

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 Class I non-sterile/non-measuring devices 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.

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

EC Certificate #: CE 00500

Signature:


Charles M. Copperberg
Director, Regulatory Affairs

July 23, 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)
E0005-3C	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	
E0017	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	
E0021-B	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	
E0502-1	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	
E0502-12	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	
E0504-1L	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	
E0504-2	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	
E0507-B	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	

Standards: These standards are applicable to the above listed products. (standard: version)
EN ISO 13485: 2003; EN ISO 14971:2000; EN 60601-1 (IEC 601-1 (1988)); EN 60601-2-2 (1998); AAMI HF18 (1986); EN ISO 14155-1:2003; EN 1041:2008; 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)
FT0501	I	Rule 1		Annex VII	35041: Electrosurgical diathermy system cable adaptor	

Standards: These standards are applicable to the above listed products. (standard: version)
EN ISO 13485: 2003; EN ISO 14971:2000; EN 55011:1998; EN 60601-1:1990; EN 60601-1-1:1993; EN 60601-1-2:2001; EN 60601-2-2 (IEC60601-2-2:1998); EN 60601-1-4:1996; EN 50419:2006; EN ISO 14155-1:2003; EN 1041:2008; EN 980:2008;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
E0009-1R	I	Rule 1		Annex VII	35042: Electrosurgical Diathermy System Cable, Reusable	

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; EN 1041:2008; 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)
E0018	I	Rule 1		Annex VII	35042: Electrosurgical Diathermy System Cable, Reusable	
E0019	I	Rule 1		Annex VII	35042: Electrosurgical Diathermy System Cable, Reusable	

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; EN 1041:2008; 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)
E0020V	I	Rule 1		Annex VII	35042, Electrosurgical diathermy system cable, reusable	
E0021S	I	Rule 1		Annex VII	35042, Electrosurgical diathermy system cable, reusable	
E0022W	I	Rule 1		Annex VII	35042, Electrosurgical diathermy system cable, reusable	

Standards: These standards are applicable to the above listed products. (standard: version)
 EN ISO 13485: 2003; EN 60601-1: 1990/A1: 1993/A2: 1995/A13: 1996; IEC 60601-2-2: 2006; 21 CFR 820; 21 CFR 801; EN ISO 14971: 2000; EN ISO 13485: 2003; EN 980: 2008; EN 1041: 2008; ISO 15223: 2000; ISTA 2A: 2006; AAMI TIR 30: 2003; AAMI TIR 12: 2004; EN ISO 17664: 2004; EN ISO 17665-1: 2006; EN ISO 14155-1:2003;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
E0509-NSB	I	Rule 1		Annex VII	47143: Electrosurgical Diathermy System Cable, 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); EN 60601-1-2 (1993); EN55011 (1991); IEC 601-2-2 (1991); AAMI HF18 (1993); EN ISO 14155-1:2003 ; EN 868-1 (1997); EN ISO 11737-1:2006; EN ISO 11137-1:2006; EN 1041:2008; 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)
E0510-NSB	I	Rule 1		Annex VII	47143: Electrosurgical Diathermy System Cable, Single Use	

Standards: These standards are applicable to the above listed products. (standard: version)
 EN ISO 13485: 2003; EN ISO 14971:2000; EN 60601-1 (1988); EN 60601-2-2 (1991); EN 60601-1-2 (1993); EN55011 (1991); AAMI HF18 (1993); EN ISO 14155-1:2003; EN ISO 11137-1:2006; EN ISO 11737-1:2006; EN 556-1:2001; EN 1041:2008; EN 980:2008; ISO 15223:2000; EN 868-1 (1997);

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
E0560	I	Rule 1		Annex VII	35042: Electrosurgical Diathermy System Cable, Reusable,	
E0560E	I	Rule 1		Annex VII	35042: Electrosurgical Diathermy System Cable, Reusable,	

Standards: These standards are applicable to the above listed products. (standard: version)
 EN ISO 13485: 2003; EN ISO 14971:2000; EN 60601-1 (1988); EN 60601-2-2 (1991); EN 60601-1-2 (1993); EN 55011 (1991); AAMI HF18 (1993); EN ISO 14155-1:2003; EN10993-1:2003 ; EN10993-3:2003; EN10993-4:2002/A1:2006 ; EN10993-5:1999; EN 1041:2008; 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)
E2999	I	Rule 1		Annex VII	35042: Electrosurgical Diathermy System Cable, Reusable	

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 (1986); EN ISO 14155-1:2003; EN 1041:2008; 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)
E2400-NSB	I	Rule 1		Annex VII	45686: Electrosurgical diathermy system conducting unit holder, 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 (1982/1991); AAMI HF18 (1986); EN ISO 14155-1:2003; EN ISO 11737-1:2006; EN ISO 11135-1:2007; EN ISO 11137-1:2006; EN 556-1:2001; EN 1041:2008; EN 980:2008; ISO 15223:2000; EN 868-1 (1997);

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
E3625	I	Rule 1		Annex VII	44979, Surgical smoke evacuation system filter	
E3630	I	Rule 1		Annex VII	44979, Surgical smoke evacuation system filter	
E3655	I	Rule 1		Annex VII	46483, Surgical smoke evacuation system tube	
E3660	I	Rule 1		Annex VII	46483, Surgical smoke evacuation system tube	
E3665	I	Rule 1		Annex VII	46483, Surgical smoke evacuation system tube	
SE3690	I	Rule 1		Annex VII	37861, Surgical smoke evacuation system	
SE3695	I	Rule 1		Annex VII	37861, Surgical smoke evacuation system	
SEA3700	I	Rule 1		Annex VII	44979, Surgical smoke evacuation system filter	
SEA3730	I	Rule 1		Annex VII	47487, Medical device electrical cable, general-purpose	
SEA3740	I	Rule 1		Annex VII	47487, Medical device electrical cable, general-purpose	
SEA3745	I	Rule 1		Annex VII	36336, Footswitch	

Standards: These standards are applicable to the above listed products. (standard: version)
 EN ISO 13485: 2003; 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); UL 60601-1: 2003, CSA 22.2 No. 601.1 M90: 1990; EN 60601-1-2: 2001 (IEC 60601-1-2: 2001/A1: 2004); EN 55011: 2007 (CISPR 11: 2004); ISTA 2A:2006; EN ISO 14155-1:2003; MEDDEV. 2.7.1, Rev. 3 (2009); ISO 10993.1 (9-92); EN ISO 10993-1:2003; ISO 11137: 1994; AAMI TIR27: 2001; IEC 60529: 2004; EN ISO 11737:1994; EN 1041:2008; EN 60601-1-4:1996; IEC 60417: 2007; IEC TR 60878: 2003; EN 980:2008; ISO 15223:2000/A2: 2004; EN ISO 50419:2006;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
LS0200	I	Rule I		Annex VII	13730, Sterilization container	

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 (IEC 60601-1:1988); AAMI HF18 (1993); ISTA 2A; EN ISO 14155-1:2003; MEDDEV. 2.7.1 Rev A (2009); ASTM Spec 967; EN 60601-2-2:2000 (IEC 60601-2-2: 1998); EN 868-1; EN 980:2008; ISO 15223:2000; EN 1041:2008;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
LS2070	I	Rule 6		Annex VII	44677, Electrosurgical diathermy system handpiece, foot-controlled, reusable	
LS3090	I	Rule 6		Annex VII	44677, Electrosurgical diathermy system handpiece, foot-controlled, reusable	

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 (IEC 60601-1: 1988); EN 60601-2-2 (IEC 60601-2-2: 1991); EN 60601-1-2: 1993 ; EN 55011: 1991 ; AAMI HF18 1993; ISTA 2A:4/19/96; EN ISO 14155-1:2003; MEDDEV. 2.7.1 Rev 3 (2009); EN ISO 10993-1:2003; EN 10993-3: 2003; EN ISO 10993-5:1999; EN ISO 10993-4: 2002/A1:2006; ASTM Spec 967; EN 868; EN ISO 11737-1:2006; EN ISO 11137-1:2006; EN 554: 1994; EN 980:2008; ISO 15223:2000; EN 1041:2008;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
LS2110	I	Rule 6		Annex VII	44677, Electrosurgical diathermy system handpiece, foot-controlled, reusable	

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 (IEC 60601-1: 1988); AAMI HF 18 (1993); ISTA 2A:2000; EN ISO 14155-1:2003; MEDDEV. 2.7.1 Rev 3(2009); EN ISO 10993-1:2003; EN 10993-3: 2003; EN ISO 10993-5:1999; EN ISO 10993-4: 2002/A1:2006 ; ASTM Spec 967; EN 60601-2-2:1991 (IEC 60601-2-2); EN 868-1; EN ISO 11137-1:2006; EN 554: 1994; EN ISO 11737-1:2006;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
LS3110	I	Rule 6		Annex VII	44677, Electrosurgical diathermy system handpiece, foot-controlled, reusable	

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 (IEC 60601-1: 1988); AAMI HF18 (1993); ISTA 2A; EN ISO 14155-1:2003 ; MEDDEV. 2.7.1 Rev 3 (2009) ; EN ISO 10993-1:2003; EN 10993-3: 2003; EN ISO 10993-5:1999; EN ISO 10993-4: 2002/A1:2006; ASTM A380: 1996; EN 60601-2-2:2000 (IEC 60601-2-2: 1998); EN 868-1; EN ISO 11137-1:2006; EN 554: 1994; EN ISO 11737-1:2006; EN 980:2008; ISO 15223:2000; EN 1041:2008;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
C123	I	Rule 1		Annex VII	35042, Electrosurgical diathermy system cable, reusable	
DPG-HP-EXT	I	Rule 1		Annex VII	35042, Electrosurgical diathermy system cable, reusable	
RFG-SC9	I	Rule 1		Annex VII	35042, Electrosurgical diathermy system cable, reusable	

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 (IEC 60601-1: 1988) ; EN 60601-1-2 (IEC 60601-1-2: 1998); EN 60601-2-2 (IEC 60601-2-2: 1998); AAMI HF-18 (2001); EN ISO 14155-1:2003; MEDDEV. 2.7.1, Rev. 3 (2009); EN ISO 10993-1; EN 55011 Class A Group 1; UL 544; EN 980:2008; ISO 15223:2000; EN 1041:2008;

Catalog Number	Class	MDD Rule	Sterile/ Measure	MDD Conformity Assessment Route	GMDN Code and term	Device subcategory (IIa) / Generic Device Group (IIb)
DGP-HP	I	Rule 1		Annex VII	11500, Electrosurgical diathermy system electrode, return, single-use	

Standards: These standards are applicable to the above listed products. (standard: version)
 EN ISO 13485: 2003; EN ISO 13485:2003; 21 CFR 820; EN ISO 14971:2000; EN 60601-2-2:2000 (IEC 60601-2-2: 1998); AAMI HF18 (2001); EN ISO 14155-1:2003; MEDDEV. 2.7.1 , Rev. 3 (2009); EN ISO 10993-1:2003; EN 10993-3: 2003; EN 10993-5: 1999; 10993-4: 2002/A1:2006; EN ISO 11135-1: 2007; EN 868-1; EN ISO 11137-1:2006; EN 60601-1: 1990/A1: 1993/A2: 1995 (IEC 60601-1); EN 980:2008; EN 1041:2008; 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)
FT0021S	I	Rule 1		Annex VII	35042: Electrosurgical diathermy system cable, reusable	

Standards: These standards are applicable to the above listed products. (standard: version) BS EN 60601-1:1990; BS EN 60601-2-2:2007; NFPA 99:2005; BS EN 17664:2004; BS EN 60601-1-1:2001, BS EN 60601-1-4:1997; IEC 60601-1-8:2006, EN ISO 14155-1:2003; BS EN 62366:2007; EN ISO 14971:2007; EN 980:2008; EN ISO 10993-1:2003; ISO 15223-1:2007; EN ISO 13485:2003; ISO 15225 AMD 1:2004; EN 50419: 2006; IEC 60417:2009; TR 60878:2003; ISTA 2A: 2006; ANSI AAMI HE74: 2001; ASTM D4169-08:2008; IEC 60601-1-6:2006; ISO 1041:2008; ISO 7000:2004