

# 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 Suction Coagulators 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, classification rules, and full quality assurance procedures 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 1.8 of Schedule 3 of the Australian Regulations and the procedure relating to the EC Declaration of Conformity as set out in Annex II of the European Directive.

Notified Body:  
BSI Product Services  
Kitemark House, Marylands Avenue,  
Hemel Hempstead,  
Hertfordshire HP2-4SQ UK  
Number: 0086

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

EC Certificate #: CE0500

Signature:   
Charles M. Copperberg  
Director, Regulatory Affairs

March 22, 2010  
Date

## 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)
E2608-6	IIb	Rule 9		Annex II	35044: Electrosurgical system Conducting unit, hand-controlled, single-use	Electrosurgical system Conducting unit, hand-controlled, single-use
E2608-6NSB	IIb	Rule 9		Annex II	35044: Electrosurgical system Conducting unit, hand-controlled, single-use	Electrosurgical system Conducting unit, hand-controlled, single-use

Standards: These standards are applicable to the above listed products. (standard : version)  
 EN ISO 13485: 2003; EN ISO 14971:2000; IEC 601-1 (1988); IEC 601-2-2 (1991); AAMI HF18 (1993); EN ISO 14155-1:2003; EN30993-1; (1994); EN30993-3 (1994); EN30993-5 (1994); EN30993-4 (1994); EN117; EN1174-1; EN1174-2; EN 60601-1: 1988 (IEC 60601-1); EN 60601-2-2:1991 (IEC 60601-2-2); EN 1041:1998; EN868; EN550 (1994); EN552 (1994); EN 980:2008; EN 1041:1998;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
E3305	IIb	Rule 9		Annex II	35044: Electrosurgical system Conducting unit, hand-controlled, single-use	Electrosurgical system Conducting unit, hand-controlled, single-use
E3305NSB	IIb	Rule 9		Annex II	35044: Electrosurgical system Conducting unit, hand-controlled, single-use	Electrosurgical system Conducting unit, hand-controlled, single-use
E3310	IIb	Rule 9		Annex II	35044: Electrosurgical system Conducting unit, hand-controlled, single-use	Electrosurgical system Conducting unit, hand-controlled, single-use
E3310NSB	IIb	Rule 9		Annex II	35044: Electrosurgical system Conducting unit, hand-controlled, single-use	Electrosurgical system Conducting unit, hand-controlled, single-use

Standards: These standards are applicable to the above listed products. (standard : version)  
 EN ISO 13485: 2003; IEC 60601-1: 2005; ASTM F1980: 2007; EN1041: 1998; EN556-1: 2001; IEC 60601-2-2: 2006; EN 980: 2008; EN ISO 10993-1: 2003; ISO 10993-10: 2002/A1: 2006; ISO 10993-11: 2006; ISO 10993-4: 2002; ISO 10993-5: 1999; ISO 11137-1: 2006; EN ISO 11607-1: 2006; EN ISO 11607-2: 2006; EN ISO 11737-1: 2006; ISO 15223: 2007; ISTA 2A: 2006; EN ISO 14155-1: 2003; EN ISO 14971: 2000;