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Consolidated EU Declaration of Conformity for Medical Devices in Class IIa & IIb

Heidenheim, 2024-06-18

We herewith declare under our sole responsibility that the class IIa and IIb 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 (6) and Annex IX for class IIa devices and according to Article 52 (4) and Annex IX for class IIb devices have been performed and the Technical Documentation is kept available.

The conformity assessment procedures are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G10 011858 0065 Rev. 03.

PAUL HARTMANN AG

i.V.


François Georgelin
Member of the Management Board

Jens Hahn
Director Regulatory Affairs Excellence

Valid until: 2025-06-30

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Oliver Neubrand
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Class IIa medical devices in conjunction with the EU Quality Management System Certificate (MDR)
No. G10 011858 0065 Rev. 03

Device Group		M020102 - COTTON GAUZES, FOLDED		
Intended Purpose		-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI	
ES-Kompressen	1395	7 (1)	40495001395KT	
Gaza Opatrunkowa Bawelniana	1144	7 (1)	40495001144JY	
Lusan compresses sterile	2592	7 (1)	40495002592L6	
Sterilux ES gauze swabs (bulk)	3254	7 (1)	40495003254KN	
Sterilux ES gauze swabs, sterile	1195	7 (1)	40495001195KH	
Sterilux gauze swabs sterile	3566	7 (1)	40495003566LC	
Telacomp	1208	7 (1)	40495001208JZ	
Telacomp E (sterile)	1420	7 (1)	40495001420JZ	
Telacomp (sterile)	1421	7 (1)	40495001421K3	

Device Group		M020199 - COTTON GAUZES - OTHER		
Intended Purpose		-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI	
Pagasling (bulk)	2227	7 (1)	40495002227KC	
Pagasling sterile	1415	7 (1)	40495001415K8	
Tamponadebinde	1355	7 (1)	40495001355KF	
Telaprep	1372	7 (1)	40495001372KF	
Telaprep (sterile)	1419	7 (1)	40495001419KG	
Telasling	1371	7 (1)	40495001371KD	
Telasling (sterile)	1267	7 (1)	40495001267KH	
Telasorb	1361	7 (1)	40495001361KA	
Telasorb E	1510	7 (1)	40495001510K3	
Telasorb E (sterile)	1416	7 (1)	40495001416KA	

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Device Group		M020201 - NON-WOVEN FOLDED GAUZES	
Intended Purpose		-	
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Dermaplast Medical Vlieskompress sterile	2494	7 (1)	40495002494L5
Giphar Non-woven compresses sterile	1190	7 (1)	40495001190K7
Medicomp (bulk)	3334	7 (1)	40495003334KM
Medicomp (sterile)	1192	7 (1)	40495001192KB
Medicomp extra (sterile)	3397	7 (1)	40495003397LD

Device Group		M040403 - HYDROCOLLOID DRESSINGS	
Intended Purpose		-	
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Cosmos Abrasions plasters	3164	4 (3)	40495003164KL
Cosmos Blister plasters	1613	4 (3)	40495001613KE
Cosmos Corns plasters	3165	4 (3)	40495003165KN
Cosmos Cut-to-size Blister Plasters	1616	4 (3)	40495001616KL
Dermaplast EFFECT abrasion plaster	2158	4 (3)	40495002158KJ
Dermaplast EFFECT Blister	3084	4 (3)	40495003084KM
Dermaplast EFFECT Blister to cut	3085	4 (3)	40495003085KP
Dermaplast EFFECT corn plaster	3086	4 (3)	40495003086KR
Dermaplast EFFECT Cold Sore Patch	3087	4 (3)	40495003087KT

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Device Group	M040406 - POLYURETHANE DRESSINGS		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Cosmopor Transparent	3522	4 (3)	40495003522KQ
DermaPlast MEDICAL	3550	4 (3)	40495003550KV
DermaPlast MEDICAL – Sterile dressing with wound pad – waterproof and transparent	3525	4 (3)	40495003525KW
Hydrofilm	1449	4 (3)	40495001449KR
Hydrofilm plus	1450	4 (3)	40495001450KA
Hydrofilm (Unbreakable)	3521	4 (3)	40495003521KN
Hydrofilm bulk sterile (Unbreakable)	3637	4 (3)	40495003637LA
Hydrofilm bulk non sterile (Unbreakable)	3638	4 (3)	40495003638LC

Device Group	T010101 - LATEX SURGICAL GLOVES		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Peha-basic Latex	2082	7 (1)	40495002082KA
Peha-micron Latex	2107	7 (1)	40495002107JZ
Peha-profile Latex	2079	7 (1)	40495002079KM
Peha-taft classic Powder-free	2081	7 (1)	40495002081K8
Peha-taft Latex	2078	7 (1)	40495002078KK
Peha-underglove Latex	2109	7 (1)	40495002109K5

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Device Group	T010102 - SYNTHETIC SURGICAL GLOVES		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Peha-isoprene Latex-free	1992	7 (1)	40495001992LK
Peha-Neon Latex-free	1991	7 (1)	40495001991LH
Peha-shield Latex-free	2102	7 (1)	40495002102JP
Peha-underglove Latex-free	2110	7 (1)	40495002110JN

Device Group	V030101 - THERMOMETERS		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Thermoval kids	2069	10 (3)	40495002069KJ
Thermoval kids flex	2070	10 (3)	40495002070K3
Thermoval rapid	2067	10 (3)	40495002067KE
Thermoval standard	2066	10 (3)	40495002066KC
Veroval baby	3630	10 (3)	40495003630KU

Device Group	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Double-ended curette non-sterile	3406	4 (3)	40495003406KM
HARTMANN Care Components Stylet	3783	6	40495003783LN
Hartmann Surgical Anatomic forceps unsterile	4142	6 (1)	40495004142KH

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Hartmann Surgical General-purpose curettes non-sterile	4165	6 (1)	40495004165KV
Hartmann Surgical Instruments Adson forceps	3374	6	40495003374KZ
Hartmann Surgical Instruments DeBakey forceps	3375	6	40495003375L3
Hartmann Surgical Instruments Halsted mosquito forceps	3380	6	40495003380KU
Hartmann Surgical Instruments Braun-Stadler episiotomy scissors	3368	6	40495003368L6
Hartmann Surgical Instruments Fine dissecting scissors	3392	6	40495003392L3
Hartmann Surgical Instruments Mayo scissors	3389	6	40495003389LE
Hartmann Surgical Instruments Mayo-Stille scissors	3388	6	40495003388LC
Hartmann Surgical Instruments Metzenbaum scissors	3370	6	40495003370KR
Hartmann Surgical Instruments Micro-scissors	3371	6	40495003371KT
Hartmann Surgical Instruments Operating scissors	3369	6	40495003369L8
Hartmann Surgical Instruments Schumacher umbilical cord scissors	3393	6	40495003393L5
Hartmann Surgical Instruments Dressing Forceps	3785	6	40495003785L5
Hartmann Surgical Instruments Kocher forceps	3381	6	40495003381KW
Hartmann Surgical Instruments Mayo-Hegar needle holder	3383	6	40495003383L2
Hartmann Surgical Instruments Micro-Adson forceps	3377	6	40495003377L7
Hartmann Surgical Instruments Micro-Mosquito forceps	3382	6	40495003382KY
Hartmann Surgical Instruments Peen forceps	3379	6	40495003379LB
Hartmann Surgical Instruments Senn-Muller retractor	3387	6	40495003387LA
Hartmann Surgical Instruments Sharp spoon	3384	6	40495003384L4
Hartmann Surgical Instruments Splinter forceps	3373	6	40495003373KX

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Hartmann Surgical Instruments Standard forceps	3376	6	40495003376L5
Hartmann Surgical Instruments Tissue Forceps Fine Point	3391	6	40495003391KZ
Hartmann Surgical Instruments Wound hook	3385	6	40495003385L6
MediSet Dermatological curette	3792	6	40495003792LP
MediSet Stylet	3784	6	40495003784LQ
Peha-instrument Adson anatomic Forceps straight	1639	6	40495001639KY
Peha-instrument Adson surgical Forceps straight	1641	6	40495001641KK
Peha-instrument Basic Sets	1625	6	40495001625KM
Peha-instrument Basic Sets Fine	1624	6	40495001624KK
Peha-instrument Braun-Stadler episiotomy scissors	1627	6	40495001627KR
Peha-instrument DeBaKey forceps straight	1640	6	40495001640KH
Peha-instrument Fox bone curettes	1658	6	40495001658L4
Peha-instrument Halsted mosquito forceps anatomic curved	1649	6	40495001649L3
Peha-instrument Jansen forceps anatomic sterile	1647	6 (1)	40495001647KX
Peha-instrument Jansen sharp spoon combination sterile	1661	6	40495001661KR
Peha-instrument Kocher forceps surgical straight	1650	6	40495001650KL
Peha-instrument lid retractors sterile	1660	6 (1)	40495001660KP
Peha-instrument Mayo-Hegar needle holders	1655	6	40495001655KW
Peha-instrument Metzenbaum scissors blunt/blunt curved	1631	6	40495001631KG
Peha-instrument dissection scissors fine sterile	1635	6 (1)	40495001635KQ
Peha-instrument	1646	6	40495001646KV

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Micro Adson anatomic forceps			
Peha-instrument Micro Adson tissue forceps	1645	6	40495001645KT
Peha-instrument Micro scissors	1632	6	40495001632KJ
Peha-instrument Micro-Mosquito forceps anatomic straight	1651	6	40495001651KN
Peha-instrument Operating scissors sterile	4126	6 (1)	40495004126KK
Peha-instrument Operating scissors straight blunt/blunt	1629	6	40495001629KV
Peha-instrument Operating scissors straight sharp/blunt	1628	6	40495001628KT
Peha-instrument Operating scissors straight sharp/sharp	1630	6	40495001630KE
Peha-instrument Pean forceps	1652	6	40495001652KQ
Peha-instrument Pean forceps anatomic straight	1648	6	40495001648KZ
Peha-instrument Raspatory sterile	4158	6	40495004158KY
Peha-instrument Schumacher umbilical cord scissors sterile	1636	6 (1)	40495001636KS
Peha-instrument Sharp spoon combinations	1664	6	40495001664KX
Peha-instrument Splinter forceps straight	1644	6	40495001644KR
Peha-instrument Standard anatomic forceps straight	1643	6	40495001643KP
Peha-instrument Standard surgical forceps straight	1642	6	40495001642KM
Peha-instrument Surgical forceps sterile	4123	6 (1)	40495004123KD
Peha-instrument Surgical hemostatic forceps sterile	4125	7 (1)	40495004125KH
Peha-instrument Volkmann sharp spoon combinations sterile	1662	6 (1)	40495001662KT
Peha-instrument Wound hook combinations	1657	6	40495001657L2
Plastic stylet unsterile	3405	6 (1)	40495003405KK

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Device Group	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Veroval duo control	2259	10 (3)	40495002259KR

Device Group	Z120402 - GENERAL MEDICINE THERAPEUTIC TREATMENT INSTRUMENTS		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
VivanoTec Pro	2924	12	40495002924L9

Device Group	Z121290 - VARIOUS OPHTHALMOLOGY INSTRUMENTS		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Hartmann Surgical Instruments Iris scissors	3372	6	40495003372KV
Peha-instrument Iris scissors curved	1634	6	40495001634KN
Peha-instrument Iris scissors straight	1633	6	40495001633KL

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Device Group	H900102 – BANDAGES FOR SUTURES		
Intended Purpose	-		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Omnistrip sterile	2502	4 (4)	40495002502KB

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Class IIb medical devices in conjunction with the EU Quality Management System Certificate (MDR)
No. G10 011858 006S Rev. 03

Device Group	M040499 – DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER		
Intended Purpose	Single-use, sterile, non-medicated dressings suitable for the treatment of wounds		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Atrauman	1384	4 (2)	40495001384KN
Atrauman Silicone	1390	4 (2)	40495001390KH
Grassolind neutral	1382	4 (2)	40495001382KJ
HydroClean	3198	4 (2)	40495003198L5
HydroClean advance	2585	4 (2)	40495002585L9
HydroClean advance cavity	3218	4 (2)	40495003218KJ
HydroClean advance mini	2841	4 (2)	40495002841L4
HydroClean cavity	3199	4 (2)	40495003199L7
HydroClean mini	2850	4 (2)	40495002850L5
Hydrocoll	1815	4 (2)	40495001815KU
Hydrocoll basic	1815	4 (2)	40495001815KU
Hydrocoll concave	1815	4 (2)	40495001815KU
Hydrocoll sacral	1815	4 (2)	40495001815KU
Hydrocoll thin	1815	4 (2)	40495001815KU
HydroTac	1831	4 (2)	40495001831KS
HydroTac Comfort	1832	4 (2)	40495001832KU
HydroTac Concave	1830	4 (2)	40495001830KQ
HydroTac Sacral	1833	4 (2)	40495001833KW
HydroTac transparent	3612	4 (2)	40495003612KS
HydroTac transparent comfort	3613	4 (2)	40495003613KU
RespoSorb Silicone	2493	4 (2)	40495002493L3
RespoSorb Silicone	3873	4 (2)	40495003873LQ
RespoSorb Silicone Border	2842	4 (2)	40495002842L6
RespoSorb Silicone Border	3301	4 (2)	40495003301K6
RespoSorb Super	1326	4 (2)	40495001326K8
Zetuvit Plus	1407	4 (2)	40495001407K9
Zetuvit Plus Superabsorber	1407	4 (2)	40495001407K9
Zetuvit Plus Silicone	2186	4 (2)	40495002186KP
Zetuvit Plus Silicone	3872	4 (2)	40495003872LN

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Zetuvit Plus Silicone Border	2843	4 (2)	40495002843L8
Zetuvit Plus Silicone Border	3300	4 (2)	40495003300K4

Device Group	M040499 – DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER		
Intended Purpose	Sterile, non-medicated, products for negative pressure wound therapy		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
VivanoMed Abdominal Kit	1809	4 (2)	40495001809KZ
VivanoMed Foam	1811	4 (2)	40495001811KL
VivanoMed Foam Kit	2852	4 (2)	40495002852L9

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