Certificate Number
AU Q00170

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Conformity Assessment Certificate

Full Quality Assurance Procedures

Schedule 3, Part 1 (excluding clause 1.6) of the *Therapeutic Goods (Medical Devices) Regulations 2002*

Issued to

Manufacturer Name: Dynek Pty Ltd

Manufacturer Address: 9 Circuit Drive
HENDON SA 5014
Australia

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

This is to certify that the manufacturer's quality management system complies with the relevant provisions of Schedule 3, Part 1 (excluding clause 1.6) of the *Therapeutic Goods (Medical Devices) Regulations 2002.* Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

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: 15 February 2024

Certificate Expiry Date: 04 August 2028

This certificate is issued under Section 41EE of the *Therapeutic Goods Act 1989* by:

Jie ZHOU
Signed electronically
Delegate of the Secretary
Medical Devices Authorisation Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Scope of Certificate

Manufacturer Facilities

	Name and Address	Scope
1	Dynek Pty Ltd 9 Circuit Drive HENDON SA 5014 Australia	Production, Packaging, labelling,final release, warehousing and dispatch.

Design and Manufacture of Device Categories

	Description	Limitations (if applicable)
1	Sutures	Sutures made from catgut, polyglycolic acid, polyvinylidene fluoride, polyester, nylon, silk, and stainless steel