EC Declaration of Conformity

This declaration is issued under the sole responsibility of the legal manufacturer:

Name of Products:	Sterilization Products
Product Codes:	See **Attachment A**
UMDNS Code:	N/A
GMDN Code:	13735 (Sterilization Packaging, Single Use) 60908 (Sterilization Container Liner)
CND Code:	S010302: Non-Woven Sterilization Devices
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: **UDI-DI: (device level)**	IE-AR-000003110 06806517SP001EY
Start of CE:	9 December 2014
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:

On behalf of O&M Halyard, Inc.

Name: Caitlin Senter, MS, RAC
Title: Director, Global Regulatory Affairs
Address: O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116
United States of America

Date: Apr 4, 2024

ATTACHMENT A: Product Codes and Descriptions for Sterilization Products (Non-Sterile)

Global SKU	Description	Basic UDI-DI
10712	Sequential H100 Sterilization Wrap 12in x 12in (30cm x 30cm)	06806517SP001EY
10715	Sequential H100 Sterilization Wrap 15in x 15in (38cm x 38cm)	06806517SP001EY
10718	Sequential H100 Sterilization Wrap 18in x 18in (45cm x 45cm)	06806517SP001EY
10720	Sequential H100 Sterilization Wrap 20in x 20in (50cm x 50cm)	06806517SP001EY
10724	Sequential H100 Sterilization Wrap 24in x 24in (60cm x 60cm)	06806517SP001EY
10730	Sequential H100 Sterilization Wrap 30in x 30in (76cm x 76cm)	06806517SP001EY
10736	Sequential H100 Sterilization Wrap 36in x 36in (91cm x 91cm)	06806517SP001EY
10740	Sequential H100 Sterilization Wrap 40in x 40in (101cm x 101cm)	06806517SP001EY
10745	Sequential H100 Sterilization Wrap 45in x 45in (114cm x 114cm)	06806517SP001EY
10748	Sequential H100 Sterilization Wrap 48in x 48in (121cm x 121cm)	06806517SP001EY
10754	Sequential H100 Sterilization Wrap 54in x 54in (137cm x137cm)	06806517SP001EY
10772	Sequential H100 Sterilization Wrap 54in x 72in (137cm x 182cm)	06806517SP001EY
10818	Sequential H300 Sterilization Wrap 18in x 18in (45cm x 45cm)	06806517SP001EY
10824	Sequential H300 Sterilization Wrap 24in x 24in (60cm x 60cm)	06806517SP001EY
10830	Sequential H300 Sterilization Wrap 30in x 30in (76cm x 76cm)	06806517SP001EY
10836	Sequential H300 Sterilization Wrap 36in x 36in (91cm x 91cm)	06806517SP001EY
10840	Sequential H300 Sterilization Wrap 40in x 40in (101cm x 101cm)	06806517SP001EY
10845	Sequential H300 Sterilization Wrap 45in x 45in (114cm x 114cm)	06806517SP001EY
10848	Sequential H300 Sterilization Wrap 48in x 48in (121cm x 121cm)	06806517SP001EY
10854	Sequential H300 Sterilization Wrap 54in x 54in (137cm x 137cm)	06806517SP001EY
10872	Sequential H300 Sterilization Wrap 54in x 72in (137cm x 182cm)	06806517SP001EY
12712	ONE-STEP* H100 Sterilization Wrap, 12in. X 12in. (30cm X 30cm)	06806517SP001EY
12718	ONE-STEP* H100 Sterilization Wrap, 18in. X 18in. (45cm X 45cm)	06806517SP001EY
12720	ONE-STEP* H100 Sterilization Wrap, 20in. X 20in. (50cm X 50cm)	06806517SP001EY
12724	ONE-STEP* H100 Sterilization Wrap, 24in. X 24in. (60cm X 60cm)	06806517SP001EY
12730	ONE-STEP* H100 Sterilization Wrap, 30in. X 30in. (76cm X 76cm)	06806517SP001EY
12736	ONE-STEP* H100 Sterilization Wrap, 36in. X 36in. (91cm X 91cm)	06806517SP001EY
12740	ONE-STEP* H100 Sterilization Wrap, 40in. X 40in. (101cm X 101cm)	06806517SP001EY
12745	ONE-STEP* H100 Sterilization Wrap, 45in. X 45in. (114cm X 114cm)	06806517SP001EY
12748	ONE-STEP* H100 Sterilization Wrap, 48in. X 48in. (121cm X 121cm)	06806517SP001EY
12754	ONE-STEP* H100 Sterilization Wrap 54in x 54in (137cm x 137 cm)	06806517SP001EY
12824	ONE-STEP* H300 Sterilization Wrap, 24in. X 24in. (60cm X 60cm)	06806517SP001EY
12830	ONE-STEP* H300 Sterilization Wrap, 30in. X 30in. (76cm X 76cm)	06806517SP001EY
12836	ONE-STEP* H300 Sterilization Wrap, 36in. X 36in. (91cm X 91cm)	06806517SP001EY
12840	ONE-STEP* H300 Sterilization Wrap, 40in. X 40in. (101cm X 101cm)	06806517SP001EY
12845	ONE-STEP* H300 Sterilization Wrap, 45in. X 45in. (114cm X 114cm)	06806517SP001EY
12848	ONE-STEP* H300 Sterilization Wrap, 48in. X 48in. (121cm X 121cm)	06806517SP001EY

12854	ONE-STEP* H300 Sterilization Wrap, 54in. X 54in. (137cm X 137cm)	06806517SP001EY
12872	ONE-STEP* H300 Sterilization Wrap, 54in. X 72in. (137cm X 182cm)	06806517SP001EY
14268	SMART-FOLD* H450 Sterilization Wrap 40in x 47in (101cm x 119cm)	06806517SP001EY
14271	SMART-FOLD* H650 Sterilization Wrap 40in x 47 in (101cm x 119cm)	06806517SP001EY
14275	SMART-FOLD* H450 Sterilization Wrap 40in x 55in (101cm x 139cm)	06806517SP001EY
14277	SMART-FOLD* H650 Sterilization Wrap 40in x 55 in (101cm x 139cm)	06806517SP001EY
14279	SMART-FOLD* H450 Sterilization Wrap 28in x 46in (71cm x 116cm)	06806517SP001EY
14281	SMART-FOLD* H650 Sterilization Wrap 28in x 46 in (71cm x 116cm)	06806517SP001EY
14309	SMART-FOLD* H650 Sterilization Wrap 48in x 61 in (121cm x 154cm)	06806517SP001EY
14313	SMART-FOLD* H450 Sterilization Wrap 48in x 61in (121cm x 154cm)	06806517SP001EY
14320	SMART-FOLD* H650 Sterilization Wrap 22in x 45 in (55cm x 114cm)	06806517SP001EY
14324	SMART-FOLD* H450 Sterilization Wrap 22in x 45in (55cm x 114cm)	06806517SP001EY
34142	QUICK CHECK* Sterilization Wrap H600 54in x 54in (137cm x 137cm)	06806517SP001EY
34143	QUICK CHECK* Sterilization Wrap H500 54in x 54in (137cm x 137cm)	06806517SP001EY
34145	QUICK CHECK* Sterilization Wrap H400 48in x 48in (121cm x 121cm)	06806517SP001EY
34146	QUICK CHECK* Sterilization Wrap H400 54in x 54in (137cm x 137cm)	06806517SP001EY
34147	QUICK CHECK* Sterilization Wrap H600 54in x 54in (137cm x 137cm)	06806517SP001EY
34148	QUICK CHECK* Sterilization Wrap H500 48in x 48in (121cm x 121cm)	06806517SP001EY
34149	QUICK CHECK* Sterilization Wrap H200 48in x 48in (121cm x 121cm)	06806517SP001EY
34151	QUICK CHECK* Sterilization Wrap H600 36in x 36in (91cm x 91cm)	06806517SP001EY
34154	QUICK CHECK* Sterilization Wrap H100 12in x 12in (30cm x 30cm)	06806517SP001EY
34156	QUICK CHECK* Sterilization Wrap H100 18in x 18in (45cm x 45cm)	06806517SP001EY
34157	QUICK CHECK* Sterilization Wrap H400 18in x 18in (45cm x 45cm)	06806517SP001EY
34158	QUICK CHECK* Sterilization Wrap H400 36in x 36in (91cm x 91cm)	06806517SP001EY
34159	QUICK CHECK* Sterilization Wrap H300 45in x 45in (114cm x 114cm)	06806517SP001EY
34160	QUICK CHECK* Sterilization Wrap H300 36in x 36in (91cm x 91cm)	06806517SP001EY
34161	QUICK CHECK* Sterilization Wrap H100 48in x 48in (121cm x 121cm)	06806517SP001EY
34162	QUICK CHECK* Sterilization Wrap H500 24in x 24in (60cm x 60cm)	06806517SP001EY
34163	QUICK CHECK* Sterilization Wrap H600 40inx40in (101cm x 101cm)	06806517SP001EY
34164	QUICK CHECK* Sterilization Wrap H600 45in x 45in (114cm x 114cm)	06806517SP001EY
34165	QUICK CHECK* Sterilization Wrap H500 30in x 30in (121cm x 121cm)	06806517SP001EY
34167	QUICK CHECK* Sterilization Wrap H200 12inx12in (30cm x 30cm)	06806517SP001EY
34168	QUICK CHECK* Sterilization Wrap H200 54inx72in (137cm x 182cm)	06806517SP001EY
34171	QUICK CHECK* Sterilization Wrap H300 24in x 24in (60cm x 60cm)	06806517SP001EY
34172	QUICK CHECK* Sterilization Wrap H100 54in x 54in (137cm x 137cm)	06806517SP001EY
34173	QUICK CHECK* Sterilization Wrap H300 30in x 30in (76cm x 76cm)	06806517SP001EY
34174	QUICK CHECK* Sterilization Wrap H200 24in x 24in (60cm x 60cm)	06806517SP001EY
34175	QUICK CHECK* Sterilization Wrap H200 30in x 30in (76cm x 76cm)	06806517SP001EY
34176	QUICK CHECK* Sterilization Wrap H100 30in x 30in (76cm x 76cm)	06806517SP001EY
34178	QUICK CHECK* Sterilization Wrap H100 24in x 24in (60cm x 60cm)	06806517SP001EY
34179	QUICK CHECK* Sterilization Wrap H500 60in x 60in (152cm x 152cm)	06806517SP001EY

34180	QUICK CHECK* Sterilization Wrap H500 18in x 18in (45cm x 45cm)	06806517SP001EY
34181	QUICK CHECK* Sterilization Wrap H300 48in x 48in (121cm x 121cm)	06806517SP001EY
34182	QUICK CHECK* Sterilization Wrap H300 54in x 54in (137cm x 137cm)	06806517SP001EY
34183	QUICK CHECK* Sterilization Wrap H400 24in x 24in (60cm x 60cm)	06806517SP001EY
34184	QUICK CHECK* Sterilization Wrap H400 40in x 40in (101cm x 101cm)	06806517SP001EY
34185	QUICK CHECK* Sterilization Wrap H200 36in x 36in (91cm x 91cm)	06806517SP001EY
34186	QUICK CHECK* Sterilization Wrap H200 40in x 40in (101cm x 101cm)	06806517SP001EY
34187	QUICK CHECK* Sterilization Wrap H200 54in x 54in (137cm x 137cm)	06806517SP001EY
34188	QUICK CHECK* Sterilization Wrap H100 45in x 45in (114cm x 114cm)	06806517SP001EY
34189	QUICK CHECK* Sterilization Wrap H300 40in x 40in (101cm x 101cm)	06806517SP001EY
34190	QUICK CHECK* Sterilization Wrap H300 54in x 72in (137cm x 182cm)	06806517SP001EY
34191	QUICK CHECK* Sterilization Wrap H400 54in x 72in (137cm x 182cm)	06806517SP001EY
34192	QUICK CHECK* Sterilization Wrap H100 20in x 20in (50cm x 50cm)	06806517SP001EY
34193	QUICK CHECK* Sterilization Wrap H200 18in x 18in (45cm x 45cm)	06806517SP001EY
34194	QUICK CHECK* Sterilization Wrap H100 36in x 36in (91cm x 91cm)	06806517SP001EY
34195	QUICK CHECK* Sterilization Wrap H500 54in x 72in (137cm x 182cm)	06806517SP001EY
34196	QUICK CHECK* Sterilization Wrap H500 54in x 90in (137cm x 228cm)	06806517SP001EY
34197	QUICK CHECK* Sterilization Wrap H600 54in x 72in (137cm x 182cm)	06806517SP001EY
34198	QUICK CHECK* Sterilization Wrap H500 45in x 45in (114cm x 114cm)	06806517SP001EY
34199	QUICK CHECK* Sterilization Wrap H500 36in x 36in (91cm x 91cm)	06806517SP001EY
34200	QUICK CHECK* Sterilization Wrap H100 40in x 40in (101cm x 101cm)	06806517SP001EY
37044	QUICK CHECK* Sterilization Wrap H200 15in x 15in (38cm x 38cm)	06806517SP001EY
37045	QUICK CHECK* Sterilization Wrap H400 18in x 18in (45cm x 45cm)	06806517SP001EY
37046	Sequential H100 Sterilization Wrap 12in x 12in (30cm x 30cm)	06806517SP001EY
37047	Sequential H100 Sterilization Wrap 15in x 15in (38cm x 38cm)	06806517SP001EY
37049	Sequential H100 Sterilization Wrap 18in x 18in (45cm x 45cm)	06806517SP001EY
37050	Sequential H100 Sterilization Wrap 20in x 20in (50cm x 50cm)	06806517SP001EY
37051	Sequential H100 Sterilization Wrap 24in x 24in (60cm x 60cm)	06806517SP001EY
46972	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H200 24in x 24 in (60cm x 60cm)	06806517SP001EY
46973	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H200 30in x 30in (76cm x 76cm)	06806517SP001EY
46974	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H200 36in x 36in (91cm x 91cm)	06806517SP001EY
46978	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H300 36in x 36in (91cm x 91cm)	06806517SP001EY
46979	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H300 40in x 40in (101cm x 101cm)	06806517SP001EY
46982	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H300 48in x 48in (121cm x 121cm)	06806517SP001EY
46984	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H300 54in x 54in (137cm x 137cm)	06806517SP001EY

46985	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H200 48in x 48in (121cm x 121cm)	06806517SP001EY
46989	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H200 40in x 40in (101cm x 101cm)	06806517SP001EY
46994	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H500 36in x 36in (91cm x 91cm)	06806517SP001EY
46995	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H400 40in x 40in (101cm x 101cm)	06806517SP001EY
46996	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H400 48in x 48in (121cm x 121cm)	06806517SP001EY
46997	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H500 48in x 48in (121cm x 121cm)	06806517SP001EY
46998	QUICK CHECK INTERLEAVED* Sequential Sterilization Wrap H500 54in x 54in (137cm x 137cm)	06806517SP001EY
48139	Absorbent Tray Liner (51 cm x 64 cm)	06806517SP001EY
62015	ONE-STEP* H200 Sterilization Wrap, 15in. X 15in. (36cm X 36cm)	06806517SP001EY
62018	ONE-STEP* H200 Sterilization Wrap, 18in. X 18in. (45cm X 45cm)	06806517SP001EY
62024	ONE-STEP* H200 Sterilization Wrap, 24in. X 24in. (60cm X 60cm)	06806517SP001EY
62030	ONE-STEP* H200 Sterilization Wrap, 30in. X 30in. (76cm X 76cm)	06806517SP001EY
62036	ONE-STEP* H200 Sterilization Wrap, 36in. X 36in. (91cm X 91cm)	06806517SP001EY
62040	ONE-STEP* H200 Sterilization Wrap, 40in. X 40in. (101cm X 101cm)	06806517SP001EY
62048	ONE-STEP* H200 Sterilization Wrap, 48in. X 48in. (121cm X 121cm)	06806517SP001EY
62054	ONE-STEP* H200 Sterilization Wrap, 54n. X 54in. (137cm X 137cm)	06806517SP001EY
62072	ONE-STEP* H200 Sterilization Wrap, 54in. X 72in. (137cm X 182cm)	06806517SP001EY
62118	ONE-STEP* H500 Sterilization Wrap, 18in. X 18in. (45cm X 45cm)	06806517SP001EY
62124	ONE-STEP* H500 Sterilization Wrap, 24in. X 24in. (60cm X 60cm)	06806517SP001EY
62130	ONE-STEP* H500 Sterilization Wrap, 30in. X 30in. (45cm X 45cm)	06806517SP001EY
62136	ONE-STEP* H500 Sterilization Wrap, 36in. X 36in. (76cm X 76cm)	06806517SP001EY
62145	ONE-STEP* H500 Sterilization Wrap, 45in. X 45in. (114cm X 114cm)	06806517SP001EY
62148	ONE-STEP* H500 Sterilization Wrap, 48in. X 48in. (121cm X 121cm)	06806517SP001EY
62154	ONE-STEP* H500 Sterilization Wrap, 54in. X 54in. (137cm X 137cm)	06806517SP001EY
62172	ONE-STEP* H500 Sterilization Wrap, 54in. X 72in. (137cm X 182cm)	06806517SP001EY
62224	ONE-STEP* H400 Sterilization Wrap, 24in. X 24in. (60cm X 60cm)	06806517SP001EY
62236	ONE-STEP* H400 Sterilization Wrap, 36in. X 36in. (91cm X 91cm)	06806517SP001EY
62240	ONE-STEP* H400 Sterilization Wrap, 40in. X 40in. (101cm X 101cm)	06806517SP001EY
62245	ONE-STEP* H400 Sterilization Wrap, 45n. X 45in. (114cm X 114cm)	06806517SP001EY
62248	ONE-STEP* H400 Sterilization Wrap, 48in. X 48in. (121cm X 121cm)	06806517SP001EY
62254	ONE-STEP* H400 Sterilization Wrap, 54in. X 54in. (137cm X 137cm)	06806517SP001EY
62272	ONE-STEP* H400 Sterilization Wrap, 54in. X 72in. (101cm X 101cm)	06806517SP001EY
62636	ONE-STEP* H600 Sterilization Wrap, 36in. X 36in. (91cm X 91cm)	06806517SP001EY
62640	ONE-STEP* H600 Sterilization Wrap, 40in. X 40in. (101cm X 101cm)	06806517SP001EY
62645	ONE-STEP* H600 Sterilization Wrap, 45in. X 45in. (114cm X 114cm)	06806517SP001EY
62648	ONE-STEP* H600 Sterilization Wrap, 48in. X 48in. (121cm X 121cm)	06806517SP001EY

68012	Sequential H200 Sterilization Wrap 12in x 12in (30cm x 30cm)	06806517SP001EY
68015	Sequential H200 Sterilization Wrap 15in x 15in (38cm x 38cm)	06806517SP001EY
68018	Sequential H200 Sterilization Wrap 18in x 18in (45cm x 45cm)	06806517SP001EY
68024	Sequential H200 Sterilization Wrap 24in x 24in (60cm x 60cm)	06806517SP001EY
68030	Sequential H200 Sterilization Wrap 30in x 30in (76cm x 76cm)	06806517SP001EY
68036	Sequential H200 Sterilization Wrap 36in x 36in (91cm x 91cm)	06806517SP001EY
68040	Sequential H200 Sterilization Wrap 40in x 40in (101cm x 101cm)	06806517SP001EY
68048	Sequential H200 Sterilization Wrap 48in x 48in (121cm x 121cm)	06806517SP001EY
68054	Sequential H200 Sterilization Wrap 54in x 54in (137cm x 137cm)	06806517SP001EY
68072	Sequential H200 Sterilization Wrap 54in x 72in (137cm x 182cm)	06806517SP001EY
68118	Sequential H500 Sterilization Wrap 18in x 18in (45cm x 45cm)	06806517SP001EY
68124	Sequential H500 Sterilization Wrap 24in x 24in (60cm x 60cm)	06806517SP001EY
68130	Sequential H500 Sterilization Wrap 30in x 30in (76cm x 76cm)	06806517SP001EY
68136	Sequential H500 Sterilization Wrap 36in x 36in (91cm x 91cm)	06806517SP001EY
68145	Sequential H500 Sterilization Wrap 45in x 45in (114cm x 114cm)	06806517SP001EY
68148	Sequential H500 Sterilization Wrap 48in x 48in (121cm x 121cm)	06806517SP001EY
68154	Sequential H500 Sterilization Wrap 54in x 54in (137cm x 137cm)	06806517SP001EY
68160	Sequential H500 Sterilization Wrap 60in x 60in (152cm x 152cm)	06806517SP001EY
68172	Sequential H500 Sterilization Wrap 54in x 72in (137cm x 182cm)	06806517SP001EY
68190	Sequential H500 Sterilization Wrap 54in x 90in (137cm x 228cm)	06806517SP001EY
68218	Sequential H400 Sterilization Wrap 18in x 18in (45cm x 45cm)	06806517SP001EY
68224	Sequential H400 Sterilization Wrap 24in x 24in (60cm x 60cm)	06806517SP001EY
68230	Sequential H400 Sterilization Wrap 30in x 30in (76cm x 76cm)	06806517SP001EY
68236	Sequential H400 Sterilization Wrap 36in x 36in (91cm x 91cm)	06806517SP001EY
68240	Sequential H400 Sterilization Wrap 40in x 40in (101cm x 101cm)	06806517SP001EY
68245	Sequential H400 Sterilization Wrap 45in x 45in (114cm x 114cm)	06806517SP001EY
68248	Sequential H400 Sterilization Wrap 48in x 48in (121cm x 121cm)	06806517SP001EY
68254	Sequential H400 Sterilization Wrap 54in x 54in (137cm x 137cm)	06806517SP001EY
68272	Sequential H400 Sterilization Wrap 54in x 72in (137cm x 182cm)	06806517SP001EY
68648	Sequential H600 Sterilization Wrap 48in x 48in 121cm x 121cm)	06806517SP001EY
68672	Sequential H600 Sterilization Wrap 54in x 62in (137cm x 182cm)	06806517SP001EY
48139	Absorbent Tray Liner 20in x 25 in (51cm x 64 cm)	06806517SP001EY
68507	Container Filters 7.5in/19cm, Round	06806517SP001EY
68509	Container Filters 9in x 9in/23cm x 23cm, Square	06806517SP001EY
49232	QUICK CHECK* REEL* H300 Sterilization Wrap 40in (101 cm)	06806517SP001EY
49231	QUICK CHECK* REEL* H300 Sterilization Wrap 48in (121 cm)	06806517SP001EY
49234	QUICK CHECK* REEL* H400 Sterilization Wrap 40in (101 cm)	06806517SP001EY
49233	QUICK CHECK* REEL* H400 Sterilization Wrap 48in (121 cm)	06806517SP001EY