EC Declaration of Conformity

Name of Products:	Surgical Drapes
Product Codes:	See **Attachment A**
UMDNS Code:	15646 (Drapes, Surgical, Disposable)
GMDN Code:	47783 (General-purpose surgical drape, single-use, sterile)
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116, USA
EU Authorized Representative:	Arc Royal Virginia Road Kells, Co Meath, Ireland
Product Standards:	BS EN 13795:2011
Start of CE:	See **Attachment A**
Conformity Assessment Route:	Annex VII and Annex V (for sterile products only)
Device Classification, Rules:	Class I Sterile, Rule 1 per Annex IX
CE certificate number:	CE **698961**
Notified Body:	BSI (2797)
Quality System Certificate:	FM 697013 (BSI)

I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

All supporting documentation that contains proof of compliance to the aforementioned Directive(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:

Name: Steve Dowdley
Title: Regulatory Affairs Associate Director
O&M Halyard, Inc.
Date: September 8, 2020

Attachment A (Product List)

This attachment specifies the products included in the above referenced Declaration of Conformity.

Product Code	Product Description	Sterilization	Start of CE Mark
14364	HALYARD BASICS* Epidural Fenestrated Drape with Tape	Sterile-EO	23-Mar-2015
29149	CVS Full Body Coverage Drape, Single Fenestration	Sterile-EO	23-Mar-2015
29155	PICC Full Body Drape, Dual Fenestration	Sterile-EO	23-Mar-2015
29219	ORTHOARTS* Extra-Long Lower Extremity Drape, 150 in x 88 in x 114 in/381 cm x 223 cm x 289 cm	Sterile-EO	23-Mar-2015
29221	Universal Spine Drape	Sterile-EO	23-Mar-2015
29222	Extra Long Lower Extremity Drape 144 in. x 80 in. x 114 in./ 365 cm x 203 cm x 289 cm	Sterile-EO	23-Mar-2015
29225	Femoral Angiography / IJ Access Combination Drape	Sterile-EO	23-Mar-2015
29227	Femoral Angiography Drape with Side and Bottom Windows	Sterile-EO	23-Mar-2015
29229	Pacemaker Drape with Fenestrated Incise	Sterile-EO	23-Mar-2015
29232	Pediatric Femoral Angiography Drape	Sterile-EO	23-Mar-2015
29234	CVARTS* ClearView Split Drape with Large Clear Anesthesia Screen and Pockets	Sterile-EO	23-Mar-2015
29236	Bariatric Drape with Clear Pouches	Sterile-EO	23-Mar-2015
29240	Laparoscopic / Lithotomy Drape with Clear Instrument Pouches	Sterile-EO	23-Mar-2015
29248	Chest U and Bar Drape Pack	Sterile-EO	23-Mar-2015
29283	Robotic Abdominal/Pelvic Drape	Sterile-EO	23-Mar-2015
31439	CVC Drape with Top Perforation Full Body, Single Fenestration 110 in. x 68 in. / 279 cm x 172 cm	Sterile-EO	23-Mar-2015
31446	PICC Drape with Side Perforations Full Body, Dual Fenestration, 110 in. x 78 in. / 279 cm x 198 cm	Sterile-EO	23-Mar-2015
33415	Vertical Isolation Drape 110 in. x 126 in. / 279 cm x 320 cm	Sterile-EO	23-Mar-2015
34902	Bottom Drape	Sterile-EO	23-Mar-2015
34904	Side Drape	Sterile-EO	23-Mar-2015
34906	Top Drape	Sterile-EO	23-Mar-2015
36930	ORTHOARTS* Extra Long Knee Arthroscopy Drape 176 in. x 92 in. x 116 in. /447 cm x 233 cm x 294 cm	Sterile-EO	12-Aug-2016
36931	Orthopedic Split “T” Drape 135 in. x 83 in. x 117 in. /342 cm x 210 cm x 297 cm	Sterile-EO	12-Aug-2016
36932	ORTHOARTS* Beach Chair Shoulder Arthroscopy Drape 162 in. x 103 in. / 411 cm x 261 cm	Sterile-EO	12-Aug-2016
42427	Percutaneous Nephrolithotomy Drape (PCNL) 118 in. x 72 in./299 cm x 182 cm	Sterile-EO	12-Aug-2016

Product Code	Product Description	Sterilization	Start of CE Mark
47614	Half Drape, 58 in. x 40 in. / 147 cm x 101 cm	Sterile-EO	11-Sept-2019
47617	Medium Drape, 73 in. x 40 in. / 185 cm x 101 cm	Sterile-EO	11-Sept-2019
47622	Large Drape	Sterile-EO	11-Sept-2019
47628	Three-Quarter Drape, 55 in. x 76 in. / 139 cm x 193 cm	Sterile-EO	11-Sept-2019
47629	Three-Quarter Drape, 55 in. x 76 in. / 139 cm x 193 cm - Handi-Bin	Sterile-EO	11-Sept-2019
47630	X-Large Drape, 76 in. x 96 in. / 193 cm x 243 cm	Sterile-EO	11-Sept-2019
47631	X-Large Drape, 76 in. x 96 in. / 193 cm x 243 cm	Sterile-EO	11-Sept-2019
59705	Absorbent Underleg Drape 62 in. x 93 in./158 cm x 235 cm	Sterile-EO	23-Mar-2015
59710	Ophthalmic Drape	Sterile-EO	23-Mar-2015
66886	Pediatric Laparotomy Drape	Sterile-EO	23-Mar-2015
76291	Utility Drape with Tape 62 in. x 95 in./157 cm x 241 cm	Sterile-EO	23-Mar-2015
76293	Utility Drape with Full Length Tape 35 in. x 62 in./ 90 cm x 157 cm	Sterile-EO	23-Mar-2015
77353	C-Section Drape with Attached Leggings 116 in. x 88 in. x 125 in./295 cm x 224 cm x 318 cm	Sterile-EO	23-Mar-2015
77382	Pediatric Femoral Angiography Drape 76 in. x 122 in./193 cm x 310 cm	Sterile-EO	23-Mar-2015
77450	Hand Drape	Sterile-EO	23-Mar-2015
77466	Craniotomy Drape with Pouch	Sterile-EO	23-Mar-2015
77707	Ophthalmic Drape with Dual Pouches 76 in x 55 in./ 193 cm x 140 cm	Sterile-EO	23-Mar-2015
77723	Vertical Isolation Drape	Sterile-EO	23-Mar-2015
77725	ORTHOARTS* U-Drape	Sterile-EO	23-Mar-2015
77776	Femoral Angiography Drape with Dual Windows 88.5 in. x 130 in./225 cm x 330 cm	Sterile-EO	23-Mar-2015
77873	Eye Drape with Incise 55 in. x 76 in./140 cm x 193 cm	Sterile-EO	23-Mar-2015
86357	CV Incise drape	Sterile-EO	23-Mar-2015
88660	KC100, Film Split Drape	Sterile-EO	23-Mar-2015
89010	ENT Drape, Fenestrated	Sterile-EO	23-Mar-2015
89016	Lower Extremity Drape	Sterile-EO	23-Mar-2015
89023	Medium Drape with Tape	Sterile-EO	23-Mar-2015
89048	Femoral Angiography Drape with Window, 83 in. x 130 in./ 210 cm x 330 cm	Sterile-EO	23-Mar-2015
89062	Craniotomy Drape with Pouch	Sterile-EO	23-Mar-2015
89066	Beach Chair Shoulder Drape with Attachable Fluid Collection Pouch	Sterile-EO	23-Mar-2015
89070	Shoulder Arthroscopy Drape 160 in. x 102 in./406 cm x 259 cm	Sterile-EO	23-Mar-2015
89101	Half Drape	Sterile-EO	23-Mar-2015
89111	Medium drape	Sterile-EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
89119	Laparoscopy “T” Drape	Sterile-EO	23-Mar-2015
89121	Large Drape	Sterile-EO	23-Mar-2015
89131	X-Large Drape	Sterile-EO	23-Mar-2015
89141	Three-Quarter Drape	Sterile-EO	23-Mar-2015
89203	Lithotomy Drape with Attached Leggings	Sterile-EO	23-Mar-2015
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	Sterile-EO	23-Mar-2015
89206	Minor Procedure Fenestrated drape	Sterile-EO	23-Mar-2015
89207	Minor Procedure Fenestrated Drape 48 in. x 60 in./ 122 cm x 152 cm	Sterile-EO	23-Mar-2015
89208	Minor Procedure Fenestrated Drape 48 in. x 60 in./ 121 cm x 152 cm	Sterile-EO	23-Mar-2015
89209	Minor Procedure Fenestrated Drape 76 in. x 124 in./ 193 cm x 314 cm	Sterile-EO	23-Mar-2015
89219	Laparoscopy/Pelviscopy Drape with Fluid Collection Pouch 112 in. x 30 in. x 124 in./284 cm x 76 cm x 314 cm	Sterile-EO	23-Mar-2015
89222	Laparoscopy / Pelviscopy Drape	Sterile-EO	23-Mar-2015
89224	Laparoscopy / Pelviscopy Drape, with Attached Leggings	Sterile-EO	23-Mar-2015
89227	Chest Drape	Sterile-EO	23-Mar-2015
89229	Laparoscopic Cholecystectomy Drape with Armboard Covers	Sterile-EO	23-Mar-2015
89233	Laparoscopic Abdominal drape	Sterile-EO	23-Mar-2015
89236	Breast Drape 100 in. x 76 in. x 124in./ 254 cm x 193 cm x 314 cm	Sterile-EO	23-Mar-2015
89241	Pediatric Laparotomy Drape	Sterile-EO	23-Mar-2015
89251	Thyroid Drape	Sterile-EO	23-Mar-2015
89255	Thyroid Drape	Sterile-EO	23-Mar-2015
89265	Knee Arthroscopy Drape	Sterile-EO	23-Mar-2015
89267	ORTHOARTS* Knee Arthroscopy Drape	Sterile-EO	23-Mar-2015
89271	Upper Extremity Drape	Sterile-EO	23-Mar-2015
89272	ORTHOARTS* Hand Drape 76 in. x 150 in. / 193 cm x 381 cm	Sterile-EO	23-Mar-2015
89274	Orthoarts* Shoulder Split Drape	Sterile-EO	23-Mar-2015
89275	ORTHOARTS* Body Split Drape 88 in. x 116 in./ 224 cm x 295 cm	Sterile-EO	23-Mar-2015
89276	Lower Extremity Drape	Sterile-EO	23-Mar-2015
89278	ORTHOARTS* Lower Extremity Drape	Sterile-EO	23-Mar-2015
89279	Universal Extremity Drape	Sterile-EO	23-Mar-2015
89281	Transverse Laparotomy Drape	Sterile-EO	23-Mar-2015
89282	Laparotomy Drape 100 in x 72 in x 120 in	Sterile-EO	23-Mar-2015
89291	Bilateral Limb Drape	Sterile-EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
89293	Utility drapes with Tape	Sterile-EO	23-Mar-2015
89301	U-Drape	Sterile-EO	23-Mar-2015
89304	Basic Ophthalmic Drape	Sterile-EO	23-Mar-2015
89305	Basic Ophthalmic Drape with Oval Fenestration	Sterile-EO	23-Mar-2015
89311	Large Ortho U-Drape	Sterile-EO	23-Mar-2015
89313	Utility Drape with Tape	Sterile-EO	23-Mar-2015
89331	Impervious Split Drape	Sterile-EO	23-Mar-2015
89333	Large Impervious Split Drape, 60 in. x 81 in./152 cm x 206 cm	Sterile-EO	23-Mar-2015
89343	Standard Absorbent Drape 36 in. x 36 in./91 cm x 91 cm	Sterile-EO	23-Mar-2015
89345	ORTHOARTS* Hip Drape with Pockets	Sterile-EO	23-Mar-2015
89346	ORTHOARTS* Hip Drape	Sterile-EO	23-Mar-2015
89347	ORTHOARTS* U-Drape	Sterile-EO	23-Mar-2015
89348	ORTHOARTS* Bar Drape	Sterile-EO	23-Mar-2015
89349	Hip Drape with Clear Leg Pockets	Sterile-EO	23-Mar-2015
89352	EENT Split Drape 76 in. x 124 in./193 cm x 314 cm	Sterile-EO	23-Mar-2015
89353	Utility Drape 35 in. x 35 in./90 cm x 90 cm	Sterile-EO	23-Mar-2015
89354	OCUARTS* Ophthalmic Drape with Pouch	Sterile-EO	23-Mar-2015
89356	OCUARTS* Full Body Ophthalmic Drape	Sterile-EO	23-Mar-2015
89358	EENT Split Drape	Sterile-EO	23-Mar-2015
89363	Utility Drape with Tape 35 in. x 35 in / 90 cm x 90 cm	Sterile-EO	23-Mar-2015
89368	Pacemaker Drape 87 in. x 135 in./221 cm x 343 cm	Sterile-EO	23-Mar-2015
89371	Knee Arthroscopy Drape with Armboard Covers	Sterile-EO	23-Mar-2015
89375	Bar Drape, 106 in. x 62 in. / 269 cm x 157 cm	Sterile-EO	23-Mar-2015
89380	Bilateral Limb Drape with Armboard Covers	Sterile-EO	23-Mar-2015
89381	Ortho Bar Drape 100 in. x 60 in./254 cm x 152 cm	Sterile-EO	23-Mar-2015
89411	Under Buttocks Drape	Sterile-EO	23-Mar-2015
89413	Under Buttocks Drape, Large 40 in. x 46 in./102 cm x 117 cm	Sterile-EO	23-Mar-2015
89414	Under Buttocks Drape with Graduated Fluid Collection Pouch	Sterile-EO	23-Mar-2015
89415	Under Buttocks Drape with Graduated Fluid Collection Pouch, 40 in. x 44 in./102 cm x 112 cm	Sterile-EO	23-Mar-2015
89421	Fenestrated EENT Drape	Sterile-EO	23-Mar-2015
89431	Head drape	Sterile-EO	23-Mar-2015
89438	Head Drape 41 in. x 32 in. / 104 cm x 81 cm	Sterile-EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
89451	Cardiovascular Split Drape	Sterile-EO	23-Mar-2015
89452	CVARTS* Heavy Duty CV Split Drape	Sterile-EO	23-Mar-2015
89453	CVARTS* Bilateral Under-Leg/Perineal Drape	Sterile-EO	23-Mar-2015
89454	CVARTS* Heavy Duty Universal Drape System	Sterile-EO	23-Mar-2015
89471	Brachial Angiography Drape	Sterile-EO	23-Mar-2015
89490	2-Piece Shoulder Arthroscopy Drape Pack	Sterile-EO	23-Mar-2015
89492	ORTHOARTS* Shoulder Arthroscopy Drape	Sterile-EO	23-Mar-2015
89501	Neuro Split Drape	Sterile-EO	23-Mar-2015
89525	Cesarean / Abdominal Fluid Collection Drape	Sterile-EO	23-Mar-2015
89526	Cesarean / Abdominal Fluid Collection Drape	Sterile-EO	23-Mar-2015
89528	C-Section Drape with Fenestrated Incise	Sterile-EO	23-Mar-2015
89529	C-Section Drape with Full Incise	Sterile-EO	23-Mar-2015
89543	HALYARD BASICS* Dental Drape 47 in. x 59 in. / 120 cm x 150 cm	Sterile-EO	23-Mar-2015
89548	Cystoscopy "T" Drape	Sterile-EO	23-Mar-2015
89583	HALYARD BASICS* Radial-Femoral Angiography Drape with Dual Windows	Sterile-EO	31-May-2015
89584	HALYARD BASICS* Under Buttocks Drape with graduated pouch	Sterile-EO	23-Mar-2015
89633	HALYARD BASICS* Cystoscopy fenestrated Drape, 75 x 185 cm, 5.5x12.5 diamond	Sterile-EO	23-Mar-2015
89635	HALYARD BASICS* Bilateral eye fenestrated drape with tape, 120 x 150 cm, horizontal rounded rectangular 7 x 16 cm	Sterile-EO	23-Mar-2015
89636	HALYARD BASICS* Epidural Fenestrated Drape, 50x75cm, 8x10 cm oval	Sterile-EO	23-Mar-2015
89637	HALYARD BASICS* Lower Extremity drape, 228 x 300 cm, 8x6 cm oval	Sterile-EO	23-Mar-2015
89638	HALYARD BASICS* Fenestrated Drape, 75x75cm, 7x10 cm oval	Sterile-EO	23-Mar-2015
89670	HALYARD BASICS* Fenestrated drape, 90 x 90 cm, 10 cm round	Sterile-EO	23-Mar-2015
89671	HALYARD BASICS* Fenestrated drape with tape, 90 x 90 cm, 10 cm round	Sterile-EO	23-Mar-2015
89672	HALYARD BASICS* Half Drape	Sterile-EO	23-Mar-2015
89673	HALYARD BASICS* Hand & Foot drape, 180 x 300 cm, 3 cm conformable fen	Sterile-EO	23-Mar-2015
89674	HALYARD BASICS* Large Drape,150 x 193 cm	Sterile-EO	23-Mar-2015
89675	HALYARD BASICS* Perineal cover drape with tape, 15 x 40 cm	Sterile-EO	23-Mar-2015
89676	HALYARD BASICS* Utility drape with tape, 150 x 240 cm (SMS)	Sterile-EO	23-Mar-2015
89677	HALYARD BASICS* Utility drape with tape, 75x75 cm	Sterile-EO	23-Mar-2015
89678	HALYARD BASICS* Utility drape, 90x90 cm	Sterile-EO	23-Mar-2015
89679	HALYARD BASICS* Utility Drape with Tape 35 in. x 35 in./ 90 cm x 90 cm	Sterile-EO	23-Mar-2015
89680	HALYARD BASICS* Variable Fenestrated Drape with Tape, 29 in. x 39 in./ 75 cm x 100 cm	Sterile-EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
89688	HALYARD BASICS* Hand Drape, 290 x 361, 3 cm conformable fen	Sterile-EO	23-Mar-2015
89704	Femoral Angiography Drape, 76 in. x 110 in./193 cm x 279 cm	Sterile-EO	23-Mar-2015
89705	Femoral Angiography Drape with Window, 83 in x 115in./211 cm x 292 cm	Sterile-EO	23-Mar-2015
89706	Femoral Angiography Drape with Dual Windows, 88.5 in. x 115 in./224 cm x 292 cm	Sterile-EO	23-Mar-2015
89709	Extra-Long Femoral Angiography Drape with Single Window	Sterile-EO	23-Mar-2015
89711	Extra-Long Femoral Angiography Drape with Dual Windows	Sterile-EO	23-Mar-2015
89714	Femoral Angiography Drape, 76 in. x 110 in./193 cm x 279 cm	Sterile-EO	08-Sept-2020
89715	Femoral Angiography Drape with Window, 83 in x 115in./211 cm x 292 cm	Sterile-EO	08-Sept-2020
89716	Femoral Angiography Drape with Dual Windows, 88.5 in. x 115 in./224 cm x 292 cm	Sterile-EO	08-Sept-2020
89731	Utility Drapes with Tape, Two Pack	Sterile-EO	23-Mar-2015
89749	Impervious Extra-Long Femoral Angiography Drape, 87 in. x 135 in./ 221 cm x 343 cm	Sterile-EO	23-Mar-2015
89828	Absorbent Drape with Tape, Small 22 in. x 24 in. / 57 cm x 60 cm	Sterile-EO	23-Mar-2015
89832	Radial U-Drape	Sterile-EO	23-Mar-2015
89835	CV Line Drape	Sterile-EO	23-Mar-2015