Australian Government

Department of Health
Therapeutic Goods Administration

Conformity Assessment Certificate

Design Examination

Schedule 3, Part 1, 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 device(s) specified on page two of this certificate.

This is to certify that the design of the device(s) identified in this certificate complies with the relevant provisions of Schedule 3, Part 1, clause 1.6 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on examination of the evidence of conformity to the Essential Principles.

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: 02 November 2021

Certificate Expiry Date: 13 August 2023

Associated CA Certificate: AU Q00170

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

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

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Scope of Certificate

Medical Devices

	Unique Product Identifier (UPI)	Limitations (if applicable)
1	Biovek	Nil
2	Vilene	Nil
3	Radene	Nil

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Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	29 August 2008	2008/001250
2.1	Recertification and reformatting of certificate	14 August 2013	2013/010712
3.1	Recertification Update to certificate numbers as part of TGA internal modification	13 August 2018	E18-213081
3.2	Extension of shelf Life from 3 to 5 years for the UPI - Biovek	02 November 2021	E21-201906
Certificate Location (Manufacturer Root File Number):			2010/010649

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Conditions

The following conditions apply automatically under Section 41EJ of the *Therapeutic Goods Act 1989*:

Entry and inspection powers

(1) A conformity assessment certificate is subject to the conditions that the manufacturer in respect of whom the certificate is issued will:
  (a) allow an authorised person:
    (i) to enter, at any reasonable time, premises (including premises outside Australia) at which the person or any other person deals with medical devices of a kind covered by the certificate; and
    (ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and
    (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
  (b) if requested to do so by an authorised person:
    (i) produce to the person such documents relating to devices of a kind covered by the certificate, or to the manufacturer's quality management system, as the person requires; and
    (ii) allow the person to copy the documents.

Review

(2) A conformity assessment certificate is subject to the condition that the manufacturer in respect of whom the certificate is issued will cooperate in any review by the Secretary of the certificate to determine whether the conformity assessment procedures relating to the following matters have been applied to the kinds of medical devices covered by the certificate:
  (a) the application of quality management systems for the manufacture of medical devices;
  (b) the certification of compliance with the essential principles;
  (c) any other requirement of the conformity assessment procedures specified in the regulations made for the purposes of subsection 41EC(2).

Notification of substantial changes

(3) A conformity assessment certificate is subject to the condition that the person in respect of whom the certificate is issued will notify the Secretary, in writing, of any plan for substantial changes to:
  (a) quality management systems; or
  (b) the product range covered by those systems; or
  (c) the product design of kinds of medical devices;
  in respect of which the certificate is issued.

Fees

(4) A conformity assessment certificate is subject to the condition that the applicant for the certificate will pay a fee, prescribed in the regulations, for a review under subsection (2), when the fee becomes due and payable.

(5) The regulations may prescribe different levels of fees for different kinds of manufacturers and medical devices.

Conditions in regulations

(5A) A conformity assessment certificate is subject to any conditions prescribed by the regulations for the purposes of this subsection.

Conditions do not limit other conditions

(6) A condition imposed under this section is in addition to any conditions imposed under this Division.