

EU Quality Management System Certificate

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

MDR 739585 R000

Manufacturer: O & M Halyard, Inc

Address:

9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Single Registration Number: Not Available

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 and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-08-04**

Date: **2021-08-04**

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

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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

Device(s)	Risk Classification
Surgical gowns	Class Is
Surgical drapes & equipment covers	Class Is
Surgical packs & surgical accessories	Class Is
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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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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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
Current	3327037	Issued



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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

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Date: **2021-08-04**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
GRI Medical & Electronic Technology Co., Ltd 1805 Honggao Road Jiaxing Zhejiang 314031 China	ETO Sterilization Manufacture
Isomedix Operations, Inc 1441 Don Haskins Drive El Paso Texas 79936 USA	ETO Sterilization
Joykey Industrial (Ping Hu) Limited NO. 2288 Xinkai Road Pinghu Economic Development Zone Pinghu 314200 Zhejiang China	ETO Sterilization
La Ada de Acuna S. De. R.L. De C.V. Av. Hidalgo No. 6 Esq., Blvd. Luis Donaldo Colosio Col. Educativa, Nogales Sonora 84093 Mexico	Manufacture

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Lianyungang Aiyeh Non-Woven Products Co., Ltd No. 9 YunYang Rd. Huangjiuni Export Processing Zone Lianyungang, Jiangsu 222047 China	Manufacture
LYG Bronco Medical Supply Co., Ltd 1-2 room, Lianyungang Economic and Technological Development Area Comprehensive Bonded Zone China (Jiangsu) Pilot Free Trade Zone Lianyungang Jiangsu 222047 China	ETO Sterilization
O & M Halyard, Inc 1 Edison Drive Alpharetta Georgia 30005 USA	Regulatory Compliance
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	Manufacture

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Principle & Will Biotech Co., Ltd. No. 2000, Xingping II Rd. Pinghu Economic Development Zone Zhejiang P.R. China	Manufacture
SAFESKIN MEDICAL & SCIENTIFIC (THAILAND), LTD. 200 moo 8 Kanchanavanich Road Tambol Prik, Amphur Sadao Songkhla, 90120 Thailand	Manufacture
Sterigenics S. de R. L. de C. V. James Watt No. 22 Parque Industrial Cuamatla Cuautitlan Izcalli Estado de México C.P. 54730 Mexico	ETO Sterilization
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization

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Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	ETO Sterilization
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	ETO Sterilization
Sterigenics US, LLC 2971 Olympic Industrial Drive SE Suite 116 Atlanta Georgia 30339 USA	ETO Sterilization
Sterigenics US, LLC 2400 Airport Road Santa Theresa New Mexico 88008 USA	ETO Sterilization

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Sterilization Services 5674 Eastport Boulevard Richmond Virginia 23231 USA	ETO Sterilization
Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Estate Moo 7, Tambol Donhwaroh Amphur Muang Chonburi 20000 Thailand	Radiation (Gamma Sterilization)
Synergy Sterilisation (M) Sdn Bhd Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	Radiation (Gamma Sterilization)

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