

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No.**UKCA 755336****Issued To:**

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

In respect of:

Design and manufacture of non-sterile units intended for cooling or heating water circulating through the heat exchanger of a membrane oxygenator used during extracorporeal life support or extracorporeal membrane oxygenation.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [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 III products an Annex II (modified as described above) Section 4 certificate 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: **2021-09-09**

Expiry Date: **2026-08-03**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Supplementary Information to UKCA 755336

Issued To:

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Device Code	Device Name	Intended purpose per IFU
Class IIb		
63370	Water heater/cooler	This unit is only intended for cooling or heating water circulating through the heat exchanger of a membrane oxygenator which are used to cool, warm or maintain normothermia of a patient during extracorporeal circulation such as ECLS or ECMO.

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List of Critical Subcontractors and Crucial Suppliers

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

Certificate No: **UKCA 755336**
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Manton Wood Enterprise Park
Worksop
Nottinghamshire
S80 2RS
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Subcontractor:

Service(s) supplied

pfm medical hico gmbh
 Bonner Straße 180
 50968 Köln
 Germany

Manufacture

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Certificate History

Certificate No: **UKCA 755336**
Date: **2021-09-09**
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United Kingdom**

Date	Reference Number	Action
2021-07-30	3480742	First Issue; Traceable to CE 687568.
Current	3498949	Certificate renewal.

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