EU Quality Management System Certificate

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

MDR 755419 R000

Manufacturer: The O R Company Pty Ltd

Address:
1/32 Silkwood Rise,
Carrum Downs,
Victoria
3201
Australia

Single Registration Number: AU-MF-000010179

EU Authorised Representative: Obelis s.a.

Address:
Bd. Général Wahis, 53,
1030 Brussels,
Belgium

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):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-03-02** Date: **2022-03-02** Expiry Date: **2027-03-01**

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

Device(s)	Risk Classification
Laparoscopic Access Device / Endoscopic Access Device	Class IIa
Gas inflators	Class Is
Non-specialist surgical instruments and kits, single-use	Class Is
Skin marking dermographic pencils and pens	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
Current	3498322	Issued

First Issued: **2022-03-02** Date: **2022-03-02** Expiry Date: **2027-03-01**

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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.

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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List of Critical Subcontractors and Crucial Suppliers

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

MDR 755419 R000

Date: **2022-03-02**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Advanced Medical Design Co., Ltd. 4F. -5F., No, 29., Wuquan 5th Rd., Wugu Dist., New Taipei City 24888, Taiwan	**Manufacture**
Baron Rubber Pty Ltd 5-15 Lakeside Drive Broadmeadows Victoria 3047 Australia	**Manufacture**
China Biotech Corporation No. 10, 33 rd., Road, Taichung Industrial Park, Taichung, Taiwan	**Radiation (Gamma Sterilization)**
Heng Chuang Plastic & Metal Co., Ltd. No.16, YingGuang Road ShangJiao District, ChangAn Town 523878 Dongguan City, Guangdong Province PEOPLE'S REPUBLIC OF CHINA	**ETO Sterilization** **Manufacture**
Sterilize Service Corporation No.2, Aly. 16, Ln. 578 Sec. 2, Meishi Rd. Yangmei Dist. Taoyuan City 32658 Taiwan	**ETO Sterilization**

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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: **2022-03-02**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Taiwan Advanced Sterilization Technology Inc. Taichung Export Processing Zone, No. 17-1, Chien Kuo Rd., Tan Tze, Taichung City, 427, Taiwan	**ETO Sterilization**
Tonglu Qianyan Medtech Co., Ltd. ShenAo Village, Jiangnan Town, Tonglu County, Hangzhou 311509 Zhejiang P.R. China	**Manufacture**
Zhejiang Huanyi Sterilization Technology Co., Ltd. No. 199, Mingzhu Avenue, Leidian Town, Deqing County, Huzhou City 313219 Zhejiang P.R. China	**ETO Sterilization**

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