

Biosense Webster, Inc.  
3333 Diamond Canyon Rd  
Diamond Bar, CA 91765  
Phone 909 839.8500

**DECLARATION OF CONFORMITY**



**Biosense Webster**  
a Johnson-Johnson company

**Distributor's Name:** Biosense Webster, Inc.  
**Distributor's Address:** 3333 Diamond Canyon Road  
Diamond Bar, CA 91765  
**Design Site:** Biosense Webster, Inc.  
**Manufacturer's Name:** Biosense Webster, Inc.  
**Manufacturer's Address:** 15715 Arrow Highway  
Irwindale, CA 91706  
**Name of Device:** CoolFlow™ Irrigation Pump  
**Manufacturing Part number(s):** M5491-03 [pump], M5491-01 (CFP 111) [shipping kit]  
**Class:** IIA  
**Rule:** 2 of MDD Annex IX  
**Technical File Number:** TF1010

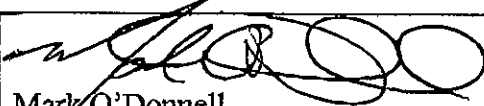
We, being the manufacturer/design site, declare that the products covered by this declaration to be in conformity with the applicable provisions of EC Directive 93\42\EEC and, thus, entitled to bear the CE Mark.

This declaration is valid for all devices described in this document originating from the aforementioned sites.

Check one:

- This declaration is supported by the following valid certificate:  
*EC Certificate of Quality Assurance, Certificate No., CE 01566*  
having been issued by British Standards Institution; Notified Body Number 0086.
- This declaration is supported by the conformance route as specified below  
(i.e., EC Type Examination, alternate Notified Body)

**Annex(es):** Annex I of EC Directive 93/42/EEC

 Mark O'Donnell Director, Regulatory Affairs	04 Feb 05	Date of Issue 4 February 2005
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<b>Authorized European Representative:</b>	Johnson & Johnson Medical nv/sa Dreve Richelle 161 Building H, B-1410 Waterloo, Belgium
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Endocardial  
Diagnostics  
and Therapy