

EC Certificate - Full Quality Assurance System

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

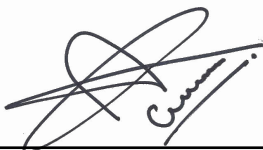
No. CE 668123
Issued To: **dms-service llc**
11845 West Olympic Blvd
Suite 880W
Los Angeles
California
90064
USA

In respect of:

Design and manufacture of ECG recorders.

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: **2017-06-09**

Date: **2019-03-05**

Expiry Date: **2022-06-08**

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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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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

QNET, BV
Kanstraat 19
5076 NP Haaren
The Netherlands

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
09 June 2017	8677960	Initial Issue.
27 February 2019	9648126	Sub-contractor NuLine Sensors LLC deleted from certificate.
Current	8872857	Traceable to NB 0086.

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