



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Deltex Medical Limited
Terminus Road
Chichester
West Sussex
PO19 8TX
United Kingdom

Holds Certificate Number:

MD 75109

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

The design, development, manufacture, repair, modification, sales and distribution of Doppler ultrasound technology haemodynamic monitors, sterile and clinically clean probes and accessories

For and on behalf of BSI:

Gary Fenton, Global Assurance Director

Originally registered: 23/09/2003

Latest Issue: 07/07/2014

Expiry Date: 06/07/2017



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

bsi.

Certificate

Full Quality Assurance

No. CE 02032



Issued to:

**Deltex Medical Limited
Terminus Road
Chichester
West Sussex
PO19 8TX
United Kingdom**

In respect of:

The design and manufacture of ultrasonic haemodynamic monitors and sterile probes.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **31 Jul 1998**

Date: **24 Apr 2013**

Expiration Date: **21 May 2018**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

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List of Significant Subcontractors

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

Certificate No. **CE 02032**
Date: **24 Apr 2013**
Issued to: **Deltex Medical Limited**
Chichester
United Kingdom

Subcontractor	Service(s) supplied
Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton Derbyshire DE55 4NJ United Kingdom	ETO Sterilization