EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Name of Products:	Equipment Covers, Sterile
Product Codes:	See **Attachment A**
UMDNS Code:	N/A
GMDN Code:	12535: Medical equipment/instrument drape, single-use
CND Code:	T030199: Covers, Instrumentary and Equipment – Others
Intended Use:	Sterile Equipment Covers are intended to be used as coverings in an operating room environment to maintain a sterile field. Equipment Covers are used in a surgical environment to help create a sterile field by covering non-sterile equipment in an operative setting.
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 1220 Old Alpharetta Road Suite 320 Alpharetta, Georgia (GA) 30005 United States of America
Manufacturer SRN :	US-MF-000043924
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN:	IE-AR-000003110
Basic UDI-DI: (device level)	06806517EC0027D
Start of CE:	23 March 2015
Conformity Assessment Route:	Annex IX, Chapters I and III of Regulation (EU) 2017/745
Risk Classification, Rules:	Class Is per Rule 4, Annex VIII Regulation (EU) 2017/745
CE certificate number:	MDR 739585
Notified Body:	BSI-NL (2797)
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.
1220 Old Alpharetta Road Suite 320
Alpharetta, Georgia (GA) 30005
United States of America

Date: 07/24/2025

ATTACHMENT A: Product Codes and Descriptions for Sterile Equipment Covers

No.	Stock Code	Description	Basic UDI-DI
1	14007	Mayo Stand Cover, Reinforced (76 cm x 145 cm)	06806517EC0027D
2	29258	Padded Heavy Duty Back Table Cover, Fan Fold (152 cm x 228 cm)	06806517EC0027D
3	29272	Padded Heavy Duty Back Table Cover, Fan Fold (203 cm x 279 cm)	06806517EC0027D
4	32985	Padded Heavy Duty Back Table Cover, Fan Fold (203 cm x 228 cm)	06806517EC0027D
5	37496	Two-Tier, Padded, Heavy Duty Back Table Cover (122 cm)	06806517EC0027D
6	37498	Two-Tier, Padded, Heavy Duty Back Table Cover (152 cm)	06806517EC0027D
7	37501	Two-Tier, Padded, Heavy Duty Back Table Cover (182 cm)	06806517EC0027D
8	42217	Standard Back Table Cover (112 cm x 229 cm)	06806517EC0027D
9	42222	Standard Back Table Cover (152 cm x 191 cm)	06806517EC0027D
10	42224	Standard Back Table Cover (152 cm x 228 cm)	06806517EC0027D
11	42226	Standard Back Table Cover, Fan Fold (177 cm x 279 cm)	06806517EC0027D
12	42301	Standard Back Table Cover (112 cm x 224 cm)	06806517EC0027D
13	42306	Heavy Duty Back Table Cover (152 cm x 229 cm)	06806517EC0027D
14	42309	Heavy Duty Back Table Cover (177 cm x 279 cm)	06806517EC0027D
15	42312	Standard Back Table Cover (191 cm x 201 cm)	06806517EC0027D
16	42345	Standard Back Table Cover (140 cm x 190 cm)	06806517EC0027D
17	47348	BASICS* Mayo Stand Cover, Zone-Reinforced (80 cm x 144 cm)	06806517EC0027D
18	77452	Large Mayo Stand Cover	06806517EC0027D
19	77883	Mayo Cover Reinforcement (60 cm x 80 cm)	06806517EC0027D
20	88673	BASICS* Back Table Cover, Zone-Reinforced (152 cm x 191 cm)	06806517EC0027D
21	89601	Mayo Stand Cover, Reinforced (58 cm x 137 cm)	06806517EC0027D
22	89602	Mayo Stand Cover, Reinforced, Extra Large	06806517EC0027D
23	89603	Mayo Stand Cover, Reinforced, 31.5 In. X 57 In./80 cm X 145 cm	06806517EC0027D
24	89621	Overhead Table Cover	06806517EC0027D
25	89632	BASICS* Back Table Cover, Zone-Reinforced 39 In. X 59 In. / 100 cm X 150 cm	06806517EC0027D