

SPARE PARTS

EQUIPMENT

PM KITS

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Vyaire Medical (CareFusion / Viasys) 16465, 51000-40081 flow sensor for AVEA

# Declaration of Conformity

**Application of Council Directive(s):** Medical Device Directive 93/42/EEC

**Standard(s) to which Conformity is Declared:**  
Safety: EN 60601-1 : 1990  
EN 60601-1-1:2001  
EN 60601-2-12:1998  
EMC: EN 60601-1-2:2001

**Manufacturer's Name:** CareFusion  
**Manufacturer's Address:** 22745 Savi Ranch Parkway  
Yorba Linda, CA 92887 USA

**EU Notified Body:** B.S.I. Product Services (Reg. No. 0086)  
**European Authorized Representative:** CareFusion Germany 234 GmbH  
Leibnizstrasse 7  
97204 Hoechberg - Germany

**Conformity Assessment:** Medical Device Directive 93/42/EEC Annex I, II

**Quality System:** ISO 13485:2003

**Risk Assessment:** ISO/EN 14971:2000/A1:2003

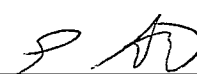
**Type of Equipment:** Medical Equipment,  
Adult/Pediatric Lung Ventilator

**Tradename:** AVEA Series Ventilators

**Device Classification:** Class IIb

*I, the undersigned, hereby declare that the equipment specified  
above conforms to the above Directive(s) and Standard(s).*

**Place:** Yorba Linda, CA 92262

  
(Signature)

**Date:** January 07, 2010

Thomas Gutierrez  
**(Full Name)**

Director Regulatory Affairs  
**(Position/Title)**

