

EC Certificate - Full Quality Assurance System

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

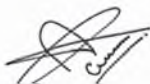
No. CE 543428
Issued To: **Research and Production Company**
"Monitor" Limited
104a Krasnokursantskaya Str
Rostov-on-Don
344068
Russian Federation

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 543428

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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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