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:	47783: General Purpose surgical drape, single-use, sterile 45021: Instrument/equipment drape, single-use, sterile
CND Code:	T030199: Covers, Instrumentary and Equipment – Others
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 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:

September 29, 2021

On behalf of O&M Halyard, Inc

Name: Steven Dowdley
Title: Director, Regulatory Affairs
Address: O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116
United States of America

Date: 30 September 2021

ATTACHMENT A: Product Codes and Descriptions for Sterile Equipment Covers

Stock Code	Description	UDI-DI
14007	Mayo Stand Cover, Reinforced (76 cm x 145 cm)	06806517EC0027D
29258	Padded Heavy Duty Back Table Cover, Fan Fold (152 cm x 228 cm)	06806517EC0027D
29272	Padded Heavy Duty Back Table Cover, Fan Fold (203 cm x 279 cm)	06806517EC0027D
32985	Padded Heavy Duty Back Table Cover, Fan Fold (203 cm x 228 cm)	06806517EC0027D
37496	Two-Tier, Padded, Heavy Duty Back Table Cover (122 cm)	06806517EC0027D
37498	Two-Tier, Padded, Heavy Duty Back Table Cover (152 cm)	06806517EC0027D
37501	Two-Tier, Padded, Heavy Duty Back Table Cover (182 cm)	06806517EC0027D
42217	Standard Back Table Cover (112 cm x 229 cm)	06806517EC0027D
42222	Standard Back Table Cover (152 cm x 191 cm)	06806517EC0027D
42224	Standard Back Table Cover (152 cm x 228 cm)	06806517EC0027D
42226	Standard Back Table Cover, Fan Fold (177 cm x 279 cm)	06806517EC0027D
42301	Standard Back Table Cover (112 cm x 224 cm)	06806517EC0027D
42306	Heavy Duty Back Table Cover (152 cm x 229 cm)	06806517EC0027D
42309	Heavy Duty Back Table Cover (177 cm x 279 cm)	06806517EC0027D
42312	Standard Back Table Cover (191 cm x 201 cm)	06806517EC0027D
42345	Standard Back Table Cover (140 cm x 190 cm)	06806517EC0027D
47348	BASICS* Mayo Stand Cover, Zone-Reinforced (80 cm x 144 cm)	06806517EC0027D
77452	Large Mayo Stand Cover	06806517EC0027D
77883	Mayo Cover Reinforcement (60 cm x 80 cm)	06806517EC0027D
88673	BASICS* Back Table Cover, Zone-Reinforced (152 cm x 191 cm)	06806517EC0027D
89601	Mayo Stand Cover, Reinforced (58 cm x 137 cm)	06806517EC0027D
89602	Mayo Stand Cover, Reinforced, Extra Large	06806517EC0027D
89621	Overhead Table Cover	06806517EC0027D