

Notified Body
Identification number

0805



Australian Government

Department of Health
Therapeutic Goods Administration

Certificate Number
MRA Q00067

EC Certificate

Full Quality Assurance Procedures

Annex II, excluding section 4, of the Council Directive 93/42/EEC on Medical Devices

Issued to

Manufacturer Name: Aus Systems Pty Limited
Manufacturer Address: 3 Charles Street
ALLENBY GARDENS SA 5009
Australia

For the Design and Manufacture of device categories listed on page 2 of this certificate.

This is to certify that the Full Quality Assurance System described below conforms to the relevant provisions of Annex II, excluding section 4, of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Full Quality Assurance System which applies at every stage from design to final controls.

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.

Commencement Date: 22 May 2019
Certificate Expiry Date: 22 May 2024
Associated CA Certificate: AU Q00223

This certificate is issued by:

Jie ZHOU

Signed electronically

Delegate of the Secretary
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia



Scope of Certificate

Manufacturer Facilities

Name and Address		Scope
1	Aus Systems Pty Limited 3 Charles Street ALLENBY GARDENS SA 5009 Australia	Production

Design and Manufacture of Device Categories

Description		Limitations (if applicable)
1	Craniofacial bone screw non-biodegradable	
2	Craniofacial bone plate non-biodegradable	
3	Rectal suction biopsy system	

Critical Suppliers

Name and Address		Scope
4	Steritech Pty Ltd 160 South Gippsland Hwy DANDENONG VIC 3175 Australia	Sterilisation

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Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	20 July 2010	2008/000589
2.1	Recertification and reformatting of certificate: <ul style="list-style-type: none">• Removal of product category: "mesh, surgical"• Removal of supplier: "Metal Craft (SA) Pty Ltd"• Change of supplier address: "Autotherm Pty Ltd" (from Hindmarsh, SA to Direk, SA)	03 June 2014	2014/007739
2.2	Update to certificate version numbers as an internal TGA modification Removal of the following suppliers listed on the certificate: <ul style="list-style-type: none">• Autotherm Pty Ltd• Alpha Carbon• Precise Tooling Australia Pty Ltd- Kaltech Pty Ltd	04 September 2017	E17-14073
3.1	Recertification	22 May 2019	E18-387314
Certificate Location (Manufacturer Root File Number):			2010/010592