



# EC CERTIFICATE

## Spectrum Medical Ltd.

Harrier 4  
Meteor Business Park  
Cheltenham Road East  
Gloucestershire GL2 9QL UNITED KINGDOM

## Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

**Design and manufacture of blood parameter monitoring equipment and equipment for extra-corporeal circulation systems**

Device Classifications:

**Class IIa  
Class IIb**

Device Descriptions and Model Type:

**Please refer to Attachment: 1**

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number A14554  
Certificate Number 474.180709  
Initial Issue Date June 19, 2006

Cycle Start Date November 18, 2017  
Effective Date July 9, 2018  
Expiry Date November 17, 2022

Authorised by

**Paul Daysh**  
Medical Notified Body Operations Manager  
For and on Behalf of UL International (UK) Ltd



**Notified Body**  
**0843**

MDD A2 S3 FQ  
00-MB-S0043 Issue: 15.0

Check Certificate  
Status: [here](#)

UL International (UK) Limited  
Wonersh House, The Guildway, Old Portsmouth Road,  
Guildford, Surrey, GU3 1LR, United Kingdom



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### Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Non Invasive Diagnostic Monitoring Systems	System M	M2	Class IIb	37238
		M3	Class IIb	37238
		M4	Class IIb	37238
Quantum Perfusion System	Quantum Pump Console	Pump Console (QPS)	Class IIb	36347
		Power Supply module (QCM)	Class IIb	36347
		Carts (QPF)	Class IIb	36347
		Quantum Ventilation Module (QVM), Part No 51-000045-00	Class IIb	31714
	Quantum Workstation	Quantum Roller Pumps (QRP)	Class IIb	36347
		Quantum Work Station (QWS)	Class IIb	37238
		Quantum Diagnostic Module (QDM)	Class IIb	37238

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