

EC Declaration of Conformity

Name of Products: Face Masks

Product Codes: See **Attachment A**

UMDNS Code: 12458 (Masks, Surgical)

GMDN Code: 35177 (Surgical face mask, Single Use)

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: BS EN 14683:2014 (except for products with * which comply to Bacterial Filtration Efficiency requirements only)

Start of CE: See **Attachment A**

Conformity Assessment Route: Annex VII

Device Classification, Rules: I, non sterile and non-measuring, Rule 1 per Annex IX

CE certificate number: N/A

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 Bunn *5-AUG-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.

Stock Code	Description	Start of CE
00146	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT * Earloops	03-June-2015
00148	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT * Earloops	03-June-2015
00152	Standard Cone Mask	03-June-2015
10729	Surgical Face Mask	03-June-2015
28797	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Earloops	06-Sep-2017
28800	Fluidshield* 3 Fog-Free Procedure Mask with SO SOFT* Earloops	06-Sep-2017
37525	Duckbill Surgical Mask	03-June-2015
46727*	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	03-June-2015
46767*	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining	03-June-2015
46827*	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	03-June-2015
46867*	FLUIDSHIELD*3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining	03-June-2015
47080	Procedure Mask with SO SOFT* Earloops	03-June-2015
47081	Procedure Mask with SO SOFT* Earloops	03-June-2015
47085	Procedure Mask with SO SOFT* Earloops	03-June-2015
47090	Procedure Mask with SO SOFT* Earloops	03-June-2015
47095	Procedure Mask with SO SOFT* Earloops	03-June-2015
47116	Procedure Mask with SO SOFT* Earloops	03-June-2015
47117	Procedure Mask with SO SOFT* Earloops	03-June-2015
47127	Child's Face Mask with SO SOFT* Earloops	03-June-2015
47137	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
47295	Teddy Bear Procedure Mask with SO SOFT* Earloops	03-June-2015
47297	FLUIDSHIELD* 3 Teddy Bear Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
47298	FLUIDSHIELD* 3 Teddy Bear Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
47500	SOFT TOUCH II* Surgical Mask	03-June-2015
47625	High Filtration Surgical Mask	03-June-2015
47650	High Filtration Fog-Free Surgical Mask	03-June-2015
47700	Pouch Style Mask with SO SOFT* Lining	03-June-2015
47717	Pouch Style Mask with SO SOFT* Lining	03-June-2015
48100	THE LITE ONE* Surgical Mask	03-June-2015
48105	THE LITE ONE* Surgical Mask	03-June-2015
48201	Surgical Mask	03-June-2015
48210	Surgical Mask	03-June-2015
48220	Duckbill Surgical Mask	03-June-2015
48247	FLUIDSHIELD* 3 Fog-Free Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type II R)	03-June-2015
48248	FLUIDSHIELD* 3 Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type II R)	03-June-2015
48296	Teddy Bear Surgical Mask	03-June-2015

Stock Code	Description	Start of CE
48297	FLUIDSHIELD* 3 Teddy Bear Surgical Mask with SO SOFT* Lining	03-June-2015
48390	Surgical Mask with SO SOFT* Lining	03-June-2015
49214	Fog-Free Surgical Mask	03-June-2015
49215	Anti-Fog Surgical Mask	03-June-2015
49216	Duckbill Fog-Free Surgical Mask	03-June-2015
49235	Anti-Fog Surgical Mask	03-June-2015
49310	ULTI-MASK* Fog-Free Surgical Mask	03-June-2015
49700	Standard Procedure Mask	03-June-2015
49701	Standard Surgical Mask	03-June-2015
59928	THE FRIENDLY* Surgical Mask	03-June-2015
62113	FLUIDSHIELD* 2 Fog-Free Surgical Mask	03-June-2015
62114	FLUIDSHIELD* 2 Fog-Free Surgical Mask	03-June-2015
62115	FLUIDSHIELD* 2 Procedure Mask with SO SOFT* Earloops	03-June-2015
62116	FLUIDSHIELD* 2 Fog-Free Procedure Mask with SO SOFT* Earloops	03-June-2015
62126*	FLUIDSHIELD* 2 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	03-June-2015
62355*	FLUIDSHIELD* 2 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	03-June-2015
62356	THE LITE ONE* Procedure Mask with SO SOFT* Earloops	03-June-2015
62357	THE LITE ONE* Procedure Mask with SO SOFT* Earloops	03-June-2015
62362	Fog-Free Procedure Mask with SO SOFT* Earloops	03-June-2015
62363	Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops Standard Face Masks	03-June-2015
62367	THE LITE ONE* Surgical Mask	03-June-2015
28804	FLUIDSHIELD* 3 Fog-Free Surgical Mask/WrapAround Anti-Glare Visor (ASTM F2100-EN 14683 Type II R)	04-May-2016
28820	FLUIDSHIELD* 3 Fog-Free Surgical Mask (ASTM F2100-EN 14683 Type II R)	04-May-2016
25867*	FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (ASTM F2100-EN 14683 (BFE))	03-June-2015
25869*	FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (ASTM F2100-EN 14683 (BFE))	03-June-2015
28802*	FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 (BFE))	03-June-2015
28806*	FLUIDSHIELD* 1 Fog-Free Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 (BFE))	03-June-2015
28808	FLUIDSHIELD* 2 Fog-Free Surgical Mask (ASTM F2100-EN 14683 Type II R)	03-June-2015
28809	FLUIDSHIELD* 2 Fog-Free Surgical Mask (ASTM F2100-EN 14683 Type IIR)	03-June-2015
28810	FLUIDSHIELD* 2 Procedure Mask with SO SOFT* Earloops (ASTM F2100-EN 14683 Type IIR)	03-June-2015
28821	FLUIDSHIELD* 2 Fog-Free Procedure Mask with SO SOFT* Earloops (ASTM F2100-EN 14683 Type IIR)	03-June-2015
47107	3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (ASTM F2100-EN 14683 Type IIR)	03-June-2015
47147	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (ASTM F2100-EN 14683 Type IIR)	03-June-2015
48207	FLUIDSHIELD* 3 Fog-Free Surgical Mask with SO SOFT* Lining	03-June-2015

Stock Code	Description	Start of CE
	(ASTM F2100-EN 14683 Type IIR)	
48208	FLUIDSHIELD* 3 Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type IIR)	03-June-2015
48237	FLUIDSHIELD* 3 Fog-Free Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type IIR)	03-June-2015