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HARTMANN
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Consolidated EU Declaration of Conformity for Medical Devices Class I

Heidenheim, 2025-07-07

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.

Martin Walther
Senior Vice President
Risk Prevention

i.V.

Christiana Hofmann
Head of Regulatory Affairs
Risk Prevention

Valid until: 2030-05-05

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090

Registered Office Heidenheim
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Intended Purpose	General single-use, non-active, non-implantable devices used in health care		
EMDN Code	T0210 - NON-SURGICAL DRAPES		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Foliodrape Patient Transfer sheet non-sterile	3819	1	40495003819LJ

Intended Purpose	General single-use, non-active, non-implantable devices used in health care		
EMDN Code	T0299 - PROTECTION DRAPES AND GARMENTS - OTHER		
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

Intended Purpose	General single-use, non-active, non-implantable devices used in health care		
EMDN Code	T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
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

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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
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 General surgery Drapes Protect	3246	1	40495003246KP

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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 Laparoscopy Drapes Protect	3251	1	40495003251KG
HARTMANN Ophthalmology Drapes Protect	3252	1	40495003252KJ
HARTMANN Other Drapes adhesive PE	3438	1	40495003438L2
HARTMANN Spinal Drapes Protect Plus	3236	1	40495003236KL
HARTMANN Stockinet Protect	3443	1	40495003443KT
HARTMANN Suction bags	3227	1	40495003227KK
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
HARTMANN Fenestrated Drapes Protect Plus	3249	1	40495003249KV
HARTMANN Leggings PE	3444	1	40495003444KV
HARTMANN leggings Protect	3445	1	40495003445KX

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Intended Purpose	General single-use, non-active, non-implantable devices used in health care		
EMDN Code	T030102 - COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
HARTMANN Instrument table covers Protect	3226	1	40495003226KH
HARTMANN Instruments Table Covers Protect Plus	3240	1	40495003240KB
HARTMANN Other equipment Covers PE	3439	1	40495003439L4
HARTMANN Other equipment Covers Protect	3448	1	40495003448L5
HARTMANN Table Covers Comfort	3462	1	40495003462KX
HARTMANN Table Covers Protect Plus	3449	1	40495003449LP
HARTMANN Table Covers reinforced	3239	1	40495003239KS

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