

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: Gas Module

Model Number(s): 762014-XXX

Model Option(s): Part of: CPFS/D™, CPX/D™, CPX/Max/D™, CCM/D™,
Cardio2 CP™, Cardio2 CP/Max™, Profiler DL/DX EX

Manufactured 9/26/05 **and beyond**

*to which this declaration relates, meets the essential health, safety,
and environmental requirements and is in conformity with the following
standard(s) or other normative document(s):*

ISO 13485

93/42/EEC Medical Device Directive

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

9/26/05

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

Medical Graphics Corporation