

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 Number(s): 800704-00X

Model Option(s): None

Manufactured 9-15-2011 **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.

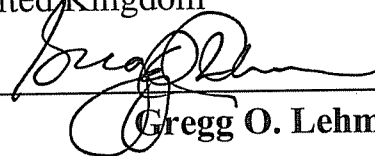
E.C. Certificate No. CE 94534

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

CE 0086

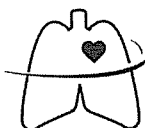
Date

9/15/11



Gregg O. Lehman
President and C.E.O.

Medical Graphics Corporation



MEDGRAPHICS™
Cardiorespiratory Diagnostics