



Atrium Medical Corporation
5 Wentworth Drive
Hudson, New Hampshire 03051

Tel. 603-880-1433
Fax 603-880-4545

Declaration of Conformance

Manufacturer: Atrium Medical Corporation
Address: 5 Wentworth Drive
Hudson, New Hampshire 03051 USA

European Representative: Atrium Medical International
Rendementsweg 24
3641 SL Mijdrecht
The Netherlands

Product: Water Seal Chest Drain
Model/Code: 2000 series, 3600 series, 4000 series, 16100, 16400

Classification: Class IIa per Rule 2

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation are retained under the premises of the manufacturer and the notified body.

Directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14, June 1993 concerning medical devices (MDD 93/42/EEC).

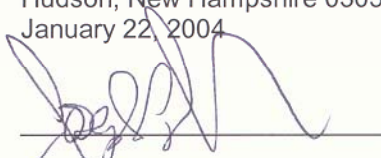
Standards: Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are:

EN ISO 9001, EN 46001, EN 540, EN 30993, EN 550, EN 556

Notified Body: TUV Product Service GmbH, Ridlerstr. 31, 80339
Munchen, Germany

Certificate: EC Certificate G1 02 06 29701 015 per Annex II.3 issued 06/06/02 and
QS Certificate Q1Z 03 04 29701 017 per EN ISO 9001:1994 and EN ISO
13485:2000 issued 04/23/03.

Place, Date: Atrium Medical Corporation
5 Wentworth Drive
Hudson, New Hampshire 03051 USA
January 22, 2004

Signature: 

Name: Joseph P. De Paolo
Position: VP Regulatory and Clinical Affairs


8/25/04
Elizabeth J. Giffis, Notary Public
My Commission Expires: 9/17/08