

# ***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: PFDx - Profiler Series**

**Model Numbers: 83050X-00X**

**Model Options: DL, DX**

**Manufactured 9-19-2007 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**

9/24/07

RA Young

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

***Medical Graphics Corporation***