CardioQuip

Declaration of Conformity

CardioQuip Declares that the identified product is in conformity with Council Directive 93/42/EEC.

Product Identification

Product:	Modular Cooler-Heater
Family Name:	MCH
Model Names:	MCH-1000(i); MCH-1000(m); MCH Refrigeration Module; MCH Thermo-Electric Cooling (TEC) Module
Name of Company:	CardioQuip LLC
Company Address:	8422 Calibration Ct., TX 77845
Authorized Representative:	Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Registration Information

Notified Body:	BSI Group The Netherlands B.V./ 2797
CE Certificate Number:	CE 679892
Date CE Marking First Applied:	March 12, 2020
Mark Applied:	CE 2797

Conformity Assessment

Device Classification:	Class IIb, Annex IX, Rule 9 Active Therapeutic Device
Route to Compliance:	Annex II (minus section 4) of Council Directive 93/42/EEC for Medical Devices

This declaration is based on meeting the Essential Requirements of the Medical Device Directives, and the following standards applicable to the device.

Conformity Standard

Quality System Certificate:	ISO 13485:2016
Certificate number:	FM 678789
Certificate Issued by:	BSI
Address on Certificate:	8422 Calibration Ct., College Station, TX 77845 USA

Product:
Modular Cooler-Heater
Family Name:
MCH
Model Name:
MCH-1000(i)
MCH-1000(m)
MCH Refrigeration Module
MCH Thermo-Electric Cooling (TEC) Module

Authorized Signature	03/12/2020	Douglas E. Pluth, CEO
	Date Signed	Name and Title