EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Dynek Pty Ltd

9 Circuit Drive
Hendon, SA 5014
Australia

that the design of the following device(s)

Monovek® Polydioxanone sutures

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 542157 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: TCFL-08 Issue 2 MONOVEK dated 2019-01-11

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_DesignExaminationPDO_AZ542157_V3.docx dated 2020-05-06

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	542157 MRA
Certificate unique ID	170769612
Effective date	2020-05-06
Expiry date	2024-05-26
Frankfurt am Main	2020-05-06

DQS Medizinprodukte GmbH

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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.