

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: CPFS/D USB Spirometer

Model Numbers: 800704-00X

Model Options: None

Manufactured 11-9-09 **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 11-10-09


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

Medical Graphics Corporation