

EC Declaration of Conformity

Name of Products: Surgical Equipment Covers and Accessories

Product Codes: See **Attachment A**

UMDNS Code: 15646 (Drapes, Surgical, Disposable)

GMDN Code: 45021 (Instrument/equipment drape, single-use, sterile)
47782 (General-purpose surgical drape, single-use, non-sterile)
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 V (for sterile products)
Annex VII (for non-sterile products)

Device Classification, Rules: Class I and Class I Sterile, Rule 1 per Annex IX

CE certificate number: CE 621867 (for sterile products only)

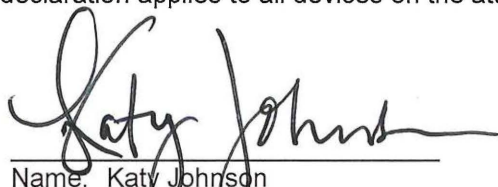
Notified Body: BSI (0086) (for sterile products only)

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: 12-May-2017

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
14007	Mayo Stand Cover, Reinforced	EO	23-Mar-2015
29242	Back Table Cover, Zone-Reinforced, Fan Fold 60 in x 90 in/ 152 cm x 228 cm	Non-sterile	09-Dec-2014
29243	Back Table Cover, Zone-Reinforced, Fan Fold 70 in x 110 in/ 177 cm x 279 cm	EO	23-Mar-2015
29244	Back Table Cover, Zone-Reinforced, Fan Fold 70 in x 110 in/ 177 cm x 279 cm	Non-sterile	09-Dec-2014
29245	Back Table Cover, Heavy Duty, Fan Fold 60 in x 90 in/ 152 cm x 228 cm	Non-sterile	09-Dec-2014
29246	Back Table Cover, Heavy Duty, Fan Fold 70 in x 110 in/ 177 cm x 279 cm	Non-sterile	09-Dec-2014
42217	Standard Back Table Cover, 112 cm x 229 cm	EO	23-Mar-2015
42222	Standard Back Table Cover, 152 cm x 191 cm	EO	23-Mar-2015
42345	Standard Back Table Cover, 140 cm x 190 cm	EO	23-Mar-2015
42224	Standard Back Table Cover, 152 cm x 228cm	EO	23-Mar-2015
42226	Standard Back Table Cover, 70 in. x 110 in. / 177 cm x 279 cm	EO	21-Oct-2016
42228NS	Standard Back Table Cover, 70 in. x 110 in. / 177 cm x 279 cm	Non-Sterile	09-Dec-2014
42312	Standard Back Table Cover, 191 cm x 201 cm	EO	23-Mar-2015
42309	Back Table Cover, Heavy-Duty, 177 cm x 279 cm	EO	23-Mar-2015
42446NS	Standard Back Table Cover, 112 cm x 112 cm	Non-sterile	09-Dec-2014
42447NS	Standard Back Table Cover, 112 cm x 198 cm	Non-sterile	09-Dec-2014
42448NS	Standard Back Table Cover, 112 cm x 229 cm	Non-sterile	09-Dec-2014
42449NS	Standard Back Table Cover, 127 cm x 229 cm	Non-sterile	09-Dec-2014
42428NS	Standard Back Table Cover, 152 cm x 191 cm	Non-sterile	09-Dec-2014
42451NS	Standard Back Table Cover, 152 cm x 229 cm	Non-sterile	09-Dec-2014
42409NS	Standard Back Table Cover, Fan Fold, 177 cm x 279 cm	Non-sterile	09-Dec-2014
42481NS	Standard Back Table Cover, 152 cm x 152 cm	Non-sterile	09-Dec-2014
42302NS	Standard Back Table Cover, Fan Fold, 112 cm x 224 cm	Non-sterile	09-Dec-2014
42365NS	Standard Back Table Cover, 140 cm x 190 cm	Non-sterile	09-Dec-2014
42480NS	Standard Back Table Cover, 152 cm x 152 cm	Non-sterile	09-Dec-2014
42225NS	Standard Back Table Cover, 152 cm x 229 cm	Non-sterile	09-Dec-2014
42233NS	Standard Back Table Cover, Fan Fold, 152 cm x 228 cm	Non-sterile	09-Dec-2014
42313NS	Standard Back Table Cover, 190 cm x 201 cm	Non-sterile	09-Dec-2014
42367NS	Back Table Cover, Heavy Duty, 177 cm x 279 cm	Non-sterile	09-Dec-2014

Product Code	Product Description	Sterilization	Start of CE Mark
42366NS	Back Table Cover, Heavy Duty, Fan Fold,152 cm x 229 cm	Non-sterile	09-Dec-2014
42428	Standard Back Table Cover 60 in. x 75 in./152 cm x 191 cm	Non-sterile	09-Dec-2014
44591	Armboard Cover 28 in. x 31.5 in. / 71 cm x 80 cm	Non-Sterile	20-July-2015
76214	Armboard Covers	EO	23-Mar-2015
76270	Diathermy Pouch	EO	23-Mar-2015
76299	Back Table Cover, Zone - Reinforced	Non-Sterile	09-Dec-2014
76300	Armboard Covers	Non-Sterile	09-Dec-2014
76331	Armboard Cover	Non-Sterile	09-Dec-2014
76334	Foot Cover	Non-sterile	09-Dec-2014
76340	Foot Cover	Non-sterile	09-Dec-2014
76345	Back Table Cover, Zone - Reinforced	Non-Sterile	09-Dec-2014
76358	Mayo Stand Cover	Non-Sterile	09-Dec-2014
76372	Back Table Cover with Control Plus Fabric Reinforcement	Non-Sterile	09-Dec-2014
76394	Baby Blanket	Non-sterile	09-Dec-2014
77345	Back Table Cover, Zone - Reinforced	EO	23-Mar-2015
77452	Large Mayo Stand Cover	EO	23-Mar-2015
77883	Mayo cover Reinforcement	EO	23-Mar-2015
78656	HALYARD BASICS* Mayo Stand Cover,58 x 137cm, ZR	Non-Sterile	09-Dec-2014
78657	HALYARD BASICS* Mayo Stand Cover, Zone Reinforced	Non-Sterile	09-Dec-2014
78668	HALYARD BASICS* Mayo Stand Cover,80 x 144cm, ZR	Non-Sterile	09-Dec-2014
78669	HALYARD BASICS* Back Table Cover, ZR, 152 x 191 cm	Non-Sterile	09-Dec-2014
78967	Diathermy Pouch	Non-sterile	09-Dec-2014
79006	E-Coat Heavy Duty Back Table Cover	Non-Sterile	09-Dec-2014
79008	E-Coat Heavy-Duty Back Table Cover, 70 in. x 110 in. HANDI-BIN	Non-Sterile	09-Dec-2014
79027	Legging, with 6 in. Cuff	Non-sterile	09-Dec-2014
79048	Legging, 31 in. x 48 in./79 cm x 122 cm	Non-sterile	09-Dec-2014
79053	Tape Strip	Non-sterile	09-Dec-2014
79058	Back Table Cover, Zone-Reinforced	Non-Sterile	09-Dec-2014
79061	Beach Chair Attachable Fluid Collection Pouch	Non-sterile	09-Dec-2014
79067	E-Coat Back Table Cover	Non-Sterile	09-Dec-2014
79068	Back Table Cover, Zone-Reinforced	Non-Sterile	09-Dec-2014
79080	Instrument Pad, 17.5 in. x 10.0 in./44 cm x 25 cm	Non-sterile	09-Dec-2014

Product Code	Product Description	Sterilization	Start of CE Mark
79092	Instrument Pouch	Non-sterile	09-Dec-2014
79093	Isolation Screen	Non-sterile	09-Dec-2014
79283	Back Table Cover, Zone - Reinforced	Non-Sterile	09-Dec-2014
79323	Back Table cover Reinforced	Non-Sterile	09-Dec-2014
79390	BTC fan fold 60" x 90"	Non-Sterile	09-Dec-2014
79408	Legging	Non-sterile	09-Dec-2014
79440	Back Table Cover, Zone-Reinforced	Non-Sterile	09-Dec-2014
79448	Back Table Cover, Zone-Reinforced	Non-Sterile	09-Dec-2014
79482	BTC Reinforced 115cmx152cm	Non-Sterile	09-Dec-2014
79498	Back Table Cover, Zone-Reinforced	Non-Sterile	09-Dec-2014
79601	Mayo stand Cover	Non-Sterile	09-Dec-2014
79602	Mayo Stand Cover, Reinforced	Non-Sterile	09-Dec-2014
79603	Mayo Stand Cover, Reinforced	Non-Sterile	09-Dec-2014
79607	Mayo Stand Cover	Non-Sterile	09-Dec-2014
79613	Back Table Cover, Reinforced, Fan Fold	Non-Sterile	09-Dec-2014
79685	Tape Strip 3M for Packs only	Non-Sterile	09-Dec-2014
79708	Back Table Cover, Zone - Reinforced, 70" x 110" - HANDI-BIN	Non-Sterile	09-Dec-2014
79720	Absorbent Towel	Non-sterile	09-Dec-2014
79725	Disposable Huck Towel	Non-sterile	09-Dec-2014
79741	HALYARD BASICS* Back Table Cover, 100 x 150 cm, reinforced	Non-Sterile	09-Dec-2014
79781	Non-Sterile Sleeve, 6 in. x 23.5 in./15 cm x 59 cm	Non-sterile	09-Dec-2014
79861	Impervious Stockinette, Small	Non-sterile	09-Dec-2014
79881	Impervious Stockinette, Large	Non-sterile	09-Dec-2014
79945	International diathermy Pouch	Non-sterile	09-Dec-2014
86275	Huck Towel Disposable	EO	23-Mar-2015
88656	HALYARD BASICS* Mayo Stand Cover, 58 x 137cm, ZR	EO	23-Mar-2015
88672	HALYARD BASICS* Mayo Stand Cover, 80 x 144cm, ZR	EO	23-Mar-2015
88673	HALYARD BASICS* Back Table Cover, ZR, 152 x 191 cm	EO	23-Mar-2015
89021	2 Disposable Huck Towels	EO	23-Mar-2015
89053	2 Tape Strips	EO	23-Mar-2015
89057	Back Table Cover, Zone-Reinforced	EO	23-Mar-2015
89080	Instrument Pad	EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
89092	Instrument Pouch	EO	23-Mar-2015
89093	Isolation Screen	EO	23-Mar-2015
89283	Back Table Cover, Reinforced, 75 in. x 79 in./191 cm x 201 cm	EO	23-Mar-2015
89323	Back Table Cover, Reinforced, 55 in. x 75 in./140 cm x 190 cm	EO	23-Mar-2015
89408	Leggings	EO	23-Mar-2015
89601	Mayo Stand Cover, Reinforced, 23 in. x 54 in./58 cm x 137 cm	EO	23-Mar-2015
89603	Mayo Table Cover 78 x 145cm	EO	23-Mar-2015
89621	Overhead Table Cover	EO	23-Mar-2015
89631	Back Table Cover, Reinforced, 60 in x 90 in./152 cm x 228 cm	EO	23-Mar-2015
89632	HALYARD BASICS* Back Table Cover, 100 x 150 cm, reinforced	EO	23-Mar-2015
89689	Tape Strip 3M for Packs only	EO	23-Mar-2015
89701	Absorbent Towels, Two Pack	EO	23-Mar-2015
89791	Sterile Sleeve, 6 in. x 23.5 in. / 15 cm x 59 cm	EO	23-Mar-2015
89811	Impervious Stockinette, Medium	EO	23-Mar-2015
89821	Impervious Stockinette, Large	EO	23-Mar-2015
89861	Impervious Stockinette, Small	EO	23-Mar-2015
89881	Impervious Stockinette, Large	EO	23-Mar-2015
89945	Diathermy Pouch	EO	23-Mar-2015