

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 649503
Issued To: **The O R Company Pty Ltd**
1/32 Silkwood Rise
Carrum Downs
Victoria
3201
Australia

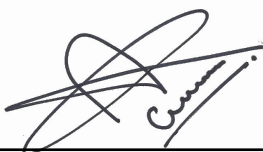
In respect of:

The manufacture of sterile trans-vaginal access devices, uterine manipulation devices, bowel packing retractors, endoscopic and laparoscopic wound access devices.

Those aspects of Annex V concerned with securing and maintaining sterility of laparoscopic cleaning and defogging devices and surgical instrument holders.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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



Albert Roossien, Regulatory Lead

First Issued: **2017-02-28**

Date: **2019-03-15**

Expiry Date: **2022-02-27**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 649503

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Tran-vaginal access and Uterine Manipulation device	--
MD 0106	Laparoscopic Access Device / Endoscopic Access Device	--
MD 0106	Retractor	--
Class Is		
MD 0106	Scope cleaning and defogging device	--
MD 0106	Surgical Instrument Holder	--

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