

EC Declaration of Conformity

Name of Products: Surgical Gowns

Product Codes: See **Attachment A**

UMDNS Code: 11901 (Gowns, Operating Room, Disposable)

GMDN Code: 35091 (Operating Room Gown, Single-use)

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

Device Classification, Rules: Class I (Sterile), as per Rule 1 of 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: 30-Jan-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
10550	MicroCool* Breathable High Performance Specialty Gown with Towel, with SECURE-FIT*, XL	Sterile - EO	23-Mar-2015
10558	MicroCool* Breathable High Performance Specialty Gown with Towel, with SECURE-FIT*, L	Sterile - EO	23-Mar-2015
10566	MicroCool* Breathable High Performance Specialty Gown with Towel, SECURE-FIT*, XXL	Sterile - EO	23-Mar-2015
11783	HALYARD BASICS* Surgical Gown, L, with Towels	Sterile - EO	23-Mar-2015
11784	HALYARD BASICS* Surgical Gown, XL, with Towels	Sterile - EO	23-Mar-2015
13337	HALYARD BASICS* Surgical Gown, X-Large, XX-Long with Towels	Sterile - EO	23-Mar-2015
13359	MicroCool* Breathable High Performance Gown with Blue Huck Towel, with SECURE-FIT*, S	Sterile - EO	23-Mar-2015
13815	HALYARD BASICS* Fabric-Reinforced Surgical Gown, X-Large, XX-Long, with Towels	Sterile - EO	23-Mar-2015
40989	MicroCool* Breathable High Performance Gown with Towels, Large	Sterile - EO	23-Mar-2015
40998	MicroCool* Breathable High Performance Gown with Towels, XL	Sterile - EO	23-Mar-2015
41000	MicroCool* Breathable High Performance Gown with Towels, L, X-Long	Sterile - EO	23-Mar-2015
41004	MicroCool* Breathable High Performance Gown with Towels, XL, X-Long	Sterile - EO	23-Mar-2015
41928	Aero Blue* Performance Surgical Gown with Towels, L	Sterile - EO	19-Jul-2016
41929	Aero Blue* Performance Surgical Gown with Towels, XL	Sterile - EO	19-Jul-2016
41930	Aero Blue* Performance Surgical Gown with Towels, L, X-Long	Sterile - EO	19-Jul-2016
41931	Aero Blue* Performance Surgical Gown with Towels, XL, X-Long	Sterile - EO	19-Jul-2016
41935	Aero Blue* Performance Surgical Gown with Mask and Towel, S	Sterile - EO	19-Jul-2016
41936	Aero Blue* Performance Surgical Gown with Mask and Towel, L	Sterile - EO	19-Jul-2016
41937	Aero Blue* Performance Surgical Gown with Mask and Towel, XL	Sterile - EO	19-Jul-2016
41938	Aero Blue* Performance Surgical Gown with Mask and Towel, XXL	Sterile - EO	19-Jul-2016
76240	Surgical Gown Pack	Sterile - EO	23-Mar-2015
41870	Aero Blue* Performance Surgical Gown with Blue Huck Towel, S	Sterile - EO	19-Jul-2016
41871	Aero Blue* Performance Surgical Gown with Blue Huck Towel, L	Sterile - EO	19-Jul-2016
41872	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XL	Sterile - EO	19-Jul-2016
41873	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XXL	Sterile - EO	19-Jul-2016
41874	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XXXL	Sterile - EO	19-Jul-2016
42620	Aero Blue* Performance Surgical Gown with Blue Huck Towel, L, X-Long	Sterile - EO	19-Jul-2016
42621	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XL, X-Long	Sterile - EO	19-Jul-2016
43939	Aero Blue* Performance Surgical Gown with Towels, XXL, X-Long	Sterile - EO	19-Jul-2016

Product Code	Product Description	Sterilization	Start of CE Mark
43940	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XXL, X-Long	Sterile - EO	19-Jul-2016
43942	Aero Blue* Performance Surgical Gown with Towels, XXL	Sterile - EO	19-Jul-2016
77456	Gown Pack I	Sterile - EO	23-Mar-2015
78940	Surgical Gown with Set-In Sleeves, 2 Towels (Medium)	Sterile - EO	23-Mar-2015
78945	Surgical Gown with Set-In Sleeves, Large	Sterile - EO	23-Mar-2015
78950	Surgical Gown with Set-In Sleeves, XL	Sterile - EO	23-Mar-2015
78955	Surgical Gown with Set-In Sleeves, 2 Towels (XXL)	Sterile - EO	23-Mar-2015
89791	Sterile Sleeve, 6 in. x 23.5 in. / 15 cm x 59 cm	Sterile - EO	23-Mar-2015
90002	Surgical Gown, Small,	Sterile - EO	23-Mar-2015
90003	Surgical Gown, Small/Medium	Sterile - EO	23-Mar-2015
90012	Surgical Gown, Large	Sterile - EO	23-Mar-2015
90013	Surgical Gown, Large, X-Long	Sterile - EO	23-Mar-2015
90016	Surgical Gown, Large, with Towels	Sterile - EO	23-Mar-2015
90018	Surgical Gown, Large	Sterile - EO	23-Mar-2015
90019	Surgical Gown, Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
90042	Surgical Gown, X-Large	Sterile - EO	23-Mar-2015
90043	Surgical Gown, X-Large, X-Long	Sterile - EO	23-Mar-2015
90046	Surgical Gown, X-Large, with Towels	Sterile - EO	23-Mar-2015
90048	Surgical Gown, X-Large	Sterile - EO	23-Mar-2015
90049	Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
90050	Surgical Gown, XX-Large	Sterile - EO	23-Mar-2015
90112	Fabric-Reinforced Surgical Gown, Large, with Towels	Sterile - EO	23-Mar-2015
90113	Fabric-Reinforced Surgical Gown, Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
90138	Surgical Gowns with Huck Towels Twin Pack (Size L & XL)	Sterile - EO	23-Mar-2015
90142	Fabric-Reinforced Surgical Gown, X-Large, with Towels	Sterile - EO	23-Mar-2015
90143	Fabric-Reinforced Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
90363	ULTRA Fabric-Reinforced Surgical Gown, Large, X-Long	Sterile - EO	23-Mar-2015
90373	ULTRA Fabric-Reinforced Surgical Gown, X-Large, X-Long	Sterile - EO	23-Mar-2015
92038	MicroCool* Breathable High Performance Gown with Towel, L, X-Long	Sterile - EO	23-Mar-2015
92042	MicroCool* Breathable High Performance Gown with Towel, XL, X-Long	Sterile - EO	23-Mar-2015
92320	MicroCool* Breathable High Performance Gown with Blue Huck Towel, with SECURE-FIT*, L	Sterile - EO	23-Mar-2015
92321	MicroCool* Breathable High Performance Gown with Blue Huck Towel, with SECURE-FIT*, XL	Sterile - EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
92323	MicroCool* Breathable High Performance Gown with Blue Huck Towel, with SECURE-FIT*, XXL	Sterile - EO	23-Mar-2015
92330	MicroCool* Breathable High Performance Specialty Gown with Blue Huck Towel, with SECURE-FIT*, L, X-Long	Sterile - EO	23-Mar-2015
92331	MicroCool* Breathable High Performance Specialty Gown with Blue Huck Towel, with SECURE-FIT*, XL, X-Long	Sterile - EO	23-Mar-2015
92333	MicroCool* Breathable High Performance Specialty Gown with Blue Huck Towel, with SECURE-FIT*, XXL, X-Long	Sterile - EO	23-Mar-2015
92336	MicroCool* Breathable High Performance Gown with Towel, Small	Sterile - EO	23-Mar-2015
92338	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, S	Sterile - EO	23-Mar-2015
92340	MicroCool* Breathable High Performance Gown with Towel, L	Sterile - EO	23-Mar-2015
92342	MicroCool* Breathable High Performance Gown with Towel, XL	Sterile - EO	23-Mar-2015
92344	MicroCool* Breathable High Performance Gown with Towel, XXL	Sterile - EO	23-Mar-2015
92347	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, XXXL	Sterile - EO	23-Mar-2015
92351	MicroCool* Breathable High Performance Specialty Gown with Towel, L	Sterile - EO	23-Mar-2015
92353	MicroCool* Breathable High Performance Specialty Gown with Towel, XL	Sterile - EO	23-Mar-2015
92354	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, L	Sterile - EO	23-Mar-2015
92355	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, XL	Sterile - EO	23-Mar-2015
92357	MicroCool* Breathable High Performance Specialty Gown with Towel, XXL	Sterile - EO	23-Mar-2015
92358	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, XXL	Sterile - EO	23-Mar-2015
95101	ULTRA Surgical Gown, Small, with Polypropylene Fabric and Towel	Sterile - EO	23-Mar-2015
95111	ULTRA Surgical Gown, Large, with Polypropylene Fabric and Towel	Sterile - EO	23-Mar-2015
95113	ULTRA Surgical Gown, Large, with Towels	Sterile - EO	23-Mar-2015
95114	ULTRA Surgical Gown, Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
95121	ULTRA Surgical Gown, X-Large, with Polypropylene Fabric and Towel	Sterile - EO	23-Mar-2015
95123	ULTRA Surgical Gown, X-Large, with Towels	Sterile - EO	23-Mar-2015
95124	ULTRA Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
95131	ULTRA Surgical, XX-Large	Sterile - EO	23-Mar-2015
95201	ULTRA Fabric-Reinforced Surgical Gown, Small	Sterile - EO	23-Mar-2015
95211	ULTRA Fabric-Reinforced Surgical Gown, Large	Sterile - EO	23-Mar-2015
95221	ULTRA Fabric-Reinforced Surgical Gown, X-Large	Sterile - EO	23-Mar-2015
95224	ULTRA Fabric-Reinforced Surgical Gown, X-Large, X-Long	Sterile - EO	23-Mar-2015
95311	ULTRA Zoned-Impervious Surgical Gown, Large	Sterile - EO	23-Mar-2015
95321	ULTRA Zoned-Impervious Surgical Gown, X-Large	Sterile - EO	23-Mar-2015
95331	ULTRA Zoned-Impervious Surgical Gown, XX-Large	Sterile - EO	23-Mar-2015
95411	ULTRA Film-Reinforced Surgical Gown, Large, with Polypropylene Fabric	Sterile - EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
95421	ULTRA Film-Reinforced Surgical Gown, X-Large, with Polypropylene Fabric	Sterile - EO	23-Mar-2015
95431	ULTRA Film-Reinforced Surgical Gown, XX-Large, with Polypropylene Fabric	Sterile - EO	23-Mar-2015
95511	ULTRA Film-Reinforced Specialty Gown, Large, with Polypropylene Fabric	Sterile - EO	23-Mar-2015
95521	ULTRA Film-Reinforced Specialty Gown, X-Large, with Polypropylene	Sterile - EO	23-Mar-2015
95531	ULTRA Specialty Gown, XX-Large	Sterile - EO	23-Mar-2015
99294	HALYARD BASICS* Surgical Gown, Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
99295	HALYARD BASICS* Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
44680	Aero Chrome* Breathable High Performance Surgical Gown, S (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44681	Aero Chrome* Breathable High Performance Surgical Gown, L (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44682	Aero Chrome* Breathable High Performance Surgical Gown, XL (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44683	Aero Chrome* Breathable High Performance Surgical Gown, XXL (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44684	Aero Chrome* Breathable High Performance Surgical Gown, XXXL (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44685	Aero Chrome* Breathable High Performance Surgical Gown, L, X-Long (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44686	Aero Chrome* Breathable High Performance Surgical Gown, XL, X-Long (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44687	Aero Chrome* Breathable High Performance Surgical Gown, XXL, X-Long (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44688	Aero Chrome* Breathable High Performance Surgical Gown, S (with Towels)	Sterile - EO	25-Aug-2016
44689	Aero Chrome* Breathable High Performance Surgical Gown, L (with Towels)	Sterile - EO	25-Aug-2016
44690	Aero Chrome* Breathable High Performance Surgical Gown, XL (with Towels)	Sterile - EO	25-Aug-2016
44691	Aero Chrome* Breathable High Performance Surgical Gown, XXL (with Towels)	Sterile - EO	25-Aug-2016
44692	Aero Chrome* Breathable High Performance Surgical Gown, XXXL (with Towels)	Sterile - EO	25-Aug-2016
44693	Aero Chrome* Breathable High Performance Surgical Gown, L, X-Long (with Towels)	Sterile - EO	25-Aug-2016
44694	Aero Chrome* Breathable High Performance Surgical Gown, XL, X-Long (with Towels)	Sterile - EO	25-Aug-2016
44695	Aero Chrome* Breathable High Performance Surgical Gown, XXL, X-Long (with Towels)	Sterile - EO	25-Aug-2016
46665	ValueSelect* Standard Surgical Gown with Towels, M	Sterile - EO	05-Jan-2017
46666	ValueSelect* Standard Surgical Gown with Towels, L	Sterile - EO	05-Jan-2017
46667	ValueSelect* Standard Surgical Gown with Towels, XL	Sterile - EO	05-Jan-2017
46668	ValueSelect* Standard Surgical Gown with Towels, XXL	Sterile - EO	05-Jan-2017
46673	ValueSelect* Film-Reinforced Surgical Gown with Towels, M	Sterile - EO	05-Jan-2017
46674	ValueSelect* Film-Reinforced Surgical Gown with Towels, L	Sterile - EO	05-Jan-2017
46675	ValueSelect* Film-Reinforced Surgical Gown with Towels, XL	Sterile - EO	05-Jan-2017
46676	ValueSelect* Film-Reinforced Surgical Gown with Towels, XXL	Sterile - EO	05-Jan-2017