By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 739585 R000

Manufacturer: O & M Halyard, Inc.

Address:
1220 Old Alpharetta Road
Suite 320
Alpharetta
Georgia
30005
USA

Single Registration Number: US-MF-000043924

EU Authorised Representative: Arc Royal

Address:
Virginia Road Kells
Co Meath
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-08-04**

Current Issue Date: **2025-03-10**

Starting Validity Date: **2025-03-10**

Expiry Date: **2026-08-03**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Surgical drapes (TUR drape & TUR pack)	Class IIa
Surgical gowns	Class Is
Surgical drapes & equipment covers	Class Is
Surgical packs & surgical accessories	Class Is
Powder Free Examination gloves	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-08-04	3327037	Issued
2021-09-24	3541634	Amended – addition of critical subcontractor for radiation (gamma sterilization)
2022-08-29	3748037	Amended – removal of two critical subcontractors for ETO sterilization
2024-01-17	30056866	Supplemented – addition of Class IIa device: surgical drapes (TUR drape & TUR pack) Amended – administrative update to previous history entries 3541634 & 3748037
2024-11-18	30230185	Amended – Change to address of critical subcontractor Amended – Addition of SRN
Current	30365482	Amended – change of Legal Manufacturer address Amended - change to device schedule. Addition of 'powder free' for examination gloves

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