By Royal Charter

EC Certificate - Full Quality Assurance System

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

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 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 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2005-03-16** Date: **2020-01-29** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 94534**

Date: **2020-01-29**

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Date	Reference Number	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.
18 February 2015	8257741	Certificate renewal.
19 March 2019	7781894	Traceable to NB 0086.
29 January 2020	9785342	Certificate Renewal.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
22 November 2022	3675686	Amended – EU representative changed from: Medical Product Service GmbH To: Medisoft SA

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22 November 2022

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 94534	93/42/EEC Annex II excluding Section 4	3675686	EU representative changed from: Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany To: Medisoft SA P.A.E. de Sorinnes, 1 Route de la Voie Cuivrée, Sorinnes 5503, Belgium

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices