

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 757107 R0000

Manufacturer: Chalice Medical Limited

Address:

Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
United Kingdom

Single Registration Number: GB-MF-000010617

EU Authorised Representative: Chalice Medical Europe GmbH

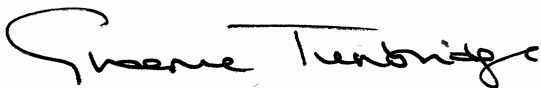
Address:

Alter Landweg 11
32584 Löhne
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-04-28**

Date: **2022-04-28**

Expiry Date: **2027-04-27**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

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

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Extracorporeal Life Support Tubing Packs	Class IIa



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512780	Issued



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List of Critical Subcontractors and Crucial Suppliers

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

MDR 757107 R0000

Date: **2022-04-28**

Critical Subcontractor/Crucial Supplier

Service(s) supplied

Synergy Health Sterilisation UK Ltd
1 Alpha Court
Capitol Park
Thorne
Doncaster
DN8 5TZ
United Kingdom

ETO Sterilization

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