



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Dyneke Pty Ltd

9 Circuit Drive
Hendon 5014
Australia

that the design of the following device(s)

Vilene® and Radene® Polyvinylidene Fluoride 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-04; Issue 6 dated 2019-11-14

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

Examination report:

0_411_18e_Report_TFR_DesignExaminationPVDF_AZ_542157_V5.docx dated 2020-11-13

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

Certificate registration no. 549004 MRA

Certificate unique ID 170772594

Effective date 2020-10-22

Expiry date 2024-05-26

Frankfurt am Main 2020-10-22

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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