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: Patient surgical drape, single-use
CND Code:	T0201: Surgical Drapes
Intended Use	Surgical Drapes are used in the surgical operating environment to create a sterile field around the operative site and to cover areas of the body and/or operating room equipment that may or may not be involved in the surgical procedure.
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 1220 Old Alpharetta Road Suite 320 Alpharetta, Georgia (GA) 30005 United States of America
Manufacturer SRN :	US-MF-000043924
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN:	IE-AR-000003110
Basic 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

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: Caitlin Senter
Title: Director, Global Regulatory Affairs
Address: O&M Halyard, Inc.
1220 Old Alpharetta Road Suite 320
Alpharetta, Georgia (GA) 30005
United States of America

Date: 09/08/2025

ATTACHMENT A: Product Codes and Descriptions for Sterile Surgical Drapes

No.	Global SKU	Product Description	Basic UDI-DI
1	29219	Extra Long ORTHOARTS* Lower Extremity Drape 150 in. x 88 in. x 114 in./381 cm x 223 cm x 289 cm	06806517SD002CE
2	29221	Universal Spine Drape 112 x 99 x 138 in.	06806517SD002CE
3	29222	Extra Long Lower Extremity Drape 144 in. x 80 in. x 114 in./365 cm x 203 cm x 289 cm	06806517SD002CE
4	29229	Pacemaker Drape with Fenestrated Incise 135 in. x 91 in. / 342 cm x 231 cm	06806517SD002CE
5	29232	Pediatric Femoral Angiography Drape 158 in. x 76.5 in. /401 cm x 194 cm	06806517SD002CE
6	29236	Bariatric Drape with Clear Pouches	06806517SD002CE
7	29283	Robotic Abdominal / Pelvic Drape, 160 in. x 104 in. / 406 cm x 264 cm	06806517SD002CE
8	31439	CVC Drape with Top Perforation Full Body, Single Fenestration, 110 in. x 68 in. / 279 cm x 172 cm	06806517SD002CE
9	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
10	34902	Bottom Drape	06806517SD002CE
11	34904	Side Drape	06806517SD002CE
12	34906	Top Drape	06806517SD002CE
13	36930	ORTHOARTS* Extra Long Knee Arthroscopy Drape, 176 in. x 92 in. x 116 in. / 447 cm x 233 cm x 294 cm	06806517SD002CE
14	36931	Orthopedic Split "T" Drape, 135 in. x 83 in. x 117 in. / 342 cm x 210 cm x 297 cm	06806517SD002CE
15	36932	ORTHOARTS* Beach Chair Shoulder Arthroscopy Drape, 162 in. x 103 in. / 411 cm x 261 cm	06806517SD002CE
16	42427	Percutaneous Nephrolithotomy Drape (PCNL) 118 in. x 72 in. / 299 cm x 182 cm	06806517SD002CE
17	47614	Half Drape - Sterile, 40 in. x 58 in.	06806517SD002CE
18	47617	Medium Drape, 73 in. x 40 in. / 185 cm x 101 cm	06806517SD002CE
19	47622	Large Drape - Sterile, 55 in. x 76 in.	06806517SD002CE
20	47628	Three-Quarter Drape, 55 in. x 76 in. / 139 cm x 193 cm	06806517SD002CE
21	47630	X-Large Drape, 76 in. x 96 in. / 193 cm x 243 cm	06806517SD002CE
22	48057	U-Drape, 76 in. x 120 in./193 cm x 304 cm	06806517SD002CE
23	48058	Universal Extremity Drape, 90 in. x 124 in./228 cm x 314 cm	06806517SD002CE
24	48062	Ortho Bar Drape, 100 in. x 60 in./254 cm x 152 cm)	06806517SD002CE
25	48065	ORTHOARTS* Lower Extremity Drape, 114 in. x 88 in. x 126 in. / 290 cm x 224 cm x 320 cm	06806517SD002CE
26	48068	Laparotomy Drape with Pouches, 100 in. x 72 in. x 124 in. / 254 cm x 182 cm x 314 cm	06806517SD002CE
27	48072	Lower Extremity Drape, 88 in. x 131 in. / 224 cm x 333 cm	06806517SD002CE
28	48075	ORTHOARTS* Bar Drape, 112 in. x 72 in. / 284 cm x 183 cm	06806517SD002CE
29	48087	Laparotomy Drape with Incise, 100 in. x 72 in. x 120 in. / 254 cm x 183 cm x 305 cm	06806517SD002CE

No.	Global SKU	Product Description	Basic UDI-DI
30	48097	Laparotomy Drape with Troughs	06806517SD002CE
31	48970	Radial Femoral Angiography Drape	06806517SD002CE
32	48972	BASICS* Utility Drape with Tape	06806517SD002CE
33	49041	Clear U-Pouch 35 in. x 30 in. / 89 cm x 76 cm	06806517SD002CE
34	49042	Clear Irrigation Pouch 19 in. x 23 in. / 50 cm x 60 cm	06806517SD002CE
35	49043	Clear Instrument Pouch 19 in. x 23 in. / 50 cm x 60 cm	06806517SD002CE
36	49044	Clear Instrument Pouch 10 in. x 18 in. / 25 cm x 47 cm	06806517SD002CE
37	49045	Clear Instrument Pouch 13 in. x 15 in. / 33 cm x 38 cm	06806517SD002CE
38	49046	Clear Towel Drape 17 in. x 11 in. / 45 cm x 30 cm	06806517SD002CE
39	49047	Clear Towel Drape 17 in. x 23 in. / 45 cm x 60 cm	06806517SD002CE
40	49048	Clear U-Drape With Aperture 47 in. x 51 in. / 120 cm x 130 cm	06806517SD002CE
41	49049	Clear U-Drape With Aperture 47 in. x 71 in. / 120 cm x 180 cm	06806517SD002CE
42	49050	Clear Incise Drape 15 in. x 15 in. / 40 cm x 40 cm	06806517SD002CE
43	49082	CV SPLIT DRAPE	06806517SD002CE
44	49083	PICC DRAPE WITH TOP AND SIDE PERFORATIONS, FULL BODY, DUAL FENESTRATION	06806517SD002CE
45	49084	NEPHROSCOPY DRAPE	06806517SD002CE
46	49085	FEMORAL ANGIOGRAPHY DRAPE WITH POUCHES	06806517SD002CE
47	49086	EXTRA LONG FEMORAL ANGIOGRAPHY DRAPE	06806517SD002CE
48	49087	CVARTS* HEAVYDUTY UNIVERSAL DRAPE	06806517SD002CE
49	49108	BASICS* Three-Quarter Drape 55 IN. X 76 IN. / 139 CM X 193 CM	06806517SD002CE
50	49110	BASICS* Minor Procedure Fenestrated Drape 30 IN. X 30 IN. / 76 CM X 76 CM	06806517SD002CE
51	49118	BASICS* Minor Procedure Fenestrated Drape 48 IN. X 60 IN. / 121 CM X 152 CM	06806517SD002CE
52	49160	OVERHEAD TABLE COVER DRAPE WITH EXTENSION	06806517SD002CE
53	59705	Absorbent Underleg Drape 62 in. x 93 in./158 cm x 235 cm	06806517SD002CE
54	76291	Utility Drape with Tape, 62 in. x 95 in./157 cm x 241 cm	06806517SD002CE
55	76293	Utility Drape with Full Length Tape, 35 in. x 62 in./90 cm x 157 cm	06806517SD002CE
56	77382	Pediatric Femoral Angiography Drape, 76 in. x 122 in./193 cm x 310 cm	06806517SD002CE
57	77450	Hand Drape	06806517SD002CE
58	77466	Craniotomy Drape with Pouch, 122 in. x 134 in./309 cm x 340 cm	06806517SD002CE
59	77723	Vertical Isolation Drape, 126 in. x 90 in. / 320 cm x 228 cm	06806517SD002CE
60	77776	Femoral Angiography Drape with Dual Windows, 88.5 in. x 130 in./225 cm x 330 cm	06806517SD002CE
61	77873	Eye Drape with Incise, 55 in. x 76 in./139 cm x 193 cm	06806517SD002CE
62	86357	Cardiovascular Bilateral Underleg Drapes - Sterile, 76 x 104 in	06806517SD002CE
63	89010	ENT Drape, Fenestrated, 76 in. x 90 in./193 cm x 228 cm	06806517SD002CE
64	89023	Medium Drape with Tape	06806517SD002CE
65	89048	Femoral Angiography Drape with Single Window, 82 in. x 130 in. / 208 cm x 330 cm	06806517SD002CE

No.	Global SKU	Product Description	Basic UDI-DI
66	89062	Craniotomy Drape with Pouch	06806517SD002CE
67	89066	Beach Chair Shoulder Drape with Attachable Fluid Collection Pouch	06806517SD002CE
68	89070	Shoulder Arthroscopy Drape, 160 in. x 102 in./406 cm x 259 cm	06806517SD002CE
69	89111	Medium Drape	06806517SD002CE
70	89119	Laparoscopy "T" Drape	06806517SD002CE
71	89121	Large Drape	06806517SD002CE
72	89131	X-Large Drape	06806517SD002CE
73	89141	Three-Quarter Drape	06806517SD002CE
74	89204	Gyn/Urology Drape with Attached Fluid Collection Pouch, 112 in. x 63 in. x 131 in./284 cm x 160 cm x 333 cm	06806517SD002CE
75	89206	Minor Procedure Fenestrated Drape 30 in. x 30 in. / 76 cm x 76 cm	06806517SD002CE
76	89207	Minor Procedure Fenestrated Drape, 48 in. x 60 in./121 cm x 152 cm	06806517SD002CE
77	89208	Minor Procedure Fenestrated Drape 48 in. x 60 in./121 cm x 152 cm	06806517SD002CE
78	89209	Minor Procedure Fenestrated Drape, 76 in. x 124 in. / 193 cm x 314 cm	06806517SD002CE
79	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
80	89222	Laparoscopy/Pelviscopy Drape	06806517SD002CE
81	89224	Laparoscopy/Pelviscopy Drape with Attached Leggings	06806517SD002CE
82	89227	Chest Drape	06806517SD002CE
83	89229	Laparoscopic Cholecystectomy Drape with Armboard Covers	06806517SD002CE
84	89233	Laparoscopic Abdominal Drape	06806517SD002CE
85	89241	Pediatric Laparotomy Drape	06806517SD002CE
86	89251	Thyroid Drape, 76 in. x 120 in./193 cm x 305 cm	06806517SD002CE
87	89255	Thyroid Drape	06806517SD002CE
88	89265	Knee Arthroscopy Drape	06806517SD002CE
89	89267	ORTHOARTS* Knee Arthroscopy Drape	06806517SD002CE
90	89271	Upper Extremity Drape	06806517SD002CE
91	89272	ORTHOARTS* Hand Drape, 114 in. x 150 in. x 62 in. / 289 cm x 381 cm x 157 cm	06806517SD002CE
92	89274	ORTHOARTS* Shoulder Split Drape (148 cm x 240 cm)	06806517SD002CE
93	89275	ORTHOARTS* Body Split Drape	06806517SD002CE
94	89276	Lower Extremity Drape	06806517SD002CE
95	89278	ORTHOARTS* Lower Extremity Drape	06806517SD002CE
96	89279	Universal Extremity Drape	06806517SD002CE
97	89281	Transverse Laparotomy Drape	06806517SD002CE
98	89282	Laparotomy Drapes - Sterile, 100 x 72 x 120 in.	06806517SD002CE
99	89291	Bilateral Limb Drape	06806517SD002CE
100	89293	Utility Drapes with Tape, 35 in. x 35 in./90 cm x 90 cm	06806517SD002CE
101	89301	U-Drape	06806517SD002CE

No.	Global SKU	Product Description	Basic UDI-DI
102	89304	Basic Ophthalmic Drape	06806517SD002CE
103	89305	Basic Ophthalmic Drape with Fenestration	06806517SD002CE
104	89311	Large Ortho U-Drape	06806517SD002CE
105	89313	Utility Drape with Tape, 30 in. x 30 in./76 cm x 76 cm	06806517SD002CE
106	89331	Impervious Split Drape	06806517SD002CE
107	89333	Large Impervious Split Drape, 60 in. x 81 in./152 cm x 206 cm	06806517SD002CE
108	89343	Standard Absorbent Drape 36 in. x 36 in./91 cm x 91 cm	06806517SD002CE
109	89345	ORTHOARTS* Hip Drape with Pockets, 114 in. x 88 in. x 126 in. / 289 cm x 223 cm x 320 cm	06806517SD002CE
110	89346	ORTHOARTS* Hip Drape	06806517SD002CE
111	89347	ORTHOARTS* U-Drape	06806517SD002CE
112	89348	ORTHOARTS* Bar Drape 112 x 72 in.	06806517SD002CE
113	89349	Hip Drape with Clear Leg Pockets, 116 in. x 88 in. x 136 in. / 294 cm x 223 cm x 345 cm	06806517SD002CE
114	89352	EENT Split Drape 76 in. x 124 in./193 cm x 314cm	06806517SD002CE
115	89353	Utility Drape, 35 in. x 35 in./90 cm x 90 cm	06806517SD002CE
116	89354	OCUARTS* Ophthalmic Drape with Pouch	06806517SD002CE
117	89356	OCUARTS* Full Body Ophthalmic Drape	06806517SD002CE
118	89358	EENT Split Drape	06806517SD002CE
119	89363	Utility Drape with Tape, 35 in. x 35 in. / 90 cm x 90 cm	06806517SD002CE
120	89368	Pacemaker Drape, 87 in. x 135 in. / 221 cm x 343 cm	06806517SD002CE
121	89371	Knee Arthroscopy Drape with Armboard Covers, 114 in. x 88 in. x 124 in./290 cm x 224 cm x 315 cm	06806517SD002CE
122	89372	Impervious Femoral Angiography Drape with Pocket, 87 in. x 135 in. / 221 cm x 343 cm	06806517SD002CE
123	89375	Bar Drape, 106 in. x 62 in. / 269 cm x 157 cm	06806517SD002CE
124	89380	Bilateral Limb Drape with Armboard Covers, 116 in. x 88 in. x 144 in. / 294 cm x 223 cm x 365 cm	06806517SD002CE
125	89381	Ortho Bar Drape 100 x 60 in.	06806517SD002CE
126	89411	Obstetric Under Buttocks Drapes - Sterile, 29.5 x 44 in.	06806517SD002CE
127	89413	Obstetric Under Buttocks Drapes - Sterile, 40 x 46 in.	06806517SD002CE
128	89415	Obstetric Under Buttocks Drapes - Sterile, 40 x 44 in.	06806517SD002CE
129	89421	Fenestrated EENT Drape	06806517SD002CE
130	89431	Head Drape	06806517SD002CE
131	89438	Head Drape 41 in. x 32 in. / 104 cm x 81 cm	06806517SD002CE
132	89451	Cardiovascular Split Drape	06806517SD002CE
133	89452	CVARTS* Cardiovascular Split Drapes - Sterile, 108 x 80 x 124 in.	06806517SD002CE
134	89453	CVARTS* Bilateral Under-Leg/Perineal Drape	06806517SD002CE
135	89471	Brachial Angiography Drape	06806517SD002CE
136	89492	ORTHOARTS* Shoulder Arthroscopy Drape	06806517SD002CE
137	89501	Neuro Split Drape	06806517SD002CE
138	89525	Cesarean/Abdominal Fluid Collection Drape	06806517SD002CE

No.	Global SKU	Product Description	Basic UDI-DI
139	89526	Cesarean/Abdominal Fluid Collection Drape with Fenestrated Incise Area	06806517SD002CE
140	89528	C-Section Fluid Collection Drape II with Fenestrated Incise	06806517SD002CE
141	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
142	89548	Cystoscopy "T" Drape, 62 in. x 40 in. x 101 in. / 157 cm x 101 cm x 256 cm	06806517SD002CE
143	89583	BASICS* Radial-Femoral Angiography Drape with Dual Windows, 94 in. x 149 in. / 240 cm x 380 cm	06806517SD002CE
144	89584	BASICS* Under Buttocks Drape with Graduated Fluid Collection Pouch, 40 in. x 44	06806517SD002CE
145	89636	BASICS* Epidural Drape with Tape 20 in. x 30 in./50 cm x 75 cm	06806517SD002CE
146	89638	BASICS* Fenestrated Drape30 in. x 30 in./75cm x 75 cm	06806517SD002CE
147	89670	BASICS* Fenestrated Drape 35 in. x 35 in./90 cm x 90 cm	06806517SD002CE
148	89671	BASICS* Fenestrated Drape with Tape 35 in. x 35 in./90 cm x 90 cm	06806517SD002CE
149	89672	BASICS* Half Drape, 44 in. x 59 in. / 112 cm x 150 cm - Sterile	06806517SD002CE
150	89673	BASICS* Hand & Foot Drape, 70 in. x 118 in. / 180 cm x 300 cm	06806517SD002CE
151	89674	BASICS* Large Drape, 59 in. x 75 in./150 cm x 193 cm - Sterile	06806517SD002CE
152	89675	BASICS* Perineal Cover Drape with Tape 6 in. x 16 in./15 cm x 40 cm	06806517SD002CE
153	89676	BASICS* Utility Drape with Tape 59 in. x 94 in./150 cm x 240 cm	06806517SD002CE
154	89677	BASICS* Utility Drape with Tape 29 in. x 29 in./75 cm x 75 cm	06806517SD002CE
155	89678	BASICS* Utility Drape 35 in. x 35 in./90 cm x 90 cm	06806517SD002CE
156	89679	BASICS* Utility Drape with Tape 35 in. x 35 in./90 cm x 90 cm	06806517SD002CE
157	89680	BASICS* Variable Fenestrated Drape with Tape 29 in. x 39 in./75 cm x 100 cm	06806517SD002CE
158	89705	Femoral Angiography Drape with Window	06806517SD002CE
159	89706	Femoral Angiography Drape with Dual Windows	06806517SD002CE
160	89709	Extra-Long Femoral Angiography Drape with Single Window	06806517SD002CE
161	89711	Extra-Long Femoral Angiography Drape with Dual Windows	06806517SD002CE
162	89714	Femoral Angiography Drape, 76 in. x 110 in.-193 cm x 279 cm	06806517SD002CE
163	89715	Femoral Angiography Drape with Window, 83 in x 115 in. - 211 cm x 292 cm	06806517SD002CE
164	89716	Femoral Angiography Drape with Dual Windows, 88.5 in. x 115 in. / 224 cm x 292 cm	06806517SD002CE
165	89749	Impervious Extra-Long Femoral Angiography Drape, 87 in. x 135 in. / 221 cm x 343 cm	06806517SD002CE
166	89751	Impervious Interventional Femoral Angiography Drape, 87 in. x 135 in. / 221 cm x 343 cm	06806517SD002CE
167	89828	Absorbent Drape with Tape, Small, 22 in. x 24 in. / 57 cm x 60 cm	06806517SD002CE
168	89832	Radial U-Drape	06806517SD002CE
169	89835	CV Line Drape	06806517SD002CE