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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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 668123**
Date:	**2019-03-05**
Issued To:	**dms-service llc** **11845 West Olympic Blvd** **Suite 880W** **Los Angeles** **California** **90064** **USA**

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

Certificate No: **CE 668123**

Date: **2019-03-05**

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Los Angeles
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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.