

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, Disposable)
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):	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:	N/A
Start of CE:	09-Dec-2014
Conformity Assessment Route:	Annex VII
Device Classification, Rules:	Class I per Annex IX
Notified Body:	N/A
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 Affairs
Halyard Health, Inc.
Date: 16-Feb-2016

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
69979	Tri-Layer AAMI2 Isolation Gown, Yellow, Large	Non-sterile
69981	Tri-Layer AAMI2 Isolation Gown, Blue, Large	Non-sterile
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

Product Code	Product Description	Sterilization
79002	Patient Robe, Universal Size	Non-Sterile
69350	General Purpose Apron	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