



# EC CERTIFICATE

## Spectrum Medical Ltd

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Cheltenham Road East  
Gloucestershire  
GL2 9QL  
UK

## 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**

Device Classification:  
**IIb**

G/UMDN Code:  
**37238**

Device Descriptions:

**Extracorporeal Blood Parameter Monitoring Equipment**

Model Type:

**M2, M3, M4 and Quantum Workstation (QWS) and Quantum Diagnostic Module (QDM)**

**We hereby declare that an examination of the full quality assurance system has been carried out per report 11903959, 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.**

File Number A14554  
Certificate No. 474.171118

Cycle Start Date 18 November 2017  
Effective Date 18 November 2017  
Expiry Date 17 November 2022

Authorised by

**Itoro Udofia**  
Certification Manager

For and on Behalf of UL International (UK) Ltd

**Notified Body**  
**0843**

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