

EC Certificate - Full Quality Assurance System

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

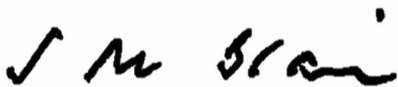
No. CE 659476
Issued To: **Contex International Technologies
(Canada) Inc.
2798 Thamesgate Drive, Unit # 5 & 6
Mississauga
Ontario
L4T 4E8
Canada**

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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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

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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