UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 752637**

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

In respect of:

Manufacture of sterile polypropylene oxygenators with and without integrated reservoirs and sterile polymethylpentene oxygenators for use in extracorporeal life support. Manufacture of sterile tubing packs with integrated various components for use in Cardiopulmonary/Extracorporeal Bypass procedures. These tubing packs include bypass tubing pack, ECMO tubing pack, cardioplegia tubing pack, haemoconcentrator set, Rheopak coated ECMO tubing pack, cardiopulmonary bypass priming set and ancillary components for bypass / ECMO procedures.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-07-30** Date: **2021-11-25** Expiry Date: **2024-05-26**

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Supplementary Information to UKCA 752637

Issued To:

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Manton Wood Enterprise Park
Worksop
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD0102	Oxygenators with and without integrated reservoirs	---
MD0102	Tubing Pack for use in Cardiopulmonary / Extracorporeal Bypass procedures	---

First Issued: **2021-07-30** Date: **2021-11-25** Expiry Date: **2024-05-26**

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Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No:	**UKCA 752637**
Date:	**2021-11-25**
Issued To:	**Chalice Medical Limited** **Manton Wood Enterprise Park** **Worksop** **Nottinghamshire** **S80 2RS** **United Kingdom**

Subcontractor:	**Service(s) supplied**
3M Deutschland GmbH Healthcare Business Carl-Schurz-Str. 1 41460 Neuss Germany	**Crucial Supplier**
Albumedix Limited Mabel Street The Meadows Nottingham NG2 3ED United Kingdom	**Crucial Supplier**
Shandong Wego New Life Medical Devices Co., Ltd. No. 18-9, Xingshan Road High-tech Industrial Development Zone 264209 Weihei Shandong province Peoples Republic of China	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Thorne) 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	**ETO Sterilization**

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UKCA Certificate - Production Quality Assurance Certificate History

Certificate No: **UKCA 752637**

Date: **2021-11-25**

Issued To: **Chalice Medical Limited**
Manton Wood Enterprise Park
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Date	Reference Number	Action
2021-07-30	3480742	First Issue; Traceable to CE 687569
Current	3552285	Extension of scope to include manufacture of sterile tubing packs. Addition of tubing packs in device table.

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