By Royal Charter

# EC Certificate - Full Quality Assurance System

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

**No.** **CE 543428**

Issued To: **Research and Production Company**
**"Monitor" Limited**
**104a Krasnokursantskaya Str**
**Rostov-on-Don**
**344068**
**Russian Federation**

In respect of:

**The design and manufacture of electrocardiographs, diagnostic monitors, multi-parameter patient monitors and spirometers**

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: **2008-11-27** Date: **2020-09-03** Expiry Date: **2023-11-26**

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**Supplementary Information to CE 543428**

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| Number | Device Name | Intended purpose per IFU |
|---|---|---|
| **Class IIb** | | |
| MD 1302<br>MDS 7010 | Patient Monitors | The patient monitor is intended to allow direct diagnosis or monitoring of vital physiological processes. |
| **Class IIa** | | |
| MD 1302<br>MDS 7010 | Electrocardiographs, spirometers and ECG Holter. | NA for class IIa devices. |

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# List of Significant Subcontractors

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

| | |
|---|---|
| Certificate No: | **CE 543428** |
| Date: | **2020-09-03** |
| Issued To: | **Research and Production Company "Monitor" Limited**<br>**104a Krasnokursantskaya Str**<br>**Rostov-on-Don**<br>**344068**<br>**Russian Federation** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| CMC Medical Devices & Drugs S.L.<br>C/ Horacio Lengo Nº18<br>CP 29006<br>Málaga<br>Spain | **EU Representative** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 543428**

Date: **2020-09-03**

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| Date | Reference Number | Action |
|---|---|---|
| 27 November 2008 | 7287033 | First Issue. |
| 3 October 2013 | 8028105 | Certificate renewal and upgrade to Annex II. Extension to scope to include multi-parameter patient monitors and spirometers. Addition of EU representative. |
| 20 November 2018 | 8941761 | Renewal. Addition of device table. New device was added: Diagnostic system for personal patient monitoring SPDM 01 RD |
| 18 February 2019 | 8862794 | Traceable to NB 0086. |
| Current | 3281417 | Change of EU Authorized representative, from: "Labtech Ltd., Vág utca 4, H-4031, Debrecen, Hungary" to: "CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No 18, CP 29006, Málaga, Spain". |