

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

The O R Company Pty Ltd  
Unit 4  
47 Wangara Road  
Cheltenham  
Victoria  
3192  
Australia

Facility ID Number: F000450

Holds Certificate No:

**MDSAP 686590**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009


**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development and manufacturing of sterile uterine manipulators, trans-vaginal access devices, endoscopic access devices, laparoscopic access devices, bowel retractors, laparoscopic cleaning and defogging devices, surgical instrument holders, gas inflators and skin marking demographic pens.

For and on behalf of BSI:

  
Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-03-01

Effective Date: 2023-02-22

Expiry Date: 2025-02-28



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 1

...making excellence a habit.™