

PAUL HARTMANN AG  
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## Consolidated EU Declaration of Conformity for Medical Devices in Class I unsterile

Heidenheim, 7. March 2022

We herewith declare under our sole responsibility that the Class I medical devices listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, 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

ppa.



François Georgelin  
Member of the Management Board



Stefan Fischer  
Senior Vice President Regulatory Affairs

Valid until: 2023-03-01

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück  
(Vorsitzende des Vorstands/CEO), François Georgelin,  
Stefan Grote, 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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| 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 arm cover non-sterile                   | 3366                 | 1                                                                         | 40495003366L2 |
| Foliodress cap Comfort                             | 1317                 | 1                                                                         | 40495001317K7 |
| Foliodress cap Universal                           | 1319                 | 1                                                                         | 40495001319KB |
| Foliodress gown Comfort Basic non-sterile          | 3362                 | 1                                                                         | 40495003362KS |
| Foliodress gown Comfort Reinforced non-sterile     | 3364                 | 1                                                                         | 40495003364KW |
| Foliodress gown Comfort Standard non-sterile       | 3363                 | 1                                                                         | 40495003363KU |
| Foliodress gown Protect Basic non-sterile          | 3396                 | 1                                                                         | 40495003396LB |
| Foliodress gown Protect Reinforced non-sterile     | 3361                 | 1                                                                         | 40495003361KQ |
| Foliodress gown Protect Standard non-sterile       | 3360                 | 1                                                                         | 40495003360KN |
| 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 |

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| HARTMANN Leggings PE      | 3444 | 1 | 40495003444KV |
| HARTMANN leggings Protect | 3445 | 1 | 40495003445KX |

| 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 |

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| Confiance Men Pad                   | 3125 | 1 | 40495003125KA |
| Confiance Men Pad                   | 3126 | 1 | 40495003126KC |
| Confiance men PANTS                 | 3105 | 1 | 40495003105K4 |
| Confiance Mobile                    | 3107 | 1 | 40495003107K8 |
| Confiance Rectangular               | 3272 | 1 | 40495003272KQ |
| Confiance Secure                    | 1021 | 1 | 40495001021JF |
| Confiance Secure (ADL)              | 3656 | 1 | 40495003656LE |
| Lindor Anatomico                    | 3110 | 1 | 40495003110JV |
| Lindor Anatomico Dia 5 dr.          | 2920 | 1 | 40495002920KZ |
| Lindor Care Anatomico               | 3111 | 1 | 40495003111JX |
| Lindor Care Anatomico (ADL)         | 3746 | 1 | 40495003746LG |
| Lindor Care Elásticos (ADL)         | 3748 | 1 | 40495003748LL |
| 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 Form (ADL)                 | 3654 | 1 | 40495003654LA |
| 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 (ADL)         | 3652 | 1 | 40495003652L6 |
| MoliCare Premium Form MEN           | 3057 | 1 | 40495003057KJ |
| MoliCare Premium Form MEN (ADL)     | 3653 | 1 | 40495003653L8 |

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| MoliCare Premium Form STOOL     | 3649 | 1 | 40495003649LH |
| MoliCare Premium Form +SIZE     | 3648 | 1 | 40495003648LF |
| 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 | 40495002954UJ |
| 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 |
| MoliMed for Men                 | 3121 | 1 | 40495003121K2 |
| MoliMed Ultra                   | 3135 | 1 | 40495003135KD |
| NURSA Form                      | 3117 | 1 | 40495003117KB |
| NURSA Form (ADL)                | 3655 | 1 | 40495003655LC |
| NURSA Slip                      | 3099 | 1 | 40495003099L2 |
| NURSA Pad                       | 3128 | 1 | 40495003128KG |
| 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 |

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| 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 |
| DermaPlast MEDICAL Fixation tape - waterproof and self-adhesive | 3549 | 1     | 40495003549LC |
| DermaPlast MEDICAL skin+ Silicone adhesive                      | 3880 | 1     | 40495003880LM |
| DermaPlast Professional Classic                                 | 1665 | 4 (1) | 40495001665KZ |
| DermaPlast Professional Water-resistant/Universal               | 1481 | 4 (1) | 40495001481KM |
| Dermaplast Protect Plus                                         | 1476 | 4 (1) | 40495001476KU |
| DermaPlast Sensitive/Soft                                       | 1473 | 4 (1) | 40495001473KN |
| DermaPlast Sensitive/Soft/Injection                             | 1474 | 4 (1) | 40495001474KQ |
| 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 |
| HARTMANN Nitrile Powderfree Examination Gloves                  | 3598 | 5 (1) | 40495003598LR |
| Hospicrepe                                                      | 1901 | 1     | 40495001901KN |
| Hospicrepe Bandage                                              | 3320 | 1     | 40495003320KA |
| Hospiform                                                       | 1196 | 1     | 40495001196KK |
| Hospilite                                                       | 1278 | 1     | 40495001278KN |
| Hydrofilm roll film dressings                                   | 1699 | 1     | 40495001699LJ |

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| 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 |
| Omnifix elastic fixation plasters | 1695 | 1            | 40495001695LA |
| Omnifix silicone                  | 3546 | 1            | 40495003546L6 |
| 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 5                      | 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-Lastoform                    | 3641 | 1            | 40495003641KZ |
| 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 |

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| 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) | 40495001032IL |
| Peha-soft syntex powderfree                               | 1942 | 5 (1) | 40495001942L4 |
| Peha-soft Vinyl                                           | 1943 | 5 (1) | 40495001943L6 |
| Platrix Plaster                                           | 1244 | 1     | 40495001244K5 |
| PütterPro 2                                               | 2982 | 1     | 40495002982LP |
| PütterPro 2 Lite                                          | 3580 | 1     | 40495003580L6 |
| Pur-Zellin                                                | 1005 | 4 (1) | 40495001005JH |
| Pur-Zellin Box                                            | 1004 | 1     | 40495001004JF |
| Pütterbinde                                               | 2119 | 1     | 40495002119K8 |
| Pütterbinde E                                             | 1336 | 1     | 40495001336KB |
| Pütterbinde E                                             | 3822 | 1     | 40495003822L7 |
| 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 |
| 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 |
| TwoPress 2 Lite                                           | 3581 | 1     | 40495003581L8 |
| Variants Omnipor spool plasters                           | 1227 | 1     | 40495001227K5 |
| Varolast Plus                                             | 1800 | 1     | 40495001800KF |

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|----------------------------|------|-------|---------------|
| 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 |
| Foliodrape Surgery preparation non-sterile        | 3762                 | 1                                                                         | 40495003762LE |
| Foliodrape Patient Transfer sheet non-sterile     | 3819                 | 1                                                                         | 40495003819LJ |
| 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 |
| 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 |

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|-------------------------------------------------------------------|------|---|---------------|
| 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 |
| 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 |

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|---------------------------------------------------------------|------|---|---------------|
| 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 |
| 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 |

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| 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 |

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