

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 679892
Issued To: **CardioQuip LLC**
8422 Calibration Ct.
College Station
Texas
77845
USA

In respect of:

The design and manufacture of heating/cooling units for use in extracorporeal circulatory support and/or thermal regulation procedures.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **2020-03-12**

Date: **2020-04-14**

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

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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.

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Supplementary Information to CE 679892

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NBOG Code	Device Name	Intended purpose per IFU
Class IIb		
MD 1403 MD 1101	Cardiopulmonary bypass system heating/cooling unit	The CardioQuip Modular Cooler-Heater (MCH) is indicated to supply temperature-controlled water to heat exchange devices (e.g.; Cardiopulmonary Bypass Heat Exchangers) to help control a patient's temperature during extracorporeal circulatory support and/or thermal regulation procedures.

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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.

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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands

EU Representative

H&S Manufacturing Services LLC
3110 N Oakland Ste 101
Mesa
Arizona
85215
USA

Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 679892**
 Date: **2020-04-14**
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Date	Reference Number	Action
12 March 2019	8792419	First issue.
Current	3167743	Change of legal manufacturer address from 3827 Old College Road Bryan, TX 77801 to current address 8422 Calibration Ct. College Station, TX 77845.

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