

Declaration of Conformity

(according to ISO/IEC Guide 22 and EN 45014)

Manufacturer's Name: Medical Graphics Corporation

**Manufacturer's Address: 350 Oak Grove Parkway
Saint Paul, Minnesota 55127 USA**

Declares under our sole responsibility that the following product:

Product Name: 1085 - Elite Series

Model Numbers: 83000X-XXX

Model Options: D, DL, DX, Platinum D, Platinum DL, Platinum DX

Manufactured 3-24-08 and beyond

to which this declaration relates, complies with European Council Directive 93/42/EEC Medical Device Directive Annex II and is in conformity with the following standard(s) or other normative document(s):

ISO 13485

EN 60601-1 Medical Electrical Equipment, General Requirements for Safety

EN 60601-1-2 General Requirements for Safety, Electromagnetic Compatibility Requirements and Tests

and is classified IIa per Annex IX, rule 10 following the provisions of 93/42/EEC, European Medical Device Directive.

E.C. Certificate No. CE 94534

**Notified Body: BSI Product Services
Maylands Avenue
Hemel Hempstead, Hertfordshire
United Kingdom**

CE 0086

Date

3/25/08

**Rodney A. Young
Rodney A. Young
President and C.E.O.**

Medical Graphics Corporation