

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Chalice Medical Limited
Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
United Kingdom

Holds Certificate Number:

MD 687571

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and manufacture of sterile and non-sterile customised tubing packs, cardiectomy/venous reservoirs, oxygenators, heat exchangers and cannulae for extracorporeal bypass, water heater/cooler for use during extracorporeal bypass procedures. Sale and distribution of medical products for the cardiac surgery and cardiac perfusion market. Manufacture of sterile and non-sterile components for extracorporeal bypass procedure tubing packs for urology use.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-06-01

Latest Revision Date: 2019-02-27

Effective Date: 2019-02-27

Expiry Date: 2021-11-09

Page: 1 of 1



003

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