.

PAUL HARTMANN AG

Dr. Raymund Heinen
CPO

ppa.

Stefan Fischer
Head of Regulatory Affairs

Valid until: 2022-03-01

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Intended Purpose	Non-active, non-implantable clothing for prevention of infection		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic-UDI-DI**
Foliodress cap Comfort	1317	1	40495001317K7
Foliodress cap Universal	1319	1	40495001319KB
Foliodress jacket Comfort blue	3078	1	40495003078KS
Foliodress jacket Comfort green	3341	1	40495003341KJ
Foliodress mask Comfort Anti Fogging	1308	1	40495001308K6
Foliodress mask Comfort Anti Splash	1307	1	40495001307K4
Foliodress mask Comfort Anti Splash Loop	3632	1	40495003632KY
Foliodress mask Comfort Loop	1311	1	40495001311JT
Foliodress mask Comfort Perfect	1306	1	40495001306K2
Foliodress mask Comfort Senso	1304	1	40495001304JW
Foliodress mask Comfort Special	1305	1	40495001305JY
Foliodress mask Protect Perfect	1309	1	40495001309K8
Foliodress mask Protect Senso	1310	1	40495001310JR
Foliodress mask Protect Special	1313	1	40495001313JX
Foliodress S isolation gown impervious non-sterile	3342	1	40495003342KL
Foliodress S isolation gown non-sterile	1263	1	40495001263K9
Foliodress suit Comfort pants blue	3077	1	40495003077KQ
Foliodress suit Comfort pants blue single-packed	3292	1	40495003292KW
Foliodress suit Comfort pants green	3340	1	40495003340KG
Foliodress suit Comfort shirt blue	3076	1	40495003076KN
Foliodress suit Comfort shirt blue single-packed	3291	1	40495003291KU
Foliodress suit Comfort shirt green	3299	1	40495003299LC
Foliodress warming collar	3079	1	40495003079KU
HARTMANN Leggings PE	3444	1	40495003444KV
HARTMANN leggings Protect	3445	1	40495003445KX

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

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Intended Purpose	Non-active, non-implantable device for use in blood pressure monitoring		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic-UDI-DI**
Veroval duo control cuffs	2844	1	40495002844LA

Intended Purpose	Non-active, non-implantable devices for incontinence care, not worn on the body		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic-UDI-DI**
Confiance Alese	3270	1	40495003270KL
Lindor Care Empapador	2957	1	40495002957LQ
Lindor Salvacamas	2957	1	40495002957LQ
MoliCare Bed Mat Eco	3266	1	40495003266KV
MoliCare Premium Bed Mat	3212	1	40495003212K6
MoliCare Premium Bed Mat (SAP)	3267	1	40495003267KX
MoliCare Premium Bed Mat Textile	3313	1	40495003313KD

Intended Purpose	Non-active, non-implantable devices for incontinence care, worn on the body		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic-UDI-DI**
Belted Product	1142	1	40495001142JU
Confiance Confort	3131	1	40495003131K5
Confiance Elastic	3293	1	40495003293KY
Confiance Lady Pad	3123	1	40495003123K6
Confiance Lady Pad	3124	1	40495003124K8
Confiance lady pants	3103	1	40495003103JY
Confiance Men Pad	3125	1	40495003125KA
Confiance Men Pad	3126	1	40495003126KC
Confiance men PANTS	3105	1	40495003105K4
Confiance Mobile	3107	1	40495003107K8

ILN 040 9500 00000 0

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Confiance Rectangular	3272	1	40495003272KQ
Confiance Secure	1021	1	40495001021JF
Lindor Anatomico	3110	1	40495003110JV
Lindor Anatomico Dia 5 dr.	2920	1	40495002920KZ
Lindor Care Anatomico	3111	1	40495003111JX
Lindor Care Slip Day	2912	1	40495002912L2
Lindor Care Slip Night	2913	1	40495002913L4
Lindor Care Slip Supernight	2914	1	40495002914L6
Lindor Fit Pants	3108	1	40495003108KA
Lindor Fit Pants (MCP)	3259	1	40495003259KY
Lindor lady Pads	3574	1	40495003574LB
Lindor LADY Pants	3576	1	40495003576LF
Lindor MEN Pads	3573	1	40495003573L9
Lindor MEN Pants	3575	1	40495003575LD
Lindor Pants	2581	1	40495002581KZ
Lindor Rectangular	3129	1	40495003129KJ
Lindor Slip Day	2909	1	40495002909LD
Lindor Slip Night	2910	1	40495002910KW
Lindor Slip Supernight	2911	1	40495002911KY
MoliCare Comfort	1178	1	40495001178KH
MoliCare Fixpants long leg	3139	1	40495003139KM
MoliCare Fixpants short leg	1018	1	40495001018JS
MoliCare Fixpants short leg	3140	1	40495003140K6
MoliCare Form	3113	1	40495003113K3
MoliCare Pad	3119	1	40495003119KF
MoliCare Pad	3120	1	40495003120JY
MoliCare Pants	3155	1	40495003155KK
MoliCare Premium Elastic	3188	1	40495003188L2
MoliCare Premium Fixpants long leg	3063	1	40495003063KD
MoliCare Premium Fixpants long leg	3137	1	40495003137KH
MoliCare Premium Fixpants short leg	3136	1	40495003136KF
MoliCare Premium Fixpants short leg	3138	1	40495003138KK
MoliCare Premium Form	3112	1	40495003112JZ
MoliCare Premium Form MEN	3057	1	40495003057KJ
MoliCare Premium Lady Pad	3118	1	40495003118KD
MoliCare Premium Lady Pad	3135	1	40495003135KD
MoliCare Premium lady pants	3102	1	40495003102JW
MoliCare Premium Men Pad	3121	1	40495003121K2
MoliCare Premium Men Pad	3122	1	40495003122K4
MoliCare Premium MEN PANTS	3104	1	40495003104K2
MoliCare Premium Mobile	3106	1	40495003106K6
MoliCare Premium Slip	3097	1	40495003097KW
MoliCare Premium Slip BTB	3096	1	40495003096KU
MoliCare Premium Slip maxi	2954	1	40495002954LJ

ILN 040 9500 00000 0

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MoliCare Premium Slip maxi plus	2955	1	40495002955LL
Molicare Premium Soft	3130	1	40495003130K3
MoliCare Rectangular	3265	1	40495003265KT
MoliCare Slip	3098	1	40495003098KY
MoliCare Slip maxi	2975	1	40495002975LS
Secure pants ultra lady	3220	1	40495003220K5
Secure pants ultra men	3221	1	40495003221K7
Secure pull-up pants	3222	1	40495003222K9
Secure slip	3223	1	40495003223KB
Strampelpeter Flockenwindeln	1008	1	40495001008JP

Intended Purpose	Non-active, non-implantable devices for wound and skin care		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic-UDI-DI**
Apoteket (elastisk binda)	3330	1	40495003330KD
Apoteket Mjuk gasbinda	3563	1	40495003563L6
Bande Cohesive	2087	1	40495002087KL
Cosmos Aqua	1535	4 (1)	40495001535KK
Cosmos Classic	1530	4 (1)	40495001530K9
Cosmos Kids	1539	4 (1)	40495001539KT
Cosmos Plast	1542	1	40495001542KG
Cosmos Por	1543	1	40495001543KJ
Cosmos Sensitive/Soft	1532	4 (1)	40495001532KD
Cosmos Soft Silicone	2908	4 (1)	40495002908LB
Cosmos Sport	1533	4 (1)	40495001533KF
Cosmos Textil/Flexible	1531	4 (1)	40495001531KB
Cosmos Water-resistant	1534	4 (1)	40495001534KH
Coverflex fast	2582	1	40495002582L3
DermaPlast ACTIVE Sport Tape; Cosmos ACTIVE Sport Tape	1071	1	40495001071JW
DermaPlast ACTIVE Sportfix	3416	1	40495003416KQ
DermaPlast Aqua	1477	4 (1)	40495001477KW
DermaPlast Classic	1471	4 (1)	40495001471KJ
DermaPlast Cofix	3318	1	40495003318KP
DermaPlast Cofix Color	3317	1	40495003317KM
DermaPlast Comfort	1513	4 (1)	40495001513K9
DermaPlast Kids	1483	4 (1)	40495001483KR
DermaPlast Medical Film Dressings	1669	1	40495001669L9
DermaPlast MEDICAL Fixation tape - breathable and self-adhesive	3548	1	40495003548LA

ILN 040 9500 00000 0

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DermaPlast MEDICAL Fixation tape - waterproof and self-adhesive	3549	1	40495003549LC
DermaPlast Professional Classic	1665	4 (1)	40495001665KZ
DermaPlast Professional Sensitive/Soft	1474	4 (1)	40495001474KQ
DermaPlast Professional Water-resistant/Universal	1481	4 (1)	40495001481KM
Dermaplast Protect Plus	1476	4 (1)	40495001476KU
DermaPlast Sensitive/Soft	1473	4 (1)	40495001473KN
DermaPlast Soft Silicone	2906	4 (1)	40495002906L7
DermaPlast stretch	3316	1	40495003316KK
DermaPlast Textil/Flexible	1472	4 (1)	40495001472KL
Dermaplast Transparent	1482	4 (1)	40495001482KP
DermaPlast Water-resistant	1480	4 (1)	40495001480KK
ES-Kompressen (unsterile)	1007	4 (1)	40495001007JM
Eycopad	1365	4 (1)	40495001365KJ
GipFix Adhesive bandages	1696	1	40495001696LC
Giphar bande extensible	3315	1	40495003315KH
Haco-crepe	1277	1	40495001277KL
Hospicrepe	1901	1	40495001901KN
Hospicrepe Bandage	3320	1	40495003320KA
Hospiform	1196	1	40495001196KK
Hospilite	1278	1	40495001278KN
Hydrofilm roll film dressings	1699	1	40495001699LJ
Idealast	1734	1	40495001734KT
Idealast-haft	1731	1	40495001731KM
Idealast-haft color	3564	1	40495003564L8
Idealbinde	2054	1	40495002054K5
Idealcrepe	1903	1	40495001903KS
Idealflex	1732	1	40495001732KP
Idealflex elastic forte	2062	1	40495002062K4
Idealflex elastic légère	2063	1	40495002063K6
Idealflex Universal	1726	1	40495001726KU
Idealtex	3333	1	40495003333KK
Lastodur light	2060	1	40495002060JY
Lastodur straff/strong	2057	1	40495002057KB
Lastodur weich/soft	2059	1	40495002059KF
Lastopress	2085	1	40495002085KG
Medicomp	1193	4 (1)	40495001193KD
Medicomp extra	2378	4 (1)	40495002378L2
Medicomp non-woven ball (bulk)	3399	4 (1)	40495003399LH
Mullro	1150	4 (1)	40495001150JT
Non-woven swabs slit cut (bulk)	3398	4 (1); 5 (1)	40495003398LF
Omnifilm spool plasters	1693	1	40495001693L6
Omnifix E fixation plasters	2553	1	40495002553KU

ILN 040 9500 00000 0

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Omnifix elastic fixation plasters	1695	1	40495001695LA
Omniplast HOSPITAL spool plasters	1683	1	40495001683L3
Omniplast spool plasters	1681	1	40495001681KX
Omniplast white spool plasters	1682	1	40495001682KZ
Omnipor HOSPITAL spool plasters	1691	1	40495001691L2
Omnipor spool plasters	1688	1	40495001688LD
Omnisilk spool plasters	1686	1	40495001686L9
Omnitape	1668	1	40495001668L7
Opaska Elastyczna Uciskowa	3572	1	40495003572L7
Pagasling (unsterile)	1368	4 (1); 5 (3)	40495001368KQ
Peha-crepp S	1845	1	40495001845L5
Peha-fix	1700	1	40495001700KA
Peha-fix (CPT bulk)	3610	1	40495003610KN
Peha-haft (CPT bulk)	3609	1	40495003609L5
Peha-haft Color latexfree	1275	1	40495001275KG
Peha-haft latexfree	1229	1	40495001229K9
Peha-Lastotel	1864	1	40495001864L9
Peha-Lastotel (CPT bulk)	3611	1	40495003611KQ
Peha-Mullbinden	1846	1	40495001846L7
Peha-soft	1941	5 (1)	40495001941L2
Peha-soft nitrile	1944	5 (1)	40495001944L8
Peha-soft nitrile fino	1024	5 (1)	40495001024JM
Peha-soft nitrile guard	1945	5 (1)	40495001945LA
Peha-soft nitrile white, Peha-soft nitrile white semilong	1032	5 (1)	40495001032JL
Peha-soft syntex powderfree	1942	5 (1)	40495001942L4
Peha-soft Vinyl	1943	5 (1)	40495001943L6
Platrix Plaster	1244	1	40495001244K5
PuetterPro 2	2982	1	40495002982LP
Pur-Zellin	1005	4 (1)	40495001005JH
Pur-Zellin Box	1004	1	40495001004JF
Pütterbinde	2119	1	40495002119K8
Pütterbinde E	1336	1	40495001336KB
PütterFlex	2122	1	40495002122JV
Pütter-haft	1735	1	40495001735KV
Pütter-haft (CPT bulk)	3608	1	40495003608L3
Pütter-Verband	2117	1	40495002117K4
Rhena Color	3329	1	40495003329KU
Rhena Gard	3327	1	40495003327KQ
Rhena Ideal (brown)	3331	1	40495003331KF
Rhena Ideal (white)	3332	1	40495003332KH
Rhena Lastic Forte	3323	1	40495003323KG
Rhena Lastic Medium	3214	1	40495003214KA
Rhena Star/ Rhena Star L	3328	1	40495003328KS

ILN 040 9500 00000 0

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Rhena Varidress	3213	1	40495003213K8
Rolta Soft	1843	1	40495001843KZ
Rolta Soft (CPT bulk)	3606	1	40495003606KX
Safix plus	1245	1	40495001245K7
Safix plus Slabs	1246	1	40495001246K9
Samu	1394	1	40495001394KR
Sterilux bande extensible	3314	1	40495003314KF
Sterilux Crepe Bandage	3319	1	40495003319KR
Sterilux ES gauze swabs (unsterile)	1152	4 (1)	40495001152JX
Stülpa Ready-for-use tubular bandages	1898	1	40495001898LS
Stülpa rolls	1897	1	40495001897LQ
Stülpa-fix	2136	1	40495002136K8
Tensocrepe	3407	1	40495003407KP
Tensocrepe R108	1230	1	40495001230JS
TubeGaze	3326	1	40495003326KN
TwoPress 2	3571	1	40495003571L5
Variants Omnipor spool plasters	1227	1	40495001227K5
Varolast Plus	1800	1	40495001800KF
Verbandmull ZZ	1148	4 (1)	40495001148K8
Zetuvit	1377	1	40495001377KR
Zetuvit (bulk unsterile)	3210	4 (1)	40495003210K2
Zetuvit E	1406	1	40495001406K7
Zetuvit E (bulk unsterile)	3211	4 (1)	40495003211K4

Intended Purpose	Non-active, non-implantable drapes and covers for prevention of infection		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic-UDI-DI**
Eco Drapes adhesive	3604	1	40495003604KT
Eco drapes non-adhesive	3545	1	40495003545L4
HARTMANN Accessories	3228	1	40495003228KM
HARTMANN Accessories Comfort	3461	1	40495003461KV
HARTMANN Adhesive tapes	3225	1	40495003225KF
HARTMANN Arthroscopy drapes Comfort	3457	1	40495003457L6
HARTMANN Arthroscopy drapes Protect	3229	1	40495003229KP
HARTMANN Arthroscopy drapes Protect Plus	3423	1	40495003423KM

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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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HARTMANN Caesarean Section drapes Protect	3230	1	40495003230K8
HARTMANN Caesarean Section drapes Protect Plus	3424	1	40495003424KP
HARTMANN Drapes adhesive Comfort	3458	1	40495003458L8
HARTMANN Drapes adhesive Protect	3231	1	40495003231KA
HARTMANN Drapes adhesive Protect Plus	3238	1	40495003238KQ
HARTMANN Drapes adhesive Protect Plus / PE	3440	1	40495003440KM
HARTMANN Drapes adhesive Protect Plus viscose	3441	1	40495003441KP
HARTMANN Drapes Comfort	3459	1	40495003459LA
HARTMANN Drapes Protect	3241	1	40495003241KD
HARTMANN Drapes Protect Plus / PE	3422	1	40495003422KK
HARTMANN ENT/Maxillofacial Surgery Drapes Comfort	3455	1	40495003455L2
HARTMANN ENT/Maxillofacial Surgery Drapes Protect	3232	1	40495003232KC
HARTMANN ENT/Maxillofacial Surgery Drapes Protect Plus	3237	1	40495003237KN
HARTMANN ENT/Maxillofacial Surgery Drapes SMS	3425	1	40495003425KR
HARTMANN Epidural Drapes adhesive PE	3429	1	40495003429KZ
HARTMANN Epidural Drapes Protect	3244	1	40495003244KK
HARTMANN Extremity Drapes Comfort	3451	1	40495003451KS
HARTMANN Extremity Drapes Protect	3430	1	40495003430KJ
HARTMANN Extremity Drapes Protect Plus	3233	1	40495003233KE
HARTMANN Extremity Drapes Protect Plus extra reinforced	3450	1	40495003450KQ
HARTMANN Fenestrated Drapes adhesive Comfort	3460	1	40495003460KT
HARTMANN Fenestrated Drapes adhesive Protect	3242	1	40495003242KF
HARTMANN Fenestrated Drapes adhesive Protect / PE	3431	1	40495003431KL
HARTMANN Fenestrated Drapes adhesive Protect Plus	3248	1	40495003248KT
HARTMANN Fenestrated Drapes adhesive SMS	3432	1	40495003432KN
HARTMANN Fenestrated Drapes Comfort	3454	1	40495003454KY
HARTMANN Fenestrated Drapes Protect	3243	1	40495003243KH

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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HARTMANN Fenestrated Drapes Protect Plus	3249	1	40495003249KV
HARTMANN General surgery Drapes Protect	3246	1	40495003246KP
HARTMANN Gynecology / Obstetrics Drapes Comfort	3452	1	40495003452KU
HARTMANN Gynecology / Obstetrics Drapes Protect	3247	1	40495003247KR
HARTMANN Gynecology Drapes Protect Plus	3250	1	40495003250KE
HARTMANN Heart / Thorax / Vascular Drape Protect	3426	1	40495003426KT
HARTMANN Heart / Thorax / Vascular Drapes Comfort	3453	1	40495003453KW
HARTMANN Heart / Thorax / Vascular Drapes Protect Plus	3235	1	40495003235KJ
HARTMANN Heart / Thorax / Vascular Drapes Protect Plus viscose PE	3427	1	40495003427KV
HARTMANN Hybrid Drapes Protect	3434	1	40495003434KS
HARTMANN Hybrid Drapes Protect Plus	3435	1	40495003435KU
HARTMANN Instrument table covers Protect	3226	1	40495003226KH
HARTMANN Instruments Table Covers Protect Plus	3240	1	40495003240KB
HARTMANN Laparoscopy Drapes Protect	3251	1	40495003251KG
HARTMANN Ophthalmology Drapes Protect	3252	1	40495003252KJ
HARTMANN Other Drapes adhesive PE	3438	1	40495003438L2
HARTMANN Other equipment Covers PE	3439	1	40495003439L4
HARTMANN Other equipment Covers Protect	3448	1	40495003448L5
HARTMANN Spinal Drapes Protect Plus	3236	1	40495003236KL
HARTMANN Stockinet Protect	3443	1	40495003443KT
HARTMANN Suction bags	3227	1	40495003227KK
HARTMANN Table Covers Comfort	3462	1	40495003462KX
HARTMANN Table Covers Protect Plus	3449	1	40495003449LP
HARTMANN Table Covers reinforced	3239	1	40495003239KS
HARTMANN Turban Drapes Protect	3446	1	40495003446KZ
HARTMANN Turban Drapes Protect / SMS	3447	1	40495003447L3
HARTMANN Universal Split Drapes Comfort	3456	1	40495003456L4

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

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HARTMANN Universal Split Drapes Protect	3245	1	40495003245KM
HARTMANN Universal Split Drapes Protect Plus	3234	1	40495003234KG
HARTMANN Universal Split Drapes Protect Plus extra reinforced	3428	1	40495003428KX
HARTMANN Urology Drapes Protect	3253	1	40495003253KL

Intended Purpose	Non-active, non-implantable single use intruments		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic-UDI-DI**
Hartmann surgical Eye retractor non sterile	3386	1	40495003386L8
Hartmann surgical instrument Tubing clamp non sterile	3378	1	40495003378L9

Intended Purpose	Non-active, non-sterile devices for oral and skin cleansing		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic-UDI-DI**
Wattestäbchen	2093	1	40495002093KF

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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 – Classe I stérile - Laboratoires PAUL HARTMANN Sàrl

3.1 Déclaration UE de conformité pour dispositifs médicaux MDR

Laboratoires PAUL HARTMANN
Châtenois
67607 SELESTAT CEDEX
France

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www.hartmann.fr

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DECLARATION UE DE CONFORMITE POUR DISPOSITIFS MEDICAUX DE CLASSE I STERILE
EU-Declaration of Conformity MDR for Class I sterile

Laboratoires PAUL HARTMANN Sàrl
9 Route de Sélestat - Châtenois
67607 Sélestat Cedex
FRANCE

Châtenois, le 22 juin 2021

Nous déclarons par la présente, *We herewith declare*,

Objet de la déclaration, *Object of declaration*: Compresses de gaze stériles 17-fils, *Sterile gauze swabs 17-threads* (1082 : Stérilux ES, 1203 : Compresses de gaze stériles Giphar)

qui a été placé pour la première fois sur le marché par les Laboratoires PAUL HARTMANN S.à.r.l, satisfait aux obligations applicables, en particulier aux Exigences Générales de Sécurité et de Performances du Règlement (EU) 2017/745 du Parlement Européen et du Conseil Européen du 05 avril 2017 sur les dispositifs médicaux.
which was first placed on the market by Laboratoires PAUL HARTMANN S.à.r.l, meets the applicable provisions, in particular the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

La procédure d'évaluation de la conformité selon l'Article 52 (7) et l'annexe XI partie A concernant la stérilité a été réalisée et la Documentation Technique est disponible.
The Conformity Assessment Procedure according to Article 52 (7) and Annex XI part A about the sterility has been performed and the Technical Documentation is kept available.

Cette déclaration UE de conformité est délivrée sous la seule responsabilité des Laboratoires PAUL HARTMANN S.à.r.l.
This EU-Declaration of Conformity is issued under the sole responsibility of the Laboratoires PAUL HARTMANN S.à.r.l.

La procédure d'évaluation de la conformité est sous la surveillance de l'Organisme Notifié :
The conformity assessment procedure is under the supervision of the Notified Body:
TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany, n° ID: 0123.

Le produit a été identifié comme un dispositif médical de Classe I selon la Règle 4 tiret 1 conformément à l'Annexe VIII du Règlement (EU) 2017/745.
The product has been identified as a medical device in risk class I according to Rule 4 dash 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 32614810824C (1082), 32614812033Y (1203)
Single Registration Number: FR-MF-000004029
EU Quality Management System Certificate (MDR): G21 031924 0022

Sandrine VERLAINE
Pharmacien Responsable

Christophe GEHL
Gérant

Annexe 3 – Classe I stérile - Laboratoires PAUL HARTMANN Sàrl

3.2 Certificat CE MDR

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 031924 0022 Rev. 00

Manufacturer:

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

SRN Manufacturer: FR-MF-000004029

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21 031924 0022 Rev. 00

Report No.: 713183563

Valid from: 2021-06-18
Valid until: 2026-03-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-06-18

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 031924 0022 Rev. 00

Classification:	I
Device Group:	M020199 - COTTON GAUZES - OTHERS
Device Properties:	MDS 1005.3 - Sterilization by moist heat

The validity of this certificate depends on conditions and/or is limited to the following: ./.

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Annexe 4 – Sets de soins stériles - Laboratoires PAUL HARTMANN Sàrl

4.1 Déclaration de producteur systèmes et nécessaires règlement (UE) 2017/745 MDR

Laboratoires PAUL HARTMANN
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67607 SELESTAT CEDEX
France

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www.hartmann.fr

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DECLARATION DE PRODUCTEUR SYSTEMES ET NECESSAIRES REGLEMENT (UE) 2017/745 (MDR)
STATEMENT OF SYSTEM/PROCEDURE PACK PRODUCER REGULATION (UE) 2017/745 (MDR)

Laboratoires PAUL HARTMANN Sàrl
9 Route de Sélestat – Châtenois - 67607 Sélestat Cedex – France

Châtenois, le / *on* 22/06/2021

Objet de la déclaration : Gamme MediSet® / *Object of declaration: MediSet® range*

Nous déclarons par la présente que pour les produits listés ci-après / *We herewith declare that for the products listed below*

- Nous avons vérifié la compatibilité mutuelle des dispositifs médicaux et, si applicable, des autres produits, en accord avec les instructions de leur fabricant et avons réalisé nos activités en suivant ces instructions / *We have verified the mutual compatibility of the medical devices and, if applicable other products, in accordance with their manufacturers' instructions and have carried out our activities in accordance with their instructions*
- Nous avons effectué l'emballage du système ou nécessaire et fourni aux utilisateurs les informations pertinentes incluant les informations fournies par les fabricants des dispositifs médicaux ou autres produits qui sont assemblés / *We package the system or procedure pack and supply relevant information to users incorporating the information supplied by the manufacturers of the medical devices or other products that are put together*
- L'activité d'assemblage de dispositifs médicaux et, si applicable, d'autres produits, est soumise à des méthodes appropriées de contrôle interne, de vérification et de validation / *The activity of combining medical devices and, if applicable, other products, is subject to appropriate methods of internal monitoring, verification and validation*

La stérilisation, lorsqu'elle est applicable, est réalisée en conformité avec les instructions des fabricants. Le process de stérilisation est sous la surveillance de l'Organisme Notifié / *Sterilization, if applicable, is carried out in accordance with the manufacturer's instructions. The sterilization process is under the supervision of the Notified Body:*
TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany, n° d'identification / identification N° 0123.

Numéro d'enregistrement unique / *Single Registration Number* (SRN): FR-PR-000004030
EU Quality Management System Certificate (MDR): No. G24 031924 0023

Produits / *Products*

No.	Produit / *Product*	UMDNS	GMDN	IUD de base / Basic UDI	MDS
1	MediSet® Injection / perfusion / *Injection / infusion*	12-157 16-615	58977	32614834975T	1005 (EO)
2	MediSet® Soins des plaies / *Wound care*	11-314	62744	32614835054Z	1005 (EO)
3	MediSet® Sondage urinaire / *Urinary catheterization*	15-564	61355	32614835044X	1005 (EO)

Sandrine VERLAINE
Pharmacien Responsable

Christophe GEHL
Gérant

Annexe 4 – Sets de soins stériles - Laboratoires PAUL HARTMANN Sàrl

4.2 Certificat CE MDR

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Systems and Procedure Packs sterilised in accordance with the manufacturer's instructions, Article 22(3))

No. G24 031924 0023 Rev. 00

Manufacturer:

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

SRN Manufacturer: FR-PR-000004030

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.
The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G24 031924 0023 Rev. 00

Report No.: 713183563

Valid from: 2021-06-18
Valid until: 2026-03-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-06-18

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Systems and Procedure Packs sterilised in accordance with the manufacturer's instructions, Article 22(3))

No. G24 031924 0023 Rev. 00

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	32614834975T
Intended Purpose:	The injection/infusion sets are designed to realize an infusion or an injection by an access way (venous, central, subcutaneous)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	32614835044X
Intended Purpose:	The urinary catheterization sets are designed to perform an urinary catheterization: - insertion of urethral catheter (not included) into the urinary bladder for drainage of urine - urinary catheter removal
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	32614835054Z
Intended Purpose:	The wound care sets are designed to perform a care allowing the healing of a wound including the cleaning or the various steps of a wound care: - old dressing removal - wound cleaning - new dressing
The validity of this certificate depends on conditions and/or is limited to the following:	./.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Annexe 5 – Classe I stérile – PAUL HARTMANN AG

5.1 Déclaration UE de conformité pour dispositifs médicaux MDR

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Consolidated EU Declaration of Conformity for Medical Devices in Class Is

Heidenheim, 01. March 2021

We herewith declare under our sole responsibility that the Class I sterile medical devices listed below, first placed on the market by PAUL HARTMANN AG (Registration Number DE/0000007683 [BfArM]), satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (7) and Annex XI part A with respect to sterility have 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, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G21 011858 0069.

PAUL HARTMANN AG

Dr. Raymund Heinen
CPO

ppa.

Stefan Fischer
Head of Regulatory Affairs

Valid until: 2022-03-01

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
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Class I sterile medical devices in conjunction with the EU Quality Management System Certificate (MDR) No. G21 011858 0069

Device Group	MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care
Device Properties	MDS 1005.2 – Sterilisation by irradiation
Intended Purpose	Non-active, non-implantable devices for anaesthesia, emergency and intensive care

Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic-UDI-DI
Peha-soft nitrile	1946	5 (1)	40495001032JL

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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 5 – Classe I stérile – PAUL HARTMANN AG

5.2 Certificat CE MDR

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 011858 0069 Rev. 00

Manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21 011858 0069 Rev. 00

Report No.: 713191741

Valid from: 2020-11-30
Valid until: 2025-11-29

Issue date: 2020-11-30

Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 011858 0069 Rev. 00

Classification:	I
Device Group:	MDN 1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care
Device Properties:	MDS 1005.2 - Sterilisation by irradiation
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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Annexe 6 – Classe IIb – PAUL HARTMANN AG

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 011858 0065 Rev. 01

Manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 011858 0065 Rev. 01

Report No.:	713162860
Preceding Certificate No.:	G10 011858 0065 Rev. 00
Valid from:	2020-12-17
Valid until:	2025-05-05
Date of Initial Issuance:	2020-05-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-12-17

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 011858 0065 Rev. 01

Classification:	IIb
Device Group:	M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHERS
Intended Purpose:	Single-use, sterile, non-medicated dressings suitable for the treatment of wounds
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report
00	2020-05-06	713162860

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Annexe 7 – Classe I stérile & Assemblage – PAUL HARTMANN AG

7.1 Déclaration CE de conformité pour dispositifs médicaux MDD

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Going further for health

EC-Declaration of Conformity for Medical Devices Class I sterile

Heidenheim, 25. February 2021

We herewith declare,

that the medical devices, listed in the appendix, which are first placed on the market by PAUL HARTMANN AG, are classified as class I sterile and meet the applicable provisions, especially the Essential Requirements of the Council Directive 93/42/EEC of 14th June 1993.

The conformity assessment procedure according to Annex VII in connection with Annex V of the Council Directive 93/42/EEC has been performed and the technical documentation is kept available.

This EC Declaration of Conformity is issued under the sole responsibility of PAUL HARTMANN AG and is valid until 25th May 2024.

The sterilization processes are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany, Identification No. 0123.

PAUL HARTMANN AG

ppa.

Dr. Raymund Heinen
CPO

Stefan Fischer
Head of Regulatory Affairs

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

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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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	DermaPlast Medical non-woven dressing	I sterile	4 (1st)	10-288
	Dermaplast MEDICAL (Light bleeding wounds; breathable, sterile wound dressing)	I sterile	4 (1st)	10-288
	Cosmopor Entry	I sterile	4 (1st)	10-288
	Pansement absorbant adhesif	I sterile	4 (1st)	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 (1st)	15-557
	Padding bandages	I sterile	1	11-326
	Rolta	I sterile	1	11-326
2.07	**Sets for patient care**			
	MediSet			
	Dental-Set	I sterile	5 (1st)	15-896 11-160
	Dialysis-Set	I sterile I sterile	1 4 (1st)	15-896 16-615
	Wound treatment/ dressing set	I sterile I sterile	1 4 (1st)	11-314 11-314
	Injection set	I sterile I sterile I sterile I sterile	1 4 (1st) 4 (1st) 4 (1st)	12-161 15-252 15-896 12-161
	Baby care set	I sterile I sterile	1 4 (1st)	10-243 10-243
	Anesthesia set	I sterile I sterile I sterile I sterile	1 4 (1st) 5 (1st)	15-202 15-202 10-127 15-664
	Catheterisation sets	I sterile I sterile	1 4 (1st)	15-564 15-564
	Suture removal set	I sterile I sterile	1 4 (1st)	15-896 15-896
	Maternity set	I sterile I sterile	1 1	10-243 12-463
	Pose set for peripheral catheterisation	I sterile	4 (1st)	12-161
	Suture set	I sterile	4 (1st)	13-892
	Surgical preparation kit	I sterile I sterile I sterile	1 1 4 (1st)	15-896 13-097 13-097

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

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

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

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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	Tongue depressor	I sterile	5 (1st)	15-249
	Aqua dest. syringe	I sterile	1	13-936
	Tongue depressor	I sterile	5 (1st)	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 (1st)	11-882
2.09	**Examination Gloves Latex**			
	Peha-soft	I sterile	5 (1st)	11-882
	Peha-soft powderfree	I sterile	5 (1st)	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 (1st)	11-661
	Stérilux Compresses ophtalmiques (Stérilux eye pads)	I sterile	4 (1st)	11-661
	Gauze swabs	I sterile	4 (1st)	10-966
	Cosmoplast Universal gauze swabs	I sterile	4 (1st)	10-966
	ES-umbilical pads	I sterile	4 (1st)	10-966
	Econolux	I sterile	4 (1st)	10-966
	DermaPlast Faltkompressen	I sterile	4 (1st)	10-966
	Sterilux cut gauze	I sterile	4 (1st)	10-966
	Dermaplast MEDICAL (Gauze Swab)	I sterile	1	10-281
2.13	**Medical instruments**			
	Peha-instrument			
	Tubing clamp	I sterile	1	10-875

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

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	Scissors	I sterile	1 1	12-695 13-481
	MediSet			
	Scissors	I sterile	1 1 1	13-480 13-502 13-481
	Forceps / clamp	I sterile	1 1 1	11-774 11-777 14-257
	Dental mirror	I sterile	5 (1st)	12-547
	Needle holder	I sterile	1	12-726
	Staple remover	I sterile	1	16-787
	Dental explorer	I sterile	5 (1st)	16-482
	Peha			
	Scissors	I sterile	1 1 1	13-480 13-502 13-481
	Forceps / clamp	I sterile	1 1 1	11-774 11-777 14-257
	Dental mirror	I sterile	5 (1st)	12-547
	Needle holder	I sterile	1	12-726
	Staple remover	I sterile	1	16-787
	Dental explorer	I sterile	5 (1st)	16-482
	Sterima			
	Scissors	I sterile	1 1 1	13-480 13-502 13-481
	Forceps / clamp	I sterile	1 1 1	11-774 11-777 14-257
	Dental mirror	I sterile	5 (1st)	12-547
	Needle holder	I sterile	1	12-726
	Staple remover	I sterile	1	16-787

Annexe 7 – Classe I stérile & Assemblage – PAUL HARTMANN AG

7.2 Déclaration Article 12

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Going further for health

Declaration for systems and procedure packs and procedure for sterilisation

Heidenheim, 2019-09-25

According to § 10 (1) of the German Medical Device Law in connection with article 12 (2) and 12 (3) of EU-Directive 93/42/EEC (MDD),

we herewith declare, that for the products listed in the attachment below:

We have verified the mutual compatibility of the devices in accordance with their manufacturers' instructions and have carried out his operations in accordance with these instructions;

We package the system or procedure pack and supply relevant information to users incorporating relevant instructions from the manufacturers; and

The whole activity is subjected to appropriate methods of internal control and inspection.

Sterilisation, if applicable, is carried out in accordance with the manufacturer's instructions. The sterilization process is under the supervision of the Notified Body:
TÜV Süd Product Service, Identification No. 0123

PAUL HARTMANN AG

ppa.

Christian Sievert
Head of Business Division

ppa.

Stefan Fischer
Head of Regulatory Affairs

This document is valid until: 2023-09-30.

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Going further for health

Declaration for systems and procedure packs and procedure for sterilisation

Heidenheim, 2019-09-25

No.	Product Groups/Product Names	UMDNS
1.	CombiSet	15-896
2.	MediSet Catheterization sets Peha Catheterization sets Sterima Catheterization sets	15-564
3.	MediSet Umbilical cord sets Peha Umbilical cord sets Sterima Umbilical cord sets	10-243
4.	MediSet Birth sets Peha Birth sets Sterima Birth sets	12-463
5.	MediSet Dialysis sets Peha Dialysis sets Sterima Dialysis sets	15-896
6.	MediSet Catheterization sets Sterima Catheterization sets	16-615
7.	MediSet Catheterization sets Sterima Catheterization sets	12-157
8.	MediSet Mouth care sets	15-896
9.	MediSet Gynaecological washing sets	12-463
10.	MediSet Antisepsis and skin preparation set	13-097
11.	MediSet Disinfection set	13-097
12.	MediSet Wound dressing set	11-314
13.	MediSet Suture set	13-892
14.	MediSet Treatment of intact and injured skin and mucous membranes	15-896
15.	MediSet Anaesthesia	15-202

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

Annexe 7 – Classe I stérile & Assemblage – PAUL HARTMANN AG

7.3 Certificat CE MDD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 011858 0063 Rev. 00

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)
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.: 713156403_2

Valid from: 2019-12-09
Valid until: 2024-05-26

Date, 2019-12-09

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 011858 0063 Rev. 00

Facility(ies):

PAUL HARTMANN AG
Paul-Hartmann-Str. 12, 89522 Heidenheim, GERMANY

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

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

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Product Names to Attachment for Certificate No.
G2S 011858 0063 Rev. 00, dated 2019-12-09

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class I sterile medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
2.01	**First aid products** e. g. Standard dressings, first aid sheets, Sterilux first aid packet	I sterile	4 (1st 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 (1st bullet)
2.03	**Tamponades** e. g. Tampograss, tamponing bandages	I sterile	5 (2nd bullet)
2.04	**Swabs** e. g. Pur-Zellin, gauze swabs	I sterile	4 (1st 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), Cosmopor Entry	I sterile	4 (1st 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 (1st bullet)

Product Service

Product Names to Attachment for Certificate No.
G2S 011858 0063 Rev. 00, dated 2019-12-09

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class I sterile medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
2.07	**Sets for patient care** 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	I sterile	1 / 2 / 4 (1st bullet) / 5 (1st bullet)
2.08	**Accessories / instruments for patient care** 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	I sterile	1 / 4 (1st bullet) / 5 (1st bullet)

Product Service

Product Names to Attachment for Certificate No.
G2S 011858 0063 Rev. 00, dated 2019-12-09

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class I sterile medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
2.09	**Examination gloves latex** e. g. Peha-soft, Peha-soft powderfree	I sterile	5 (1st 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
	e. g. CombiSet		e.g. 1 / 4 / 5
2.12	**Wound care products based on absorbent cotton gauze** e. g. Eycopad, Gauze swabs, Cosmoplast Universal gauze swabs, ES-umbilical pads, Econolux, DermaPlast Faltkompressen, Sterilux cut gauze Sterilux gauze jacket, Dermaplast MEDICAL (Gauze Swab), Stérilux eye pads	I sterile	1/ 4 (1st bullet)
2.13	**Medical instruments** 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	I sterile	1 / 4 (1st bullet) / 5 (1st bullet)

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Product Names to Attachment for Certificate No.
G2S 011858 0063 Rev. 00, dated 2019-12-09

- 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
Rev. 01-2020, project no. 713156403_2 + 713162860

Hamburg, 2020-01-24

Hendrik Schorler
AP5 - Department Manager

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Inspire trust.

To whom it may concern

Munich, 2021-02-02
Order No.: 713206847_3

Confirmation concerning Certificates G1 011858 0064 Rev. 00, G2S 011858 0063 Rev. 00 and related devices

We confirm the following certificates:

G1 011858 0064 Rev. 00 (valid until 2024-05-26)
G2S 011858 0063 Rev. 00 (valid until 2024-05-26)

issued to the legal medical device manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

cover the Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) with the scope (G1 011858 0064 Rev. 00):

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)

and the following devices:

Product name	Product group
HydroTac Border Multisite	4.02 Hydroactive dressings and accessories
Zetuvit Plus Silicone Border	4.02 Hydroactive dressings and accessories
RespoSorb Silicone Border	4.02 Hydroactive dressings and accessories

Product Service

and cover the Directive 93/42/EEC on Medical Devices Annex V with the scope (G2S 011858 0063 Rev. 00):

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

and the following device

Product name	Product group
Cosmopor I.V. transparent	2.05 Adhesive dressings

Further we confirm an implemented quality assurance system for manufacture of devices in class I in sterile conditions, sterilized systems or procedure packs listed in the scope of the above-mentioned EC-Certificate (G2S 011858 0063 Rev. 00) and its attachments.

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificate is valid.

R. Köhler

i.A. Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH
Medical Health Services
Foreign Affairs

Product Service

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Add value.
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To whom it may concern

Munich, 2021-01-26
Order No.: 713206847_2

Confirmation concerning Certificate G2S 011858 0063 Rev. 00 and related device

We confirm the following certificate:

G2S 011858 0063 Rev. 00 (valid until 2024-05-26)

issued to the legal medical device manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

covers the Directive 93/42/EEC on Medical Devices Annex V with the scope:
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)
Systems and procedure packs according to Article 12 of Directive 93/42/EEC

and the following device

Product name	Product group
Cosmopor I.V. transparent	2.05 Adhesive dressings

Further we confirm an implemented quality assurance system for manufacture of devices in class I in sterile conditions, sterilized systems or procedure packs listed in the scope of the above-mentioned EC-Certificate and its attachments.

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.
The above-mentioned certificate is valid.

R. Köhler

i.A. Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH
Medical Health Services
Foreign Affairs

Annexe 8 – Classes IIa et IIb – PAUL HARTMANN AG

8.1 Déclaration CE de conformité pour dispositifs médicaux MDD

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EC-Declaration of Conformity for Medical Devices Class IIa, IIb and III

Heidenheim, 25. February 2021

We herewith declare,

that the medical devices, listed in the appendix, which are first placed on the market by PAUL HARTMANN AG, are classified as class IIa, IIb and III and meet the applicable provisions, especially the Essential Requirements of the Council Directive 93/42/EEC of 14th June 1993.

The conformity assessment procedure for the IIa and IIb products according to Annex II excluding 4 of the Council Directive 93/42/EEC has been performed and the technical documentation is kept available. For the class III products the required conformity assessment procedure according to Council Directive 93/42/EEC Annex II including Section 4 has been performed and the technical documentation is kept available.

This EC Declaration of Conformity is issued under the sole responsibility of PAUL HARTMANN AG and is valid until 25th May 2024.

The conformity assessment procedure is under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany, Identification No. 0123.

PAUL HARTMANN AG

ppa.

Dr. Raymund Heinen
CPO

Stefan Fischer
Head of Regulatory Affairs

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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	IIa	7	10-966
	Sterilux ES	IIa	7	10-966
	Sterilux gauze swabs	IIa	7	10-966
	Standard gauze swabs	IIa	7	10-966
	Mulpa swabs	IIa	7	10-966
	Sterilux gauze sponges (USP)	IIa	7	10-966
	Lusan gauze swabs	IIa	7	10-966
	Sterilux gauze swabs on a roll	IIa	7	10-966
	Pagasling	IIa	7	13-700
	Pagalong	IIa	7	13-700
	Medicomp	IIa	7	15-216
	Medicomp extra	IIa	7	15-216
	Absorbent cotton gauze	IIa	7	10-281
3.02	**Special wound closure and covering products**			
	Hydrofilm	IIa	4 (3rd)	17-428
	Hydrofilm non-sterile for Kit Packagers	IIa	4 (3rd)	17-428
	Visulin	IIa	4 (3rd)	17-428
	Hydrofilm plus	IIa	4 (3rd)	10-288
	Tiritas MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing)	IIa	4 (3rd)	10-288
	Omnistrip	IIa	4 (3rd)	10-288
	Omnistrip reinforced	IIa	4 (3rd)	10-288
	Dermaplast Omnistrip	IIa	4 (3rd)	10-288
	Dermaplast MEDICAL (Wound closure strips, sterile)	IIa	4 (3rd)	10-288
	Dermaplast hydrocolloid plaster for:			
	minor wounds	IIa	4 (3rd)	10-288
	abrasions	IIa	4 (3rd)	10-288
	Blisters	IIa	4 (3rd)	10-288
	cold sores	IIa	4 (3rd)	10-288
	corns	IIa	4 (3rd)	10-288
	Tiritas hydrocolloid plaster for:			
	minor wounds	IIa	4 (3rd)	10-288

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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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	abrasions	IIa	4 (3rd)	10-288
	Blisters	IIa	4 (3rd)	10-288
	cold sores	IIa	4 (3rd)	10-288
	corns	IIa	4 (3rd)	10-288
	Cosmos hydrocolloid plaster for:			
	minor wounds	IIa	4 (3rd)	10-288
	abrasions	IIa	4 (3rd)	10-288
	Blisters	IIa	4 (3rd)	10-288
	cold sores	IIa	4 (3rd)	10-288
	corns	IIa	4 (3rd)	10-288
	DermaActive hydrocolloid plaster for:			
	minor wounds	IIa	4 (3rd)	10-288
	abrasions	IIa	4 (3rd)	10-288
	Blisters	IIa	4 (3rd)	10-288
	cold sores	IIa	4 (3rd)	10-288
	corns	IIa	4 (3rd)	10-288
	DermaPlast EFFECT Abrasion	IIa	4 (3rd)	10-288
	Dermaplast Medical Transparent dressing	IIa	4 (3rd)	10-288
	Dermaplast MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing)	IIa	4 (3rd)	10-288
	Dermaplast MEDICAL (Cuts and lacerations)	IIa	4 (3rd)	10-288
	DermaPlast EFFECT To cut blisters & minor wounds	IIa	4 (3rd)	10-288
	DermaPlast EFFECT blister large	IIa	4 (3rd)	10-288
	DermaPlast EFFECT blister heel	IIa	4 (3rd)	10-288
	DermaPlast EFFECT blister small	IIa	4 (3rd)	10-288
	DermaPlast EFFECT corns	IIa	4 (3rd)	10-288
	DermaPlast EFFECT minor wounds	IIa	4 (3rd)	10-288
	DermaPlast EFFECT cold sores	IIa	4 (3rd)	10-288
	Dermaplast burn plaster	IIa	4 (3rd)	10-288
	Tiritas burn plaster	IIa	4 (3rd)	11-322
	Cosmos burn plaster	IIa	4 (3rd)	11-322
	DermaActive burn plaster	IIa	4 (3rd)	11-322
	Dermaplast MEDICAL (Burns)	IIa	4 (3rd)	11-322
	Tiritas MEDICAL (Burns)	IIa	4 (3rd)	11-322
	DermaPlast EFFECT Burns	IIa	4 (3rd)	11-322
3.03	**Sets for patient care**			

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MediSet				
	Catheterisation sets	IIa	2	15-564
			5 (2nd)	15-564
			6	15-564
			7	15-564
	Set for anaesthesia	IIa	2	15-202
			6	15-202
			7	15-202
	Set for anaesthesia	IIa	2	10-127
			6	10-127
			7	10-127
	Wound treatment sets/wound dressing sets	IIa	2	11-314
			6	11-314
			7	11-314
	Infusion set	IIa	2	12-157
			7	12-157
	Injection set	IIa	6	12-157
			7	12-157
	Set for central-venous catheterisation	IIa	2	16-615
			6	16-615
			7	16-615
	Suture set	IIa	5 (2nd)	13-892
			6	13-892
			7	13-892
	Dialysis set	IIa	2	15-896
			6	15-896
			7	15-896
	Surgical set	IIa	2	12-463
			5 (2nd)	12-463
			6	12-463
			7	12-463
	Surgical set	IIa	2	15-896
			5 (2nd)	15-896
			6	15-896
			7	15-896
	Birth set	IIa	7	10-243
	Arthrography set	IIa	6	15-316
			7	15-316
Peha				
	Catheterisation sets	IIa	2	15-564
			5 (2nd)	15-564
			6	15-564
			7	15-564
	Set for anaesthesia	IIa	2	15-202
			6	15-202
			7	15-202
	Set for anaesthesia	IIa	2	10-127
			6	10-127

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			7	10-127
	Wound treatment sets/wound dressing sets	IIa	2	11-314
			6	11-314
			7	11-314
	Infusion set	IIa	2	12-157
			7	12-157
	Injection set	IIa	6	12-157
			7	12-157
	Set for central-venous catheterisation	IIa	2	16-615
			6	16-615
			7	16-615
	Suture set	IIa	5 (2nd)	13-892
			6	13-892
			7	13-892
	Dialysis set	IIa	2	15-896
			6	15-896
			7	15-896
	Surgical set	IIa	2	12-463
			5 (2nd)	12-463
			6	12-463
			7	12-463
	Surgical set	IIa	2	15-896
			5 (2nd)	15-896
			6	15-896
			7	15-896
	Birth set	IIa	7	10-243
	Arthrography set	IIa	6	15-316
			7	15-316
Sterima				
	Catheterisation sets	IIa	2	15-564
			5 (2nd)	15-564
			6	15-564
			7	15-564
	Set for anaesthesia	IIa	2	15-202
			6	15-202
			7	15-202
	Set for anaesthesia	IIa	2	10-127
			6	10-127
			7	10-127
	Wound treatment sets/wound dressing sets	IIa	2	11-314
			6	11-314
			7	11-314
	Infusion set	IIa	2	12-157
			7	12-157
	Injection set	IIa	6	12-157
			7	12-157
	Set for central-venous catheterisation	IIa	2	16-615
			6	16-615

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			7	16-615
	Suture set	IIa	5 (2nd)	13-892
			6	13-892
			7	13-892
	Dialysis set	IIa	2	15-896
			6	15-896
			7	15-896
	Surgical set	IIa	2	12-463
			5 (2nd)	12-463
			6	12-463
			7	12-463
	Surgical set	IIa	2	15-896
			5 (2nd)	15-896
			6	15-896
			7	15-896
	Birth set	IIa	7	10-243
	Arthrography set	IIa	6	15-316
			7	15-316
	Samu-med	IIa	5 (2nd)	16-164
	DermaPlast wound treatment kits for the treatment of:			
	abrasions	IIa	4 (3rd)	11-314
	burns	IIa	4 (3rd)	11-314
	cuts	IIa	4 (3rd)	11-314
	blisters	IIa	4 (3rd)	11-314
	DermaActive wound treatment kits for the treatment of:			
	abrasions	IIa	4 (3rd)	11-314
	burns	IIa	4 (3rd)	11-314
	cuts	IIa	4 (3rd)	11-314
	blisters	IIa	4 (3rd)	11-314
3.04	**Surgical wound management products**			
	Telatrast surgical absorbents non-sterile:			
	Telasorb	IIa	7	10-281
	Telasling	IIa	7	13-705
	Telaprep	IIa	7	13-705
	Telacomp	IIa	7	10-966
	Telatrast-module-system sterile:			
	Telasorb	IIa	7	10-281
	Telasorb E	IIa	7	10-281
	Telasling	IIa	7	13-705
	Telaprep	IIa	7	13-705

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	Telacomp	IIa	7	10-966
	Telacomp E	IIa	7	10-966
	Sterilux X-ray Gauze Sponges (USP)	IIa	7	10-966
	Telaset sterile	IIa	7	11-314
3.05	**Surgical gloves Latex**			
	Peha-taft	IIa	7	11-883
	Peha-taft classic (powderfree)	IIa	7	11-883
	Peha-micron plus powderfree	IIa	7	11-883
	Peha-taft plus powderfree	IIa	7	11-883
	Peha-profile plus powderfree	IIa	7	11-883
	Peha-basic LATEX	IIa	7	11-883
	Peha-micron LATEX	IIa	7	11-883
	Peha-profile LATEX	IIa	7	11-883
	Peha-taft classic POWDERED	IIa	7	11-883
	Peha-taft classic POWDERFREE	IIa	7	11-883
	Peha-taft LATEX	IIa	7	11-883
	Peha-underglove LATEX	IIa	7	11-883
3.06	**Surgical gloves non-Latex**			
	Peha-neon plus powderfree	IIa	7	11-884
	Peha-isoprene plus powderfree	IIa	7	11-884
	Peha-isoprene LATEXFREE	IIa	7	11-884
	Peha-neon LATEXFREE	IIa	7	11-884
	Peha-shield LATEXFREE	IIa	7	11-884
	Peha-underglove LATEXFREE	IIa	7	11-884
3.07	**Customised surgical procedure sets**			
	Foliodrape Sets/Foliodrape for indication-related procedures: General surgery ophthalmology gynaecology obstetrics cardiosurgery chest surgery vascular surgery ENT oral surgery maxillofacial surgery neurosurgery orthopaedics urology	IIa IIa IIa IIa	2 6 7 11	15-896 15-896 15-896 15-896

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

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	CombiSets/CombiSet for indication-related procedures: General surgery ophthalmology gynaecology obstetrics cardiosurgery chest surgery vascular surgery ENT oral surgery maxillofacial surgery neurosurgery orthopaedics urology	IIa IIa IIa IIa	2 6 7 11	15-896 15-896 15-896 15-896
3.08	**Electronic clinical thermometers**			
	Thermoval basic	IIa	10 (3rd)	14-032
	Thermoval Rapid	IIa	10 (3rd)	14-032
	Thermoval rapid flex	IIa	10 (3rd)	14-032
	Thermoval standard	IIa	10 (3rd)	14-032
	Thermoval kids	IIa	10 (3rd)	14-032
	Thermoval kids flex	IIa	10 (3rd)	14-032
	Cosmos thermometers electronic	IIa	10 (3rd)	14-032
	Thermoval duo scan	IIa	10 (3rd)	14-036
	Thermoval baby	IIa	10 (3rd)	14-036
3.09	**Electronic blood pressure monitors**			
	Tensoval mobile	IIa	10 (3rd)	16-173
	Tensoval comfort	IIa	10 (3rd)	16-173
	Tensoval compact	IIa	10 (3rd)	16-173
	Tensoval duo control	IIa	10 (3rd)	16-173
	Tensoval mobil classic	IIa	10 (3rd)	16-173
	Tensoval comfort classic	IIa	10 (3rd)	16-173
	Veroval duo control	IIa	10 (3rd)	16-173
3.10	**Medical instruments**			
	Peha-instrument			
	Scissors	IIa	6	13-493
			6	13-480
			6	13-488
			6	13-492
	Forceps	IIa	6	14-257
			6	11-791
			6	11-797

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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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Fax: +49 (0) 7321 36-3636
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			6	10-865
	Needle holder	IIa	6	12-726
	Wound hook	IIa	6	13-373
	Sharp spoon	IIa	6	11-084
	Basic Set	IIa	6	17-168
	MediSet			
	Curette	IIa	4 (3rd)	11-084
	Forceps	IIa	6	11-797
	Grooved director	IIa	6	13-117
	Stylet	IIa	6	13-833
	Scissors	IIa	6	13-480
	Sterima			
	Curette	IIa	4 (3rd)	11-084
	Forceps	IIa	6	11-797
	Grooved director	IIa	6	13-117
	Stylet	IIa	6	13-833
	Scissors	IIa	6	13-480
3.11	**Products for negative pressure wound therapy**			
	VivanoTec Pro	IIa	11	10-223

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Running No.	Product Groups / Product Names	Classification in accordance with Directive 93/42/EEC	Rule	UMDNS
4.01	**Impregnated tulle and special dressings**			
	Grassolind neutral	IIb	4 (2nd)	11-325
	Atrauman	IIb	4 (2nd)	11-325
	Branolind	IIb	4 (2nd)	11-325
	Hydrotüll / Hydrotul	IIb	4 (2nd)	11-325
	Atrauman Silicone	IIb	4 (2nd)	11-325
	Interface	IIb	4 (2nd)	15-216
4.02	**Hydroactive dressings and accessories**			
	Hydrosorb	IIb	4 (2nd)	15-216
	Hydrosorb comfort	IIb	4 (2nd)	15-216
	Hydrosorb Gel	IIb	4 (2nd)	15-216
	HydroClean	IIb	4 (2nd)	15-216
	HydroClean cavité	IIb	4 (2nd)	15-216
	HydroClean cavity	IIb	4 (2nd)	15-216
	HydroClean active	IIb	4 (2nd)	15-216
	HydroClean active cavité	IIb	4 (2nd)	15-216
	HydroClean plus	IIb	4 (2nd)	15-216
	HydroClean plus cavity	IIb	4 (2nd)	15-216
	HydroClean mini	IIb	4 (2nd)	15-216
	HydroClean advance	IIb	4 (2nd)	15-216
	HydroClean advance mini	IIb	4 (2nd)	15-216
	HydroClean plus mini	IIb	4 (2nd)	15-216
	HydroClean advance cavity	IIb	4 (2nd)	15-216
	Hydrocoll	IIb	4 (2nd)	15-216
	Hydrocoll concave	IIb	4 (2nd)	15-216
	Hydrocoll sacral	IIb	4 (2nd)	15-216
	Hydrocoll thin	IIb	4 (2nd)	15-216
	Sorbalgon	IIb	4 (2nd)	15-216
	Sorbalgon T	IIb	4 (2nd)	15-216
	Zetuvit plus	IIb	4 (2nd)	15-216
	Resposorb Super	IIb	4 (2nd)	15-216
	Zetuvit Plus Silicone	IIb	4 (2nd)	15-216
	RespoSorb Silicone	IIb	4 (2nd)	15-216
	HydroTac	IIb	4 (2nd)	15-216
	HydroTac comfort	IIb	4 (2nd)	15-216
	HydroTac concave	IIb	4 (2nd)	15-216

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

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

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	HydroTac sacral	IIb	4 (2nd)	15-216
	HydroTac transparent	IIb	4 (2nd)	15-216
	HydroTac transparent comfort	IIb	4 (2nd)	15-216
	PermaFoam	IIb	4 (2nd)	11-323
	PermaFoam sacral	IIb	4 (2nd)	11-323
	PermaFoam concave	IIb	4 (2nd)	11-323
	PermaFoam cavity	IIb	4 (2nd)	11-323
	PermaFoam comfort	IIb	4 (2nd)	11-323
	PermaFoam tracheostomy	IIb	4 (2nd)	15-624
	Zetuvit Plus Silicone Border / RespoSorb Silicone Border	IIb	4 (2nd)	15-216
	HydroTac Border Multisite	IIb	4 (2nd)	15-216
4.03	**Products for negative pressure wound therapy**			
	VivanoMed Foam Kit	IIb	4 (2nd)	11-314
	VivanoMed Foam Round Kit	IIb	4 (2nd)	11-314
	VivanoMed Foam Thin Kit	IIb	4 (2nd)	11-314
	VivanoMed Abdominal Kit	IIb	8	11-314
	VivanoMed Foam	IIb	4 (2nd)	11-323
	VivanoMed Silicone Layer	IIb	4 (2nd)	11-325
4.04	**Customised surgical procedure sets**			
	Foliodrape Sets/Foliodrape for indication-related procedures: General surgery ophthalmology gynaecology obstetrics cardiosurgery chest surgery vascular surgery ENT oral surgery maxillofacial surgery neurosurgery orthopaedics urology	IIb IIb IIb	5 7 9	15-896 15-896 15-896
	CombiSets/CombiSet for indication-related procedures: General surgery ophthalmology gynaecology obstetrics cardiosurgery chest surgery	IIb IIb IIb	5 7 9	15-896 15-896 15-896

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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	vascular surgery ENT oral surgery maxillofacial surgery neurosurgery orthopaedics urology			
5.01	**Wound dressings (class III)**			
	Atrauman Ag (EC Design Examination Certificate No. G7 011858 0068 Rev. 00)	III	13	11-325

Annexe 8 – Classes IIa et IIb – PAUL HARTMANN AG

8.2 Certificat CE MDD

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 011858 0064 Rev. 01

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.**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 011858 0064 Rev. 01

Report No.: 713197447

Valid from: 2021-02-02
Valid until: 2024-05-26

Date, 2021-02-02

Christoph Dicks
Head of Certification/Notified Body

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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ZLG-BS-244.10.08

TÜV SÜD 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 011858 0064 Rev. 01

Class IIa 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
- Customized surgical procedure sets
- Electronic clinical thermometers
- Electronic blood pressure monitors
- Medical instruments
- Products for Negative Pressure Wound Therapy

Class IIb medical devices

- Impregnated tulle dressings and special dressings
- Hydroactive dressings and accessories
- Products for Negative Pressure Wound Therapy
- Customized surgical procedure sets

Class III medical devices

- Wound Dressing impregnated with Silver (Ag)

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Product Service

Product Names to the Attachment of Certificate No. G1 011858 0064 Rev. 01, dated 2021-02-02

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
3.01	**Wound management products and dressings** 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 Pagasling Pagalong Medicomp Medicomp extra Absorbent cotton gauze	II a	4 (3rd bullet) / 7
3.02	**Special wound closure and covering products** e. g. Hydrofilm Hydrofilm non-sterile for Kit Packagers Visulin Hydrofilm plus Tiritas MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing) Omnistrip Omnistrip reinforced Dermaplast Omnistrip Dermaplast MEDICAL (Wound closure strips, sterile) Dermaplast hydrocolloid plaster for: minor wounds abrasions Blisters cold sores corns Tiritas hydrocolloid plaster for: minor wounds abrasions Blisters	II a	4 (3rd bullet)

cold sores
corns
Cosmos hydrocolloid plaster for:
minor wounds
abrasions
Blisters
cold sores
corns
DermaActive hydrocolloid plaster for:
minor wounds
abrasions
Blisters
cold sores
corns
DermaPlast EFFECT Abrasion
Dermaplast Medical Transparent dressing
Dermaplast MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing)
Dermaplast MEDICAL (Cuts and lacerations)
DermaPlast EFFECT To cut 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
Dermaplast burn plaster
Tiritas burn plaster
Cosmos burn plaster
DermaActive burn plaster
Dermaplast MEDICAL (Burns)
Tiritas MEDICAL (Burns)
DermaPlast EFFECT Burns

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
3.03	**Sets for patient care** e. g. MediSet, Peha, Sterima - Catheterisation sets - Set for anaesthesia	II a	2 / 4 (3rd bullet) 5 (2nd bullet) / 6 / 7

	- 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		
3.04	**Surgical wound management products** 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 sterile	II a	7

Product Service

Product Names to the Attachment of Certificate
No. G1 011858 0064 Rev. 01, dated 2021-02-02

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
3.05	**Surgical gloves Latex** 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	II a	7
3.06	**Surgical gloves non-Latex** e. g. Peha-neon plus powderfree, Peha-isoprene plus powderfree Peha-isoprene LATEXFREE, Peha-neon LATEXFREE, Peha-shield LATEXFREE, Peha-underglove LATEXFREE	II a	7
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	II a	2 / 6 / 7 / 11

Product Service

Product Names to the Attachment of Certificate
No. G1 011858 0064 Rev. 01, dated 2021-02-02

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II a medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
3.08	**Electronic clinical thermometers** e. g. Thermoval basic Thermoval Rapid Thermoval rapid flex Thermoval standard Thermoval kids Thermoval kids flex Cosmos thermometers electronic Thermoval duo scan Thermoval baby	II a	10 (3rd bullet)
3.09	**Electronic blood pressure monitors** e. g. Tensoval mobile Tensoval comfort Tensoval compact Tensoval duo control Tensoval mobil classic Tensoval comfort classic Veroval duo control	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

3.11	**Products for negative pressure wound therapy** e.g. VivanoTec Pro	IIa	11

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II b medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
4.01	**Impregnated tulle dressings and special dressings** e. g. Grassolind neutral, Atrauman, Branolind, Hydrotüll / Hydrotul, Interface, Atrauman Silicone,	II b	4 (2nd bullet)
4.02	**Hydroactive dressings and accessories** e. g. Hydrosorb Hydrosorb comfort Hydrosorb Gel HydroClean HydroClean cavité HydroClean cavity HydroClean active HydroClean active cavité HydroClean plus HydroClean plus cavity HydroClean mini HydroClean advance HydroClean advance mini HydroClean plus mini HydroClean advance cavity Hydrocoll Hydrocoll concave Hydrocoll sacral Hydrocoll thin Sorbalgon Sorbalgon T Zetuvit plus Resposorb Super Zetuvit Plus Silicone RespoSorb Silicone HydroTac	II b	4 (2nd bullet)

Product Service

Product Names to the Attachment of Certificate
No. G1 011858 0064 Rev. 01, dated 2021-02-02

HydroTac comfort
HydroTac concave
HydroTac sacral
HydroTac transparent
HydroTac transparent comfort
PermaFoam
PermaFoam sacral
PermaFoam concave
PermaFoam cavity
PermaFoam comfort
PermaFoam tracheostomy
Zetuvit Plus Silicone Border /
RespoSorb Silicone Border
HydroTac Border Multisite

Product Service

Product Names to the Attachment of Certificate No. G1 011858 0064 Rev. 01, dated 2021-02-02

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class II b medical devices

Item No.	*Product Groups/Product Names*	*Classification in accordance with 93/42/EEC*	*Rule*
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 (2nd 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	II b	5, 7, 9

Class III medical devices

5.01	**Impregnated tulle dressings and special dressings** Atrauman Ag	III	13

Product Service

Product Names to the Attachment of Certificate No. G1 011858 0064 Rev. 01, dated 2021-02-02

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, Projekt Nr. 713119437
Rev. 01-2018, project no. 713143983
Rev. 01-2019, project no. 713143983 + 713162860
Rev. 01-2020, project no. 713156403_1
Rev. 01-2021, project no. 713197447

Hamburg, 2021-02-18

Hendrik Schorler
Hendrik Schorler (Feb 23, 2021 08:53 GMT+1)

Hendrik Schorler
PS-MHS-AP5

Annexe 9 – Classe III – PAUL HARTMANN AG

Certificat CE MDD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 011858 0068 Rev. 00

Manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

Product: **Wound Dressing**
Model(s): **Atrauman Ag**

Parameter:

REF	Name	Size	Sales Unit
499 570	Atrauman Ag	5 x 5 cm	P3
499 571	Atrauman Ag	5 x 5 cm	P10
499 572	Atrauman Ag	10 x 10 cm	P3
499 573	Atrauman Ag	10 x 10 cm	P10
499 574	Atrauman Ag	10 x 20 cm	P3
499 575	Atrauman Ag	10 x 20 cm	P10

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713180407

Valid from: 2020-07-02
Valid until: 2024-05-26

Date, 2020-07-02

Christoph Dicks
Head of Certification/Notified Body

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

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