

Certificate

Full Quality Assurance

No. CE 94534



Issued to:

Medical Graphics Corporation
350 Oak Grove Parkway
St. Paul
Minnesota
55127
USA

In respect of:

The design and manufacture of Cardiorespiratory Diagnostic Systems.

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 the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'D. Ford', with a horizontal line underneath.

David Ford, Director, Healthcare and Testing Services

First Issued: 16 Mar 2005

Date: 16 Mar 2010

Expiration Date: 15 Mar 2015

Page: 1 of 1

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 94534**
Date: **16 Mar 2010**
Issued to: **Medical Graphics Corporation**
St. Paul
USA

Subcontractor	Service(s) supplied
Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany	EU Representative

History of Quality Assurance Certificate

Certificate No: CE 94534
Issue Date: 16 March 2010
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Date	Reference	Action
16 March 2005		First issue Transfer from TÜV PRODUCT SERVICE, Certificate No.: G1 03 07 32331 004
16 March 2010	7497021	Addition of Medical Product Service GmbH as EU Representative to the list of significant subcontractors. Certificate renewal