By Royal Charter

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:
4/47 Wangara Road
Cheltenham
Victoria
3192
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: **2022-06-27** Expiry Date: **2027-03-01**

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 755419 R000

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

Device(s)	Risk Classification
Uterine Manipulator and Elevator (With or Without Tube for Trans-Vaginal Access)	Class IIa
Tube for Trans-Vaginal Access	Class IIa
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.	

First Issued: **2022-03-02** Date: **2022-06-27** Expiry Date: **2027-03-01**

...making excellence a habit.™

By Royal Charter

EU Quality Management System Certificate

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

MDR 755419 R000

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
2022-03-02	3498322	Issued
Current	3692802	Supplemented – Addition of device group: Uterine Manipulator and Elevator With or Without Trans-Vaginal Access Tube, Tube for trans-Vaginal Access. Amended – Change of legal manufacturer address from 1/32 Silkwood Rise, Carrum Downs, Victoria, 3201, Australia to 4/47, Wangara Road, Cheltenham, Victoria, 3192, Australia.

First Issued: **2022-03-02** Date: **2022-06-27** Expiry Date: **2027-03-01**

...making excellence a habit.™