

# Declaration of Conformity

We, VALLEYLAB  
a division of Tyco Healthcare Group LP  
5920 Longbow Drive  
Boulder, Colorado 80301  
USA

Declare under our sole responsibility that the Valleylab Pumps, Class I non-sterile and non-measuring, with catalog numbers listed in Appendix 1 of this declaration are in conformity with the

Essential requirements of the Medical Device Directive, 93/42/EEC, (M5)

And

Essential principles and classification rules of the Australian Therapeutic Goods  
(Medical Device) Regulations 2002

These devices have been verified as conforming via the procedure relating to the Declaration of Conformity as set out in Clause 6.6 of Schedule 3 of the Australian Regulations and the procedure relating to the EC Declaration of Conformity as set out in Annex VII of the European Directive.

These devices are considered machinery within the meaning of Article 2(a) of the Machinery Directive, 2006/42/EC and meet the applicable requirements of Annex 1.

EC Authorized Rep:  
Tyco Healthcare UK Ltd.,  
Gosport, PO13 0AS, UK

EC Certificate #: CE 00500

Signature:   
Charles M. Copperberg  
Director, Regulatory Affairs

March 22, 2010  
Date

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## Appendix 1

This appendix declares the products included in the above referenced Declaration of Conformity:

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
VTPUMP	I	Rule 12		Annex VII	36664, Pump, powered	

Standards: These standards are applicable to the above listed products. (standard: version)  
 EN ISO 13485: 2003; 21 CFR 820; EN ISO 14971:2000; EN 60601-1:1990/A1: 1993/A2: 1995  
 (IEC 60601-1: 1988/A1: 1991/A2: 1995); EN 60601-1-2:2001+A1:2004 (IEC 60601-1-2: 2001) ;  
 EN 55011:1998 (CISPR 11: 1997 Modified); ISTA 2A:2006 ; EN ISO 14155-1:2003; MEDDEV.  
 2.7.1Rev. 3 (2009); EN 1041:2008; Directive 80/181/EEC+M3:9/2/2000; ANSI/AAMI SW68:2001;  
 EN 60601-1-4:1996; EN 980:2008; ISO 15223:2000;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
PE-PM	I	Rule 12		Annex VII	36664, Pump, powered	

Standards: These standards are applicable to the above listed products. (standard: version)  
 EN ISO 13485: 2003; 21 CFR 820; EN ISO 14971:2000; EN 60601-2-2:1991 (IEC 60601-2-2) ; EN  
 60601-1-2: 2002; EN 55011: 2000; AAMI HF18 (1993); ISTA 2A ; EN ISO 14155-1:2003; MEDDEV.  
 2.7.1, Rev. 3 (2009); EN 60601-1 (IEC 60601-1: 1988); EN 1041:2008; EN 60601-2-2:1998 (IEC  
 60601-2-2) ; Council Directive 80/181/EEC; EN 60601-1-4:1996; IEC 60417:2004; EN 980:2008;  
 ISO 15223:2000;