

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): Halyard Health, Inc.
5405 Windward Parkway
Alpharetta, Georgia (GA) 30004, USA

EU Authorized Representative: Halyard Belgium BVBA
Leonardo Da Vincilaan 1
1930 Zaventem
Belgium

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 621867

Notified Body: BSI (0086)

Quality System Certificate: FM 620884 (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 Halyard Health, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:



Name: Katy Johnson
Title: Regulatory Affairs Technical Leader
Halyard Health, Inc.
Date: 03-Nov-2016

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
29247	Utility Drapes, with Tape, Four Pack	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
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

Product Code	Product Description	Sterilization	Start of CE Mark
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
77311	Under Buttocks Drape, Zone Reinforced, 38 in. x 44 in./97 cm x 112 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
77681	Radial-Femoral Angiography Drape	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
77828	Laparoscopy Drape with Attached Leggings	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
89040	Femoral Angiography Drape, 76 in. x 130 in./193 cm x 330 cm	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
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

Product Code	Product Description	Sterilization	Start of CE Mark
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
89211	Laparotomy Drape	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 124 in./ 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
89291	Bilateral Limb Drape	Sterile-EO	23-Mar-2015
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

Product Code	Product Description	Sterilization	Start of CE Mark
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
89369	Bariatric Drape	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
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

Product Code	Product Description	Sterilization	Start of CE Mark
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
89582	HALYARD BASICS* Femoral Angiography drape, 2 fenestrations	Sterile-EO	23-Mar-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
89634	HALYARD BASICS* Fenestrated drape, 75 x 75 cm, 3 x 5 cm rectangular	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
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

Product Code	Product Description	Sterilization	Start of CE Mark
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
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
89836	Absorbent Drape with Tape	Sterile-EO	23-Mar-2015