

EC Declaration of Conformity

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

Name of Products:	Apparel
Product Codes:	See Attachment A
UMDNS Code:	N/A
GMDN Code:	15056 (Shoe cover) 43315 (Surgical Hood) 32297 (Surgical Cap, Single-Use) 35092 (Patient Gown, Single-Use) 35492 (Isolation Gown, Single-Use) 58382 (Scrub Suit, Single-Use) 61938 (Surgical/examination garment kit) 32170 (Professional examination gown, single-use)
CND Code:	T0207: Headcovers T0208: Shoe Covers T0205: Non-Surgical Gowns T0299: Protective Covers and Garments
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:	IE-AR-000003110
Basic UDI-DI:	06806517AP0018S

Start of CE:	4 February 2015
Conformity Assessment Route:	Technical Documentation according to Annex II & III; Declaration of Conformity according to Annex IV of Regulation (EU) 2017/745
Risk Classification, Rules:	Class I NS per Rule 1, Annex VIII Regulation (EU) 2017/745
CE certificate number:	N/A
Notified Body:	BSI-NL
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:

Angela L. Bunn
 Angela L. Bunn (Dec 13, 2022 13:26 EST)

On behalf of O&M Halyard, Inc

Name: Angela L. Bunn
 Title: Senior Director, Global Regulatory Affairs
 Address: O&M Halyard, Inc.
 9120 Lockwood Blvd.
 Mechanicsville, Virginia (VA) 23116
 United States of America

Date: **Dec 13, 2022**

ATTACHMENT A: Product Codes and Descriptions for Apparel Products

Stock Code	Description	Basic UDI-DI
10033	BASICS* Plus Lab Coat, Blue Extra Large	06806517AP0018S
10034	BASICS* Plus Lab Coat, Blue Extra Extra Large	06806517AP0018S
10040	Universal Precautions Lab Coat, White – Small	06806517AP0018S
10041	Universal Precaution Lab Coat, White – Medium	06806517AP0018S
10042	Universal Precaution Lab Coat, White – Large	06806517AP0018S
10043	Universal Precautions Lab Coat, White – Extra-Large	06806517AP0018S
10044	Universal Precautions Lab Coat, White – XX Large	06806517AP0018S
10045	Universal Precautions Lab Coat, Blue – Small	06806517AP0018S
10046	Universal Precautions Lab Coat, Blue – Medium	06806517AP0018S
10047	Universal Precautions Lab Coat, Blue – Large	06806517AP0018S
10048	Universal Precautions Lab Coat, Blue – Extra Large	06806517AP0018S
10049	Universal Precautions Lab Coat, Blue – XX Large	06806517AP0018S
10067	Professional Lab Jacket, Blue – Medium	06806517AP0018S
10075	Extra Protection Coverall, L, White	06806517AP0018S
10078	Professional Lab Jacket, Blue – Large	06806517AP0018S
10085	Extra Protection Coverall, XL, White	06806517AP0018S
10087	Professional Lab Jacket, Blue – Extra-Large	06806517AP0018S
10095	Extra Protection Coverall, XXL, White	06806517AP0018S
10096	Extra Protection Coverall, XXXL, White	06806517AP0018S
10157	Lab Coat, White, XXX-Large	06806517AP0018S
13962	BASICS* Tri-Layer Gown	06806517AP0018S
43148	Isolation Gown	06806517AP0018S
54100	Tri-Layer AAMI 1 Isolation Gown, Yellow- Large	06806517AP0018S
54101	Tri-Layer AAMI 1 Isolation Gown, Yellow – Extra Large	06806517AP0018S
54110	Tri-Layer AAMI 1 Isolation Gown, Blue - Large	06806517AP0018S
54310	Tri-Layer AAMI 3 Isolation Gown, Blue - Large	06806517AP0018S
54311	Tri-Layer AAMI 3 Isolation Gown, Blue – Extra Large	06806517AP0018S
69025	Procedure Gown, Blue - Large	06806517AP0018S
69028	Procedure Gown, Blue – Extra Large	06806517AP0018S
69110	Surgical Hood, Blue – Universal Size	06806517AP0018S
69114	BASICS* Shoe Cover	06806517AP0018S
69121	BASICS* Shoe Cover, Extra Large	06806517AP0018S
69124	Cover Gown, Yellow – Universal Size	06806517AP0018S
69125	Cover Gown, Yellow – Large	06806517AP0018S
69127	Cover Gown, Blue - Large	06806517AP0018S
69240	Surgical Cap KAYCEL* Fabric, Blue – Universal Size	06806517AP0018S

69252	X-TRA TRACTION* Shoe Cover, Blue – Universal Size	06806517AP0018S
69253	ANKLE GUARD* Shoe Cover, Blue – Universal Size	06806517AP0018S
69254	X-TRA TRACTION* Shoe Cover, Blue – Large	06806517AP0018S
69316	Film Gown, Blue with Thumb Hooks – Extra Large	06806517AP0018S
69350	Apron	06806517AP0018S
69353	ANKLE GUARD* Shoe Cover, Blue – Extra Large	06806517AP0018S
69490	Film Gown, Blue with Thumb Hooks – Universal Size	06806517AP0018S
69551	Heavy Duty Shoe Cover, Blue – Universal Size	06806517AP0018S
69571	HI GUARD* Full Coverage Boot, Blue – Universal Size	06806517AP0018S
69572	HI GUARD* Ultra High Full Coverage Boot, Blue-Universal Size	06806517AP0018S
69600	Impervious Comfort Gown, Blue with Knit Cuffs – Large	06806517AP0018S
69601	Impervious Comfort Gown, Blue with Knit Cuffs – Extra Large	06806517AP0018S
69602	Impervious Comfort Gown, Blue with Thumb Hooks – Large	06806517AP0018S
69603	Impervious Comfort Gown, Blue with Thumb Hooks – Extra Large	06806517AP0018S
69671	HI GUARD* Full Coverage Boot, Blue – Extra Large	06806517AP0018S
69672	HI GUARD* Ultra Full Coverage Boot, Extra Large	06806517AP0018S
69701	Scrub Shirt, Blue - Medium	06806517AP0018S
69702	Scrub Shirt, Blue – Large	06806517AP0018S
69703	Scrub Shirt, Blue, Extra Large	06806517AP0018S
69704	Scrub Shirt, Blue – Extra Extra Large	06806517AP0018S
69711	Scrub Pants, Blue – Medium	06806517AP0018S
69712	Scrub Pants, Blue – Large	06806517AP0018S
69713	Scrub Pants, Blue – Extra Large	06806517AP0018S
69714	Scrub Pants, Blue- Extra, Extra Large	06806517AP0018S
69801	Spunbond Bouffant Cap, Blue - Large	06806517AP0018S
69979	Tri-Layer AAMI 2 Isolation Gown, Yellow - Large	06806517AP0018S
69981	Tri-Layer AAMI 2 Isolation Gown, Blue – Universal Size	06806517AP0018S
69987	Tri-Layer AAMI 2 Isolation Gown, Blue – Extra Large	06806517AP0018S
69988	Tri-Layer AAMI 2 Isolation Gown, Yellow – Extra Large	06806517AP0018S
75631	Protective Coverall, L, Blue	06806517AP0018S
75641	Protective Coverall, XL, Blue	06806517AP0018S
75651	Protective Coverall, XXL, Blue	06806517AP0018S
79002	Patient Robe, Universal Size	06806517AP0018S