Certificate Number
MRA Q00069

Australian Government

Department of Health
Therapeutic Goods Administration

EC Certificate

Production Quality Assurance Procedures

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

This is to certify that the quality management system described below conforms to the relevant provisions of Annex V of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Quality Management System for production and final inspection to ensure that each medical device to which the system is applied conforms to the product described in the Type Examination or the technical documentation as applicable.

Manufacturer Name:	Logikal Health Products Pty Ltd
Manufacturer Address:	Unit 3, 18-20 Accolade Avenue MORISSET NSW 2264 Australia
Commencement Date:	29 April 2014
Certificate Expiry Date:	28 April 2019
Associated CA Cerificate	AU Q00152

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked. Its validity is dependent on the currency of the associated CA Certificate listed above.

This certificate is issued by:

Maria Yang
Signed electronically
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
Australia

Notified Body Identification Number

0805

Australian Government

Department of Health

Therapeutic Goods Administration

Scope of Certificate

Manufacturer Facilities

	Name and Address	Scope
1.	Unit 3, 18-20 Accolade Avenue MORISSET NSW 2264 Australia	• Head Office • Production • Packing • Labelling • Final Release • Warehousing
2.	Unit 5, 18-20 Accolade Avenue MORISSET NSW 2264 Australia	• Warehousing • Packing • Dispatch
3.	Unit 6, 18-20 Accolade Avenue MORISSET NSW 2264 Australia	• Warehousing • Packing

Device Categories

	Description	Limitations (if applicable)
1.	Laryngeal airways (reusable and single-use)	
2.	Infusion administration sets	
3.	Infusion pressure regulators	
4.	Endoscopic irrigation/aspiration units	
5.	Pessaries	In this certificate, devices covered under the term pessaries are not intended for contraception or prevention of sexually transmissible diseases
6.	Thoracic drainage systems	
7.	Rigid sigmoidoscopes	

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Critical Suppliers

	Name and Address	Scope
1.	Steritech Pty Ltd 5 Widemere Road Wetherill Park NSW 2164 Australia	Sterilisation

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Certificate History

Version	Details	Issue Date	File Reference
1	Initial certification	26 June 2009	2007/004245 & 2009/000100
1a	Addition of 3 GMDN codes to Schedule of Product Categories: Airway, laryngeal, reusable [45035] Airway, laryngeal, single-use [45036] Sigmoidoscope, rigid [15058]	26 August 2009	2009/003751
2	Removal of 3 GMDN codes: Dialysis start/stop set [32142] Sigmoidoscope, rigid [15058] Tubing set, heart-lung bypass [35441]	10 September 2010	2010/003295
3	Addition of 1 GMDN code: Sigmoidoscope, rigid [15058]	29 September 2011	2011/009887
4	Addition of new manufacturing facility: Unit 5, 18-20 Accolade Avenue Morisset NSW 2264 Australia Clarification of existing facility address to include: Unit 6, 18-20 Accolade Avenue Morisset NSW 2264 Australia Removal of GMDN codes from device categories	16 April 2012	2012/000187
5	Re-certification Removal of product category: Wound Drainage Kits	29 April 2014	2014/000237
Certificate Location (Manufacturer Root File Number):			2010/010688