By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 659476**

Issued To: **Contex International Technologies (Canada) Inc.**
2798 Thamesgate Drive, Unit # 5 & 6
Mississauga
Ontario
L4T 4E8
Canada

In respect of:

Design and Manufacture of Arrhythmia monitors.

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-06-28** Date: **2017-06-28** Expiry Date: **2022-06-27**

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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 659476**
Date:	**2017-06-28**
Issued To:	**Contex International Technologies (Canada) Inc.** **2798 Thamesgate Drive, Unit # 5 & 6** **Mississauga** **Ontario** **L4T 4E8** **Canada**

Subcontractor:	**Service(s) supplied**
National Cardiac Monitoring Centre (UK) Limited 3 Roundwood Park Harpenden AL5 3AB United Kingdom	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
28 June 2017	8586064	Initial Issue

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