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Consolidated EU Declaration of Conformity for Medical Devices in Class Is

Heidenheim, 2023-03-01

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, 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) 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

i.V.

François Georgelin
Member of the Management Board

Jens Hahn
Director Regulatory Affairs Excellence

Valid until: 2024-06-30

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Class I sterile medical devices in conjunction with the EU Quality Assurance Certificate (MDR) No. G21 011858 0069

Device Group	T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER		
Device Properties	MDS 1005.1 Ethylene Oxide Sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Foliodrape Accessories Armrest covers protect sterile	1895	1	40495001895LL
Foliodrape Accessories Fixation sterile	1883	1	40495001883LD
Foliodrape Accessories Leggings sterile	1889	1	40495001889LR
Foliodrape Accessories Stockinettes sterile	1881	1	40495001881L9
Foliodrape Accessories Suction bags sterile	1891	1	40495001891LC
Foliodrape Arthroscopy drapes protect sterile	1999	1	40495001999LZ
Foliodrape ENT/Maxillofacial Surgery drapes protect plus sterile	2033	1	40495002033JV
Foliodrape Epidural drapes protect sterile	2143	1	40495002143K5
Foliodrape Extremity drapes protect plus sterile	2018	1	40495002018JZ
Foliodrape Fenestrated drapes adhesive protect plus sterile	2141	1	40495002141JZ
Foliodrape Fenestrated drapes adhesive protect sterile	2029	1	40495002029K6
Foliodrape Fenestrated drapes protect sterile	2142	1	40495002142K3
Foliodrape Other accessories sterile	1892	1	40495001892LE
Foliodrape Surgical drapes adhesive protect sterile	2005	1	40495002005JQ
Foliodrape Surgical drapes adhesive protect plus sterile	2034	1	40495002034JX
Foliodrape Surgical drapes protect sterile	2140	1	40495002140JX

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Foliodrape Universal Split drape protect sterile	2144	1	40495002144K7
Foliodrape Universal Split drapes protect plus sterile	2021	1	40495002021JN

Device Group	M040101 - ADHESIVE DRESSINGS, WITH ABSORBENT PAD		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Cosmopor	1438	4 (1)	40495001438KL
Cosmopor Advance	1455	4 (1)	40495001455KL
Cosmopor E	1439	4 (1)	40495001439KN
Cosmopor Entry	3561	4 (1)	40495003561L2
Cosmopor Skin Color	2838	4 (1)	40495002838LF
Cosmopor Silicone	3523	4 (1)	40495003523KS
Cosmopor Waterproof	1465	4 (1)	40495001465KP
DermaPlast MEDICAL Sterile dressing with wound pad - breathable	3547	4 (1)	40495003547L8
DermaPlast MEDICAL skin+ Absorbent adhesive dressing with silicone contact layer	3888	4 (1)	40495003888M5
M-plast steriler Wundverband	3556	4 (1)	40495003556L9

Device Group	M040102 - FIXING DRESSINGS		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Cosmopor I.V.	3555	4 (1)	40495003555L7
Cosmopor I.V. transparent	1448	4 (1)	40495001448KP
VivanoMed Gel Strip	3968	1	40495003968M4

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Device Group	M040301 – EYE PADS, COTTON OR NON-WOVEN MATERIALS		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Eycopad sterile	1364	4 (1)	40495001364KG
Sterilux Compresses opthalmiques	3570	4 (1)	40495003570L3

Device Group	T030102 – COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Foliodrape Instruments table covers sterile	2038	1	40495002038K7
Foliodrape Other equipment covers sterile	1887	1	40495001887LM
Foliodrape Table covers protect sterile	2139	1	40495002139KE
Foliodrape Table covers protect plus sterile	2106	1	40495002106JX
Foliodrape Table covers reinforced sterile	2037	1	40495002037K5

Device Group	T0202 – SURGICAL PROCEDURALS KITS (EXCLUDING SURGICAL INSTRUMENTS KITS)		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Foliodrape Sets Angiography protect plus sterile	2013	1	40495002013JP
Foliodrape Sets Caesarean sections protect plus sterile	2024	1	40495002024JU

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Foliodrape Sets ENT/Maxilofacial surgery sms sterile	3419	1	40495003419KW
Foliodrape Sets Extremity protect sterile	2337	1	40495002337KL
Foliodrape Sets Extremity protect plus sterile	1684	1	40495001684L5
Foliodrape Sets General Surgery protect sterile	2232	1	40495002232K5
Foliodrape Sets General Surgery protect plus sterile	1507	1	40495001507KE
Foliodrape Sets Gynecology / Obstetrics protect sterile	2548	1	40495002548L3
Foliodrape Sets Gynecology / Obstetrics protect plus sterile	2023	1	40495002023JS
Foliodrape Sets Hand / Foot protect sterile	1995	1	40495001995LR
Foliodrape Sets Hand / Foot protect plus sterile	1875	1	40495001875LE
Foliodrape Sets Heart / Thorax / Vascular protect plus sterile	2022	1	40495002022JQ
Foliodrape Sets Heart / Thorax / Vascular protect plus viscose sterile	2212	1	40495002212JX
Foliodrape Sets Hip protect plus sterile	2570	1	40495002570KU
Foliodrape Sets Maxillofacial Surgery protect sterile	2014	1	40495002014JR
Foliodrape Sets Maxillofacial Surgery protect plus sterile	2032	1	40495002032JT
Foliodrape Sets Neurosurgery protect plus sterile	1873	1	40495001873LA
Foliodrape Sets Ophtalmology protect sterile	2008	1	40495002008JW
Foliodrape Sets Ophtalmology SMS sterile	2214	1	40495002214K3
Foliodrape sets Orthopedy PE sterile	3527	1	40495003527L2
Foliodrape Sets Shoulder Arthroscopy protect sterile	2233	1	40495002233K7
Foliodrape Sets Shoulder Arthroscopy protect plus viscose sterile	2568	1	40495002568L9
Foliodrape Sets Urology protect sterile	1993	1	40495001993LM

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Device Group	T0299 – PROTECTION DRAPES AND GARMENTS – OTHER		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Foliodress S isolation gown impervious sterile	3343	1	40495003343KN
Foliodress S isolation gown sterile	1264	1	40495001264KB

Device Group	Z129080 – VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS – HARDWARE ACCESSORIES		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Peha-instrument bandage scissors sterile	1637	1	40495001637KU
MediSet Scissors blunt/blunt sterile	3788	1	40495003788LY
MediSet Scissors sharp/blunt sterile	3789	1	40495003789M2
MediSet Scissors sharp/sharp sterile	3790	1	40495003790LK

Device Group	Z120190 – VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Peha-instrument tubing clamps without serrations sterile	1654	1	40495001654KU

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Device Group	T010202 – SYNTHETIC EXAMINATION / TREATMENT GLOVES		
Device Properties	MDS 1005.2 – Sterilization by irradiation		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Peha-soft nitrile sterile	1946	5 (1)	40495001946LC

Device Group	M020102 – COTTON GAUZES, FOLDED		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
DermaPlast Compress	1424	4 (1)	40495001424K9
Peha Schlitzkompressen	1398	4 (1)	40495001398KZ

Device Group	M020101 – COTTON GAUZES, CUT		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Cut Gauze sterile	1015	4 (1)	40495001015JL
Gauze sterile	1143	4 (1)	40495001143JW

Device Group	M020101 – COTTON GAUZES, CUT		
Device Properties	MDS 1005.3 Sterilization by moist heat		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Cut Gauze sterile	1015	4 (1)	40495001015JL
Gauze sterile	1143	4 (1)	40495001143JW

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Device Group	M020107 – COTTON GAUZES IN ROLLS		
Device Properties	MDS 1005.3 Sterilization by moist heat		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Gauze bandages sterile	1236	4 (1)	40495001236K6

Device Group	M020201 – NON-WOVEN FOLDED GAUZES		
Device Properties	MDS 1005.3 Sterilization by moist heat		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Medicomp drain	1383	4 (1)	40495001383KL

Device Group	M040201 – ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-WOVEN WRAPS		
Device Properties	MDS 1005.3 Sterilization by moist heat		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Pansement Absorbant Stérile	1404	4 (1)	40495001404K3
Zetuvit (sterile)	1401	4 (1)	40495001401JV
Zetuvit E (sterile)	1409	4 (1)	40495001409KD

Device Group	M040299 – NON-ADHESIVE ABSORBENT DRESSINGS – OTHER		
Device Properties	MDS 1005.3 Sterilization by moist heat		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Samu (steril)	1940	1	40495001940KY

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Device Group	A0699 – DRAINAGE AND FLUID COLLECTION DEVICES – OTHER		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
VivanoTec Exudate Canister	1012	1	40495001012JE
VivanoTec Port	1804	1	40495001804KP
VivanoTec Y-Connector	1805	1	40495001805KR

Device Group	H02010106 - METAL SURGICAL STAPLE REMOVERS, SINGLE-USE		
Device Properties	MDS 1005.1 Ethylene Oxide sterilization		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Mediset Staple remover	3786	1	40495003786LU