EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Name of Products:	Surgical Gowns, Sterile
Product Codes:	See **Attachment A**
UMDNS Code:	N/A
GMDN Code:	35091: Operating Room Gown, Single-Use
CND Code:	T0204: Surgical Gowns
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
Manufacturer SRN :	N/A
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN: **UDI-DI: (device level)**	IE-AR-000003110 06806517TUR001LT
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: Steven Dowdley
Title: Director, Regulatory Affairs
Address: O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116
United States of America

Date: August 11, 2021

HALYARD
Part of the Owens & Minor Family

ATTACHMENT A: Product Codes and Descriptions for Sterile Surgical Gowns

Stock Code	Description	UDI-DI
11783	BASICS* Surgical Gown, L, with Towels	06806517SG002D3
11784	BASICS* Surgical Gown, XL, with Towels	06806517SG002D3
11337	BASICS* Surgical Gown, XL, Extra-Extra Long with Towels	06806517SG002D3
13815	BASICS* Fabric-Reinforced Surgical Gown, XL, Extra-Extra Long with Towels	06806517SG002D3
41724	AERO BLUE* Performance Surgical Gown, X-Long, L	06806517SG002D3
41726	AERO BLUE* Performance Surgical Gown, X-Long, XL	06806517SG002D3
41732	AERO BLUE* Performance Surgical Gown, S	06806517SG002D3
41733	AERO BLUE* Performance Surgical Gown, L	06806517SG002D3
41734	AERO BLUE* Performance Surgical Gown, XL	06806517SG002D3
41735	AERO BLUE* Performance Surgical Gown, XXL	06806517SG002D3
41736	AERO BLUE* Performance Surgical Gown, XXXL	06806517SG002D3
41870	AERO BLUE* Performance Surgical Gown with Blue Huck Towel, Small	06806517SG002D3
41871	AERO BLUE* Performance Surgical Gown with Blue Huck Towel, Large	06806517SG002D3
41872	AERO BLUE* Performance Surgical Gown with Blue Huck Towel, Extra Large	06806517SG002D3
41873	AERO BLUE* Performance Surgical Gown with Blue Huck Towel, XXL	06806517SG002D3
41874	AERO BLUE* Performance Surgical Gown with Blue Huck Towel, XXXL	06806517SG002D3
41928	AERO BLUE* Performance Surgical Gown with Towels, L	06806517SG002D3
41929	AERO BLUE* Performance Surgical Gown with Towels, XL	06806517SG002D3
41930	AERO BLUE* Performance Surgical Gown with Towels, Extra Long, L	06806517SG002D3
41931	AERO BLUE* Performance Surgical Gown with Towels, Extra Long, XL	06806517SG002D3
42620	AERO BLUE* Performance Surgical Gown with Blue Huck Towel, Extra Long, Large	06806517SG002D3
42621	AERO BLUE* Performance Surgical Gown with Blue Huck Towel, Extra Long, Extra Large	06806517SG002D3
43624	AERO BLUE* Performance Surgical Gown, XXL, X-Long	06806517SG002D3
43938	AERO BLUE* Performance Surgical Gown with Towel, X-Long, XXL	06806517SG002D3
43939	AERO BLUE* Performance Surgical Gown with Towels, Extra Long, XXL	06806517SG002D3
43940	AERO BLUE* Performance Surgical Gown with Blue Huck Towel, Extra Long, XXL	06806517SG002D3
43942	AERO BLUE* Performance Surgical Gown with Towels, XXL	06806517SG002D3
44672	AERO CHROME* Breathable Performance Surgical Gown with Towel, Small	06806517SG002D3
44673	AERO CHROME* Breathable Performance Surgical Gown with Towel, Large	06806517SG002D3
44674	AERO CHROME* Breathable Performance Surgical Gown with Towel, Extra Large	06806517SG002D3
44675	AERO CHROME* Breathable Performance Surgical Gown with Towel, XXL	06806517SG002D3
44676	AERO CHROME* Breathable Performance Surgical Gown with Towel, XXXL	06806517SG002D3
44677	AERO CHROME* Breathable Performance Surgical Gown with Towel, Large, Extra Long	06806517SG002D3
44678	AERO CHROME* Breathable Performance Surgical Gown with Towel, Extra Large, Extra Long	06806517SG002D3
44679	Aero Chrome* Breathable Performance Surgical Gown with Towel, XXL, X-Long	06806517SG002D3

44680	AERO CHROME* Breathable High Performance Surgical Gown with Blue Huck Towel, S	06806517SG002D3
44681	AERO CHROME* Breathable High Performance Surgical Gown with Blue Huck Towel, L	06806517SG002D3
44682	AERO CHROME* Breathable High Performance Surgical Gown with Blue Huck Towel, XL	06806517SG002D3
44683	AERO CHROME* Breathable High Performance Surgical Gown with Blue Huck Towel, XXL	06806517SG002D3
44684	AERO CHROME* Breathable High Performance Surgical Gown with Blue Huck Towel, XXXL	06806517SG002D3
44685	AERO CHROME* Breathable High Performance Surgical Gown with Blue Huck Towel, L, Extra Long	06806517SG002D3
44686	AERO CHROME* Breathable High Performance Surgical Gown with Blue Huck Towel, XL, Extra Long	06806517SG002D3
44687	AERO CHROME* Breathable High Performance Surgical Gown with Blue Huck Towel, XXL, Extra Long	06806517SG002D3
44688	AERO CHROME* Breathable High Performance Surgical Gown, with Towels, S	06806517SG002D3
44689	AERO CHROME* Breathable High Performance Surgical Gown, with Towels, L	06806517SG002D3
44690	AERO CHROME* Breathable High Performance Surgical Gown, with Towels, XL	06806517SG002D3
44691	AERO CHROME* Breathable High Performance Surgical Gown, with Towels, XXL	06806517SG002D3
44693	AERO CHROME* Breathable High Performance Surgical Gown, with Towels, L, Extra Long	06806517SG002D3
44694	AERO CHROME* Breathable High Performance Surgical Gown, with Towels, XL, Extra Long	06806517SG002D3
44695	AERO CHROME* Breathable High Performance Surgical Gown, with Towels, XXL, Extra Long	06806517SG002D3
44699	Aero Chrome* Select Breathable Performance Surgical Gown, L	06806517SG002D3
44706	Aero Chrome* Select Breathable Performance Surgical Gown, XL	06806517SG002D3
44707	Aero Chrome* Select Breathable Performance Surgical Gown, XXL	06806517SG002D3
44709	AERO CHROME* SELECT Breathable Performance Surgical Gown with Blue Huck Towel, XL	06806517SG002D3
44710	AERO CHROME* SELECT Breathable Performance Surgical Gown with Blue Huck Towel, XXL	06806517SG002D3
44810	AERO CHROME* SELECT Breathable Performance Surgical Gown with Blue Huck Towel, XXL	06806517SG002D3
45181	Non-Reinforced Surgical Gown with Set-In Sleeves - XXL	06806517SG002D3
46864	SPECTRUM* Non-Reinforced Surgical Gown with Towel, M	06806517SG002D3
46865	SPECTRUM* Non-Reinforced Surgical Gown with Towel, L	06806517SG002D3
46866	SPECTRUM* Non-Reinforced Surgical Gown with Towel, XL	06806517SG002D3
46868	SPECTRUM* Non-Reinforced Surgical Gown with Towel, XXL	06806517SG002D3
46869	SPECTRUM* Non-Reinforced Surgical Gown with Towel, XXXL	06806517SG002D3
46879	SPECTRUM* Non-Reinforced Surgical Gown with Towel, L	06806517SG002D3
46881	SPECTRUM* Non-Reinforced Surgical Gown with Towel, XL	06806517SG002D3
46882	SPECTRUM* Non-Reinforced Surgical Gown with Towel, XXL	06806517SG002D3
46894	ULTRA Surgical Gown with Mask, M	06806517SG002D3
46895	ULTRA Surgical Gown with Mask, L	06806517SG002D3
46896	ULTRA Surgical Gown with Mask, LL	06806517SG002D3
46897	ULTRA Surgical Gown, M	06806517SG002D3
46898	ULTRA Surgical Gown, L	06806517SG002D3

46899	ULTRA Surgical Gown, LL	06806517SG002D3
46924	SPECTRUM* Non-Reinforced Surgical Gown with Towels, M	06806517SG002D3
46925	SPECTRUM* Non-Reinforced Surgical Gown with Towels, L	06806517SG002D3
46926	SPECTRUM* Non-Reinforced Surgical Gown with Towels, XL	06806517SG002D3
47256	SPECTRUM* Non-Reinforced Surgical Gown with Towels, XXL	06806517SG002D3
47579	Aero Chrome* A-Line Breathable Performance Surgical Gown with Towel, L, X-Long	06806517SG002D3
47580	Aero Chrome* A-Line Breathable Performance Surgical Gown with Towel, XL, X-Long	06806517SG002D3
47581	Aero Chrome* A-Line Breathable Performance Surgical Gown with Towel, XXL, X-Long	06806517SG002D3
48395	Aero Chrome* Breathable High Performance Surgical Gown with Towels, L	06806517SG002D3
48396	Aero Chrome* Breathable High Performance Surgical Gown with Towels, XL	06806517SG002D3
48397	Aero Chrome* Breathable High Performance Surgical Gown with Towels, L, X-Long	06806517SG002D3
48398	Aero Chrome* Breathable High Performance Surgical Gown with Towels, XL, X-Long	06806517SG002D3
48402	Aero Chrome* Breathable High Performance Surgical Gown with Towels, XXL, X-Long	06806517SG002D3
48403	Aero Chrome* Breathable High Performance Surgical Gown with Towels, XXL	06806517SG002D3
76240	Surgical Gown Pack	06806517SG002D3
77456	Gown Pack I	06806517SG002D3
77595	ULTRA Surgical Gown with Tape Mask, M	06806517SG002D3
77596	ULTRA Surgical Gown with Tape Mask, L	06806517SG002D3
77597	ULTRA Surgical Gown with Tape Mask, LL	06806517SG002D3
78005	ULTRA Surgical Gown with Mask, M (Japanese)	06806517SG002D3
78009	ULTRA Surgical Gown with Mask, L (Japanese)	06806517SG002D3
78012	Surgical Gown, L	06806517SG002D3
78022	ULTRA Surgical Gown with Mask, LL	06806517SG002D3
78034	ULTRA Surgical Gown, M (Japanese)	06806517SG002D3
78042	Surgical Gown X-Large	06806517SG002D3
78052	ULTRA Surgical Gown, L (Japanese)	06806517SG002D3
78055	ULTRA Surgical Gown, LL (Japanese)	06806517SG002D3
78920	Surgical Gown, M	06806517SG002D3
78925	Surgical Gown, L	06806517SG002D3
78930	Surgical Gown, XL	06806517SG002D3
78940	Surgical Gown with Set-In Sleeves, 2 Towels, Medium	06806517SG002D3
78945	Surgical Gown with Set-In Sleeves, 2 Towels, Large	06806517SG002D3
78950	Surgical Gown with Set-In Sleeves, 2 Towels, Extra Large	06806517SG002D3
78955	Surgical Gown with Set-In Sleeves, 2 Towels, XXL	06806517SG002D3
90002	Surgical Gown, Small, with Towel	06806517SG002D3
90003	Surgical Gown, Small/Medium	06806517SG002D3
90012	Surgical Gown, Large, with Towel	06806517SG002D3
90013	Surgical Gown, Large, Extra Long, with Towel	06806517SG002D3
90016	Surgical Gown, Large, with Towel	06806517SG002D3

90018	Surgical Gown, Large with 1 Blue Huck Towel	06806517SG002D3
90019	Surgical Gown, Large, Extra Long, with Towel	06806517SG002D3
90042	Surgical Gown, Extra Large, with Towel	06806517SG002D3
90043	Surgical Gown, Extra Large, Extra Long, with Towel	06806517SG002D3
90046	Surgical Gown, Extra Large, with Towel	06806517SG002D3
90048	Surgical Gown, Extra Large	06806517SG002D3
90049	Surgical Gown, Extra Large, Extra Long, with Towel	06806517SG002D3
90050	Surgical Gown, XXL	06806517SG002D3
90113	Fabric Reinforced Surgical Gown, Large, Extra Long, With Towel	06806517SG002D3
90142	Fabric Reinforced Surgical Gown, Extra Large, with Towel	06806517SG002D3
90143	Fabric Reinforced Surgical Gown, Extra Large, Extra Long, with Towel	06806517SG002D3
90212	Tie-Back Fabric-Reinforced Surgical Gown, Large, with Towel	06806517SG002D3
90363	ULTRA* Fabric Reinforced Surgical Gown, Large, Extra Long, with Neck Protection and Thumb Loops, with Towel	06806517SG002D3
90373	ULTRA* Fabric Reinforced Surgical Gown, Extra Large, Extra Long	06806517SG002D3
95011	Surgical Gown, Large	06806517SG002D3
95021	Surgical Gown, X-Large	06806517SG002D3
95101	ULTRA* Surgical Gown with Polypropylene Fabric and Towel, Small	06806517SG002D3
95111	ULTRA* Surgical Gown with Polypropylene Fabric and Towel, Large	06806517SG002D3
95113	ULTRA* Surgical Gown, Large, with Towels	06806517SG002D3
95114	ULTRA* Surgical Gown, Large, Extra Long, with Towels	06806517SG002D3
95121	ULTRA* Surgical Gown with Polypropylene Fabric and Towel, Extra Large	06806517SG002D3
95123	ULTRA* Surgical Gown, Extra Large, with Towels	06806517SG002D3
95124	ULTRA* Surgical Gown, Extra Large, Extra Long with Towels	06806517SG002D3
95131	ULTRA* Surgical Gown, Extra-Extra Large, with Towels	06806517SG002D3
95201	ULTRA* Fabric Reinforced Surgical Gown, Small	06806517SG002D3
95211	ULTRA* Fabric Reinforced Surgical Gown with Towel , Large	06806517SG002D3
95221	ULTRA* Fabric Reinforced Surgical Gown with Towel , Extra Large	06806517SG002D3
95224	ULTRA* Fabric Reinforced Surgical Gown, Extra Large, Extra Long	06806517SG002D3
95231	ULTRA* Fabric Reinforced Surgical Gown with Towel , XXL	06806517SG002D3
95311	ULTRA Zoned-Impervious Surgical Gown with Towel, L	06806517SG002D3
95321	ULTRA* Zoned-Impervious Surgical Gown with Towel, Extra Large	06806517SG002D3
95331	ULTRA* Zoned-Impervious Surgical Gown with Towel, XXL	06806517SG002D3
95411	ULTRA* Film Reinforced Surgical Gown with Polypropylene Fabric and Towel, Large	06806517SG002D3
95421	ULTRA* Film Reinforced Surgical Gown with Polypropylene Fabric and Towel, Extra Large	06806517SG002D3
95431	ULTRA* Film Reinforced Surgical Gown with Polypropylene Fabric and Towel, XXL	06806517SG002D3
95511	ULTRA* Film Reinforced Specialty Gown with Polypropylene Fabric and Towel, Large	06806517SG002D3
95521	ULTRA* Film Reinforced Specialty Gown with Polypropylene Fabric and Towel, Extra Large	06806517SG002D3
95531	ULTRA* Film Reinforced Specialty Gown with Polypropylene Fabric and Towel, XXL	06806517SG002D3

95224	ULTRA* Fabric Reinforced Surgical Gown, Extra Large, Extra Long	06806517SG002D3
95231	ULTRA* Fabric Reinforced Surgical Gown with Towel , XXL	06806517SG002D3
95311	ULTRA Zoned-Impervious Surgical Gown with Towel, L	06806517SG002D3
95321	ULTRA* Zoned-Impervious Surgical Gown with Towel, Extra Large	06806517SG002D3
99284	BASICS* Surgical Gown with Towel, L	06806517SG002D3
99285	BASICS* Surgical Gown with Towel, XL	06806517SG002D3
99287	BASICS* Surgical Gown, Large, with Towel	06806517SG002D3
99288	BASICS* Surgical Gown with Towel, XL	06806517SG002D3
99294	BASICS* Surgical Gown, Large, Extra Long, with Towels	06806517SG002D3
99295	BASICS* Surgical Gown, Extra Large, Extra Long, with Towels	06806517SG002D3