

EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Name of Products:	Surgical Drapes, Sterile
Product Codes:	See Attachment A
UMDNS Code:	N/A
GMDN Code:	47783: General Purpose Surgical Drape, Single-Use, Sterile
CND Code:	T0201: Surgical Drapes
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
Manufacturer SRN :	N/A
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN:	IE-AR-000003110
UDI-DI: (device level)	06806517SD002CE
Start of CE:	23 March 2015
Conformity Assessment Route:	Annex IX, Chapter I and III of Regulation (EU) 2017/745
Risk Classification, Rules:	Class Is per Rule 4, Annex VIII Regulation (EU) 2017/745
CE certificate number:	MDR 739585
Notified Body:	BSI-NL (2797)

Quality System Certificate:	FM 697013
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COMMON SPECIFICATIONS: **NOT APPLICABLE**

STATEMENT: I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of Regulation (EU) 2017/745 concerning Medical Devices.

All supporting documentation that contains proof of compliance to the aforementioned Regulation(s) is retained under the premises of O&M Halyard, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:



On behalf of O&M Halyard, Inc

Name: Steven Dowdley
Title: Director, Regulatory Affairs
Address: O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116
United States of America

Date: August 11, 2021

ATTACHMENT A: Product Codes and Descriptions for Sterile Surgical Drapes

Global SKU	Product Description	UDI-DI
29232	Pediatric Femoral Angiography Drape 158 in. x 76.5 in. / 401 cm x 194 cm	06806517SD002CE
29236	Bariatric Drape with Clear Pouches	06806517SD002CE
29283	Robotic Abdominal / Pelvic Drape, 160 in. x 104 in. / 406 cm x 264 cm	06806517SD002CE
31439	CVC Drape with Top Perforation Full Body, Single Fenestration, 110 in. x 68 in. / 279 cm x 172 cm	06806517SD002CE
31446	PICC Drape with Side Perforations Full Body, Dual Fenestration, 110 in. x 78 in. / 279 cm x 198 cm* Split U-Drape (223 cm x 274 cm)	06806517SD002CE
34902	Bottom Drape	06806517SD002CE
34904	Side Drape	06806517SD002CE
34906	Top Drape	06806517SD002CE
36930	ORTHOARTS* Extra Long Knee Arthroscopy Drape, 176 in. x 92 in. x 116 in. / 447 cm x 233 cm x 294 cm	06806517SD002CE
36931	Orthopedic Split "T" Drape, 135 in. x 83 in. x 117 in. / 342 cm x 210 cm x 297 cm	06806517SD002CE
36932	ORTHOARTS* Beach Chair Shoulder Arthroscopy Drape, 162 in. x 103 in. / 411 cm x 261 cm	06806517SD002CE
42427	Percutaneous Nephrolithotomy Drape (PCNL) 118 in. x 72 in. / 299 cm x 182 cm	06806517SD002CE
47617	Medium Drape, 73 in. x 40 in. / 185 cm x 101 cm	06806517SD002CE
47628	Three-Quarter Drape, 55 in. x 76 in. / 139 cm x 193 cm	06806517SD002CE
47630	X-Large Drape, 76 in. x 96 in. / 193 cm x 243 cm	06806517SD002CE
48057	U-Drape, 76 in. x 120 in./193 cm x 304 cm	06806517SD002CE
48058	Universal Extremity Drape, 90 in. x 124 in./228 cm x 314 cm	06806517SD002CE
48062	Ortho Bar Drape, 100 in. x 60 in./254 cm x 152 cm)	06806517SD002CE
48065	ORTHOARTS* Lower Extremity Drape, 114 in. x 88 in. x 126 in. / 290 cm x 224 cm x 320 cm	06806517SD002CE
48068	Laparotomy Drape with Pouches, 100 in. x 72 in. x 124 in. / 254 cm x 182 cm x 314 cm	06806517SD002CE
48072	Lower Extremity Drape, 88 in. x 131 in. / 224 cm x 333 cm	06806517SD002CE
48075	ORTHOARTS* Bar Drape, 112 in. x 72 in. / 284 cm x 183 cm	06806517SD002CE
48087	Laparotomy Drape with Incise, 100 in. x 72 in. x 120 in. / 254 cm x 183 cm x 305 cm	06806517SD002CE
48097	Laparotomy Drape with Troughs	06806517SD002CE
77450	Hand Drape	06806517SD002CE
77723	Vertical Isolation Drape, 126 in. x 90 in. / 320 cm x 228 cm	06806517SD002CE
89023	Medium Drape with Tape	06806517SD002CE
89062	Craniotomy Drape with Pouch	06806517SD002CE
89066	Beach Chair Shoulder Drape with Attachable Fluid Collection Pouch	06806517SD002CE
89111	Medium Drape	06806517SD002CE
89119	Laparoscopy "T" Drape	06806517SD002CE
89121	Large Drape	06806517SD002CE

89131	X-Large Drape	06806517SD002CE
89141	Three-Quarter Drape	06806517SD002CE
89207	Minor Procedure Fenestrated Drape, 48 in. x 60 in./121 cm x 152 cm	06806517SD002CE
89209	Minor Procedure Fenestrated Drape, 76 in. x 124 in. / 193 cm x 314 cm	06806517SD002CE
89219	Laparoscopy/Pelviscopy Drape with Fluid Collection Pouch, 112 in. x 30 in. x 124 in. / 284 cm x 76 cm x 314 cm	06806517SD002CE
89222	Laparoscopy/Pelviscopy Drape	06806517SD002CE
89224	Laparoscopy/Pelviscopy Drape with Attached Leggings	06806517SD002CE
89227	Chest Drape	06806517SD002CE
89229	Laparoscopic Cholecystectomy Drape with Armboard Covers	06806517SD002CE
89233	Laparoscopic Abdominal Drape	06806517SD002CE
89241	Pediatric Laparotomy Drape	06806517SD002CE
89255	Thyroid Drape	06806517SD002CE
89265	Knee Arthroscopy Drape	06806517SD002CE
89267	ORTHOARTS* Knee Arthroscopy Drape	06806517SD002CE
89271	Upper Extremity Drape	06806517SD002CE
89272	ORTHOARTS* Hand Drape, 114 in. x 150 in. x 62 in. / 289 cm x 381 cm x 157 cm	06806517SD002CE
89274	ORTHOARTS* Shoulder Split Drape (148 cm x 240 cm)	06806517SD002CE
89275	ORTHOARTS* Body Split Drape	06806517SD002CE
89276	Lower Extremity Drape	06806517SD002CE
89278	ORTHOARTS* Lower Extremity Drape	06806517SD002CE
89279	Universal Extremity Drape	06806517SD002CE
89281	Transverse Laparotomy Drape	06806517SD002CE
89291	Bilateral Limb Drape	06806517SD002CE
89301	U-Drape	06806517SD002CE
89304	Basic Ophthalmic Drape	06806517SD002CE
89305	Basic Ophthalmic Drape with Fenestration	06806517SD002CE
89311	Large Ortho U-Drape	06806517SD002CE
89331	Impervious Split Drape	06806517SD002CE
89333	Large Impervious Split Drape, 60 in. x 81 in./152 cm x 206 cm	06806517SD002CE
89343	Standard Absorbent Drape 36 in. x 36 in./91 cm x 91 cm	06806517SD002CE
89345	ORTHOARTS* Hip Drape with Pockets, 114 in. x 88 in. x 126 in. / 289 cm x 223 cm x 320 cm	06806517SD002CE
89346	ORTHOARTS* Hip Drape	06806517SD002CE
89347	ORTHOARTS* U-Drape	06806517SD002CE
89349	Hip Drape with Clear Leg Pockets, 116 in. x 88 in. x 136 in. / 294 cm x 223 cm x 345 cm	06806517SD002CE
89354	OCUARTS* Ophthalmic Drape with Pouch	06806517SD002CE
89356	OCUARTS* Full Body Ophthalmic Drape	06806517SD002CE
89358	EENT Split Drape	06806517SD002CE
89363	Utility Drape with Tape, 35 in. x 35 in. / 90 cm x 90 cm	06806517SD002CE

89368	Pacemaker Drape, 87 in. x 135 in. / 221 cm x 343 cm	06806517SD002CE
89371	Knee Arthroscopy Drape with Armboard Covers, 114 in. x 88 in. x 124 in./290 cm x 224 cm x 315 cm	06806517SD002CE
89372	Impervious Femoral Angiography Drape with Pocket, 87 in. x 135 in. / 221 cm x 343 cm	06806517SD002CE
89375	Bar Drape, 106 in. x 62 in. / 269 cm x 157 cm	06806517SD002CE
89380	Bilateral Limb Drape with Armboard Covers, 116 in. x 88 in. x 144 in. / 294 cm x 223 cm x 365 cm	06806517SD002CE
89421	Fenestrated EENT Drape	06806517SD002CE
89431	Head Drape	06806517SD002CE
89438	Head Drape 41 in. x 32 in. / 104 cm x 81 cm	06806517SD002CE
89451	Cardiovascular Split Drape	06806517SD002CE
89453	CVARTS* Bilateral Under-Leg/Perineal Drape	06806517SD002CE
89471	Brachial Angiography Drape	06806517SD002CE
89492	ORTHOARTS* Shoulder Arthroscopy Drape	06806517SD002CE
89501	Neuro Split Drape	06806517SD002CE
89525	Cesarean/Abdominal Fluid Collection Drape	06806517SD002CE
89526	Cesarean/Abdominal Fluid Collection Drape with Fenestrated Incise Area	06806517SD002CE
89528	C-Section Fluid Collection Drape II with Fenestrated Incise	06806517SD002CE
89529	C-Section Fluid Collection Drape II with Full Incise, 100 in. x 72 in. x 120 in. / 254 cm x 183 cm x 305 cm	06806517SD002CE
89548	Cystoscopy "T" Drape, 62 in. x 40 in. x 101 in. / 157 cm x 101 cm x 256 cm	06806517SD002CE
89583	BASICS* Radial-Femoral Angiography Drape with Dual Windows, 94 in. x 149 in. / 240 cm x 380 cm	06806517SD002CE
89636	BASICS* Epidural Drape with Tape 20 in. x 30 in./50 cm x 75 cm	06806517SD002CE
89705	Femoral Angiography Drape with Window	06806517SD002CE
89706	Femoral Angiography Drape with Dual Windows	06806517SD002CE
89709	Extra-Long Femoral Angiography Drape with Single Window	06806517SD002CE
89711	Extra-Long Femoral Angiography Drape with Dual Windows	06806517SD002CE
89749	Impervious Extra-Long Femoral Angiography Drape, 87 in. x 135 in. / 221 cm x 343 cm	06806517SD002CE
89751	Impervious Interventional Femoral Angiography Drape, 87 in. x 135 in. / 221 cm x 343 cm	06806517SD002CE
89828	Absorbent Drape with Tape, Small, 22 in. x 24 in. / 57 cm x 60 cm	06806517SD002CE
89832	Radial U-Drape	06806517SD002CE
89835	CV Line Drape	06806517SD002CE