

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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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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo N°18
CP 29006
Málaga
Spain

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 543428**
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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".