By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 616020**

Issued To: **Medical Components, Inc.**
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

In respect of:

Design, development and manufacture of non-sterile ECG-based peripherally inserted central catheter placement and tip location confirmation systems.

Those aspects of Annex II concerned with securing and maintaining sterile conditions of accessories for ECG-based peripherally inserted central catheter placement and tip location confirmation systems.

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):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **15 May 2015** Date: **11 September 2015** Expiry Date: **14 May 2020**

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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:

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Date:	**11 September 2015**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Lextech Global Services 1431 Opus Place Suite 200 Downers Grove Illinois 60515 USA	**Software**
Martech East 1500 Delp Drive Harleysville Pennsylvania 19438 USA	**Manufacture**
MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany	**EU Representative**

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Subcontractor:	**Service(s) supplied**
Nostix, LLC 5541 Central Avenue, Suite 170 Boulder Colorado 80301 USA	**Design** **Manufacture**
Sterigenics 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
The Electronic Assembly Company 150 South Front St. Souderton Pennsylvania 18964 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
VPI Technology Group 11814 S. Election Road Suite 200 Draper Utah 84020 USA	**Software**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616020**

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USA

Date	Reference Number	Action
15 May 2015	8177168	First Issue
11 September 2015	8360908	Addition of significant subcontractors; The Electronic Assembly Company for Manufacture, Martech East for Manufacture, VPI Technology Group for software, and Lextech Global Services for software.