By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 687569**

Issued To: **Chalice Medical Limited**
Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
United Kingdom

In respect of:

Manufacture of sterile oxygenators, cardiotomy/venous reservoirs and cannula for use in extracorporeal bypass and tubing packs for use in extracorporeal bypass and urology. Manufacture of sterile components for use in extracorporeal bypass including connectors, adapters, tubing lines, caps for connectors and tubing, filters and tubing organisers and tubing holders.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2018-06-01** Date: **2018-06-01** Expiry Date: **2021-08-03**

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