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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):

Albert Roossien, Regulatory Lead

First Issued: **2008-11-27** Date: **2019-02-18** Expiry Date: **2023-11-26**

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Date: 2019.05.17 09:22:54 EEST
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Supplementary Information to CE 543428

Issued To:

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

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

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