

PAUL HARTMANN AG
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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

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
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Registered Office Heidenheim
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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

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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

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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

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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

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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

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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

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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

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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

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Vorstand/Management Board: Britta Fünfstück
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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
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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

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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 instruments	
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

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