

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 and cardiectomy/venous reservoirs for use in extracorporeal bypass

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-06-01**

Date: **2021-05-21**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Supplementary Information to CE 687569

Issued To:

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

Device code	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Paragon Oxygenator (coated)	Both the Paragon PP and Paragon PMP are hollow fibre membrane oxygenators for application during extracorporeal Life Support where extracorporeal oxygenation and carbon dioxide elimination is required. The integrated heat exchanger makes it possible to regulate the blood temperature, so that the oxygenator serves both, achieving hypothermia or maintaining normothermia.
MD 0102	Reservoir (uncoated)	The reservoir is intended to store and filter blood during Extracorporeal Life Support

First Issued: **2018-06-01**Date: **2021-05-21**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Production Quality Assurance

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 687569**
 Date: **2021-05-21**
 Issued To: **Chalice Medical Limited**
Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
United Kingdom

Subcontractor:	Service(s) supplied
3M Deutschland GmbH Membranes Business Unit Carl-Schurz-Str. 1 Deutschland Neuss 41453 Germany	Crucial Supplier
Albumedix Ltd. Mabel Street Nottingham NG2 3ED United Kingdom	Crucial Supplier
Chalice Medical Europe GmbH Alter Landweg 11 32584 Löhne Germany	EU Representative

...making excellence a habit.™

EC Certificate - Production Quality Assurance

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 687569**
 Date: **2021-05-21**
 Issued To: **Chalice Medical Limited**
Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
United Kingdom

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

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 687569**
 Date: **2021-05-21**
 Issued To: **Chalice Medical Limited**
Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
United Kingdom

Date	Reference Number	Action
01 June 2018	8883037	First issue, Transfer from another notify body.
06 February 2019	8940655	Traceable to NB 0086.
29 March 2021	3375896	Addition of EU-Representative. Addition of significant subcontractor Shandong Wego for the service of manufacture. Addition of supplementary product table. Change of address for Albumedix Ltd. Removal of Mecora for the service of manufacture from the list of significant subcontractors. Removal of category "cannula" from the scope of certification. Correction of address of Synergy Health Sterilisation UK Ltd for the service of ETO Sterilisation.
Current	3424611	Removal of category "tubing packs and sterile components" from the scope of certification. Adjustment of supplementary product table.

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.