EC Certificate Production Quality Assurance System: Certificate GB00/51451

The management system of

Chalice Medical Limited

Unit 1 – 2 Manton Wood Enterprise Park, Drayton Court,
Worksop, Nottinghamshire, S80 2RS, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile and Non sterile cardiopulmonary bypass sets, cardiotomy/venous reservoirs, oxygenators, heat exchangers and cannulae for extracorporeal bypass.
Sterile and Non-sterile components for use within extracorporeal bypass.
Sterile and Non-Sterile Tubing Packs for Urology Use.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 26 April 2017 until 03 August 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 May 2019
Issue 15. Certified since 20 March 2000

Certification is based on reports numbered GB/PC 200698

Authorised by

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