

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

Start of CE: See **Attachment A**

Conformity Assessment Route: Annex VII

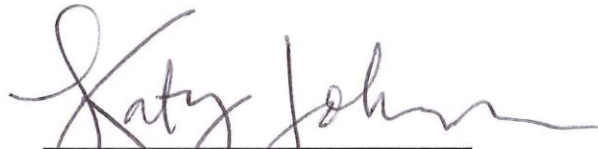
Device Classification, Rules: I, non sterile and non-measuring, Rule 1 per Annex IX

CE certificate number: N/A

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 Leader
Halyard Health, Inc.
Date: 02-Nov-2016

Attachment A (Product List)

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

Stock Code	Description	Start of CE
146	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
148	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
152	Standard Cone Mask	03-June-2015
10729	Surgical Face Mask	03-June-2015
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
48297	FLUIDSHIELD* 3 Teddy Bear Surgical Mask with SO SOFT* Lining	03-June-2015
48390	Surgical Mask with SO SOFT* Lining	03-June-2015

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

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