



EC Declaration of Conformity

Name of Products: Apparel

Product Codes: See **Attachment A**

UMDNS Code: 13574 (Cover,Shoe)
13882 (Surgical Head Coverings)
11897 (Gowns, disposable)
11901 (Gowns, Operating Room, Disposables)

GMDN Code: 15056 (Non-conductive shoe cover)
43315 (Surgical Hood)
32297 (Cap, Surgical, Single Use)
35092 (Gowns, Patient, Single Use)
35091 (Gown, Operating Room, Single Use)
58382 (Disposable scrub suit, non-sterile)

Legal Manufacturer (Place of Issue): O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116, USA

EU Authorized Representative: Arc Royal
Virginia Road Kells, Co
Meath, Ireland

Product Standards: N/A

Start of CE: 09-Dec-2014

Conformity Assessment Route: Annex VII

Device Classification, Rules: Class I per Annex IX

Quality System Certificate: FM 697013 (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 O&M Halyard, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:

Name: Angela L. Bunn, RAC 10-APR-19
Title: Director, Regulatory Affairs Global Products Division
O&M Halyard, Inc.



Attachment A (Product List)

This attachment specifies the products included in the above referenced Declaration of Conformity.

Product Code	Product Description	Sterilization
69114	BASICS* Shoe Cover, Regular Size, Blue	Non-sterile
69121	BASICS* Shoe Cover, XL, Blue	Non-sterile
69252	X-TRA TRACTION* Shoe Cover, Universal Size, Blue	Non-sterile
69253	ANKLE GUARD* Shoe Cover, Universal Size, Blue	Non-sterile
69254	X-TRA TRACTION* Shoe Cover Blue, X-Large	Non-sterile
69353	ANKLE GUARD* Shoe Cover, X-Large, Blue	Non-sterile
69551	Heavy Duty Shoe Cover, Universal Size, Blue	Non-sterile
69571	HI GUARD* Regular Full Coverage Boot, Universal Size	Non-sterile
69572	HI GUARD* Ultra Full Coverage Boot, Universal Size	Non-sterile
69671	HI GUARD* Regular Full Coverage Boot, X-Large	Non-sterile
69672	HI GUARD* Ultra Full Coverage Boot, X-Large	Non-sterile

Product Code	Product Description	Sterilization
44648	Bloodborne Pathogen Protection Hood	Non-Sterile
69110	Protective Surgical Hood, Universal Size, Blue	Non-sterile
69240	Surgical Cap, KAYCEL* Fabric, Universal Size, Blue	Non-sterile
69801	Spunbond Bouffant Cap, L Blue	Non-sterile
69803	Spunbond Bouffant Cap, XL, Blue	Non-sterile
54100	Tri-Layer AAMI1 Isolation Gown, Yellow, Large	Non-sterile
54101	Tri-Layer AAMI1 Isolation Gown, Yellow, X-Large	Non-sterile
54110	Tri-Layer AAMI1 Isolation Gown, Blue, Medium	Non-sterile
54111	Tri-Layer AAMI1 Isolation Gown, Blue, X-Large	Non-sterile
54310	Tri-Layer AAMI3 Isolation Gown, Blue, Large	Non-sterile
54311	Tri-Layer AAMI3 Isolation Gown, Blue, X-Large	Non-sterile
69025	Procedure Gown / Blue / Large	Non-sterile
69028	Procedure Gown / Blue / X-Large	Non-sterile
69124	Cover Gown, Yellow, L	Non-sterile
69125	Cover Gown, Yellow, XL	Non-sterile
69127	Cover Gown, Blue, L	Non-sterile
69129	Cover Gown, Blue, XL	Non-sterile
69190	Tri-Layer AAMI2 Isolation Gown, L, Yellow	Non-sterile
69191	Tri-Layer AAMI2 Isolation Gown, XL, Yellow	Non-sterile
69316	Film Gown, Blue, Open Back, Thumb Hooks, Extra-Large	Non-sterile
69455	Impervious Open-Back Gown / Blue / Knit Cuffs / Large	Non-sterile
69490	Film Gown, Blue, Open Back, Thumb Hooks, Universal Size	Non-sterile
69600	Impervious Comfort Gown / Blue / Knit Cuffs / Large Size	Non-sterile
69601	Impervious Comfort Gown / Blue / Knit Cuffs / XX-Large	Non-sterile
69602	Impervious Comfort Gown / Blue / Thumb Hooks / Large	Non-sterile
69603	Impervious Comfort Gown / Blue / Thumb Hooks / XX-Large	Non-sterile
69766	Patient Gown	Non-sterile
69979	Tri-Layer AAMI2 Isolation Gown, Yellow, Large	Non-sterile
69981	Tri-Layer AAMI2 Isolation Gown, Blue, Large	Non-sterile



Product Code	Product Description	Sterilization
69986	Tri-Layer AAMI2 Isolation Gown, Yellow/Elastic Cuff, Large	Non-sterile
69987	Tri-Layer AAMI2 Isolation Gown, Blue, X-Large	Non-sterile
69988	Tri-Layer AAMI2 Isolation Gown, Yellow, X-Large	Non-sterile
69989	Tri-Layer AAMI2 Isolation Gown, Yellow, X-Large	Non-sterile
79002	Patient Robe, Universal Size	Non-Sterile
69350	General Purpose Apron	Non-Sterile
69701	Scrub Shirt, Blue, Medium	Non-Sterile
69702	Scrub Shirt/Blue/Large	Non-Sterile
69703	Scrub Shirt/Blue/X-Large	Non-Sterile
69704	Scrub Shirt/Blue/X-Large	Non-Sterile
69711	Scrub Shirt/Pants/Medium	Non-Sterile
69712	Scrub Shirt/Blue/Large	Non-Sterile
69713	Scrub Shirt/Blue/X-Large	Non-Sterile
69714	Scrub Shirt/Blue/XX-Large	Non-Sterile