

Declaration of Conformity

Name of Manufacturer: **Spectrum Medical Ltd**

Address of Manufacturer: Harrier 4,
Meteor Business Park,
Cheltenham Road East,
Gloucestershire
GL2 9QL
England

Product: **Cardiopulmonary bypass system heating/cooling unit**

Quantum HCU System	GMDN	Classification	Rule
Quantum Heater-Cooler Unit Extracorporeal Blood Heater-Cooler System	17206	IIb	9

It is hereby declared that the medical devices specified above conforms to:

- The Essential Requirements listed in Annex I of the EC Directive 93/42/EEC (Medical Devices Directive) as transposed into national legislation of the member states.
- EN ISO 13485: 2016
- EN ISO 14971:2012
- BS EN 60601-1: 2006
- BS EN 60601-1-2:2015
- BS EN 60601-1-6:2010
- BS EN 60601-1-8:2007
- BS EN 60601-2-49:2001
- BS EN 1041:2008
- ETSI EN 301 489-1: V2.1.1 (2017-02)
- The RoHS Directive 2011/65/EU

This declaration is supported by the Polish Centre for Testing and Certification certificate No.1434-MDD-007/2020 in accordance with Annex II (excluding Section 4) of EC Directive 93/42/EEC (as amended).

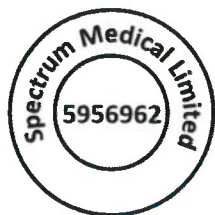
I declare as the authorised responsible person, that the products herewith are in conformity with the stated Directives and related standards.

Name: Mark Drain

Signature: 

Position: Chief Financial Officer

Date: 12 August 20





Product description and accessories

Name and address of Legal & Actual Manufacturer:	Spectrum Medical Ltd Harrier 4, Meteor Business Park, Cheltenham Road East, Gloucestershire. GL2 9QL England
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GMDN Code	17206
GMDN Term	Cardiopulmonary bypass Heating/Cooling Unit
Classification	IIb Rule 9

Quantum Heater Cooler			
Description	Part No.	GTIN	Part Type
Quantum Heater-Cooler Region 1	51-000058-00	05060434420961	MD
Quantum Heater-Cooler Region 2	51-000063-00	05060434420978	MD
Accessory Component			
CoolFlow SM.03.DTX Heat Transfer Fluid 1.5L	51-000089-00	05060434422255	Accessory to the Quantum Heater-Cooler
Hose Kit - 9.5mm Bore - 4.5m long	52-000047-00	05060434422491	Accessory to the Quantum Heater-Cooler
Hose Kit - 9.5mm Bore - 2.5m long	52-000046-00	05060434422484	Accessory to the Quantum Heater-Cooler
Hose Kit - 9.5mm Bore - 6.5m long	52-000056-00	05060434422682	Accessory to the Quantum Heater-Cooler
Hose Kit - 12.5mm Bore - 4.5m long	52-000045-00	05060434422477	Accessory to the Quantum Heater-Cooler
Hose Kit - 12.5mm Bore - 2.5m long	52-000044-00	05060434422460	Accessory to the Quantum Heater-Cooler
Hose Kit - 12.5mm Bore - 6.5m long	52-000055-00	05060434422675	Accessory to the Quantum Heater-Cooler
Accessories Non-Medical Device			
Hose Kit - Charger	52-000048-00	05060434422507	Non-medical device
Heater Cooler Charger Kit 50HZ	52-000052-00	05060434422644	Non-medical device
Heater Cooler Charger Kit 60HZ	52-000054-00	05060434422668	Non-medical device
Double HX Mounting Arm (sml/lrg)	52-000031-00	05060434422187	Non-medical device
Double HX Mounting Arm (sml/sml)	52-000032-00	05060434422194	Non-medical device



Double HX Mounting Arm (lrg/lrg)	52-000033-00	05060434422200	Non-medical device
Single HX Mounting Arm (sml)	52-000029-00	05060434422163	Non-medical device
Single HX Mounting Arm (lrg)	52-000030-00	05060434422170	Non-medical device
S5 - Vertical Mount Clamp	52-000035-00	05060434422224	Non-medical device