EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Dynek Pty Ltd

9 Circuit Drive
Hendon, SA 5014
Australia

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Monovek® Polydioxanone sutures, class III
Vilene® and Radene® Polyvinylidene Fluoride Sutures, class III
Biovek® Polyglycolic Acid sutures, class III
Nylene® Nylon sutures, class IIb
Dyflex®, Teflex®, Polyflex® and Dyloc® Polyester sutures, class IIb
Dysilk® Silk sutures, class IIb
Dyflex® and Teflex® Polyester sutures, class III
Polypropylene sutures, class III
Polypropylene sutures, class IIb
Dycrom® Stainless Steel sutures, class IIb

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	542157 MR2
Certificate unique ID	170776066
Effective date	2021-05-11
Expiry date	2024-04-18
Frankfurt am Main	2021-05-11

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.