

## PROHLÁŠENÍ O SHODĚ

### **My, Valleylab**

divize Tyco Healthcare Group LP  
5920n Longbow Drive  
Boulder, Colorado 80301  
USA

tímto potvrzujeme se vši zodpovědností, že elektrochirurgické generátory s katalogovými čísly uvedenými v Dodatku I tohoto prohlášení jsou v souladu se

Základními principy a klasifikačními předpisy nařízení pro australské terapeutické výrobky (lékařské přístroje) z r.2002

a

směrnicí pro lékařské přístroje č. ze dne 14.června 1993

Tyto přístroje byly ověřeny jako vyhovující na základě postupu, který odpovídá Prohlášení o shodě, jak je stanoveno v odstavci 1.8 a 6.6 doložky 3 australských nařízení a postupu, který odpovídá Prohlášení EC o souladu, jak je uvedeno v Dodatku II evropské směrnice.

(podpis: Charles M. Cooperbrg)  
manažer řízení

20 . červenec 2004  
datum

Prohlášení č.        107A  
Certifikát EC:        CE 00500  
Příslušný úřad:      BSI Product Services, 0086  
Normy:                UL544, EN980, EN55011, EN1441,  
                             EN60417, EN60878, EN(IEC)60601-1,  
                             EN(IEC)60601-1-2, EN(IEC)60601-2-2  
                             AANI HF 18  
  
Datum revize:        20. červenec 2004  
Nahrazuje:           6.března 2003

Dodatek 1

Pro Prohášení o shodě číslo 107A

Revizní datum: 20. červen 2004

Katalogové číslo		Třída	MDD	MDD	GMDN Kód
Force 2-20PCH	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 300	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 10A	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 2-20CEM	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 2-20PC	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 2-8CEM	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 2-8PCH	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 20A	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 30	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 30A	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force 40AS	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force EZ	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force EZ-20	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force EZ-8	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force EZ-C	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force EZ-8C	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force FX-8	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force FX-8C	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force FX-8A	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.

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Dodatek 1

Pro Prohášení o shodě číslo 107A

Revizní datum: 20. červen 2004

Katalogové číslo		Třída	MDD	MDD	GMDN Kód
Force 40S	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
Force FX-8CA	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
SURGII-8	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
SURGII-8PE	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
SURGII-8ZD	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
SURGII-8ZE	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
SURGII-20	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
SURGII-20PE	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
SURGII-20ZD	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.
SURGII-20ZE	IIb	Rule 9	Annex II		Electrosurgical unit, general-purpose.

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# 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 Electrosurgical Generators with catalog numbers listed in Annex I of this declaration are in conformity with the

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

And the

Medical Device Directive, 93/42/EEC, 14 June 1993

These devices have been verified as conforming via the procedure relating to the Declaration of Conformity as set out in Clause 1.8 & 6.6 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.

  
\_\_\_\_\_  
Manager, Regulatory

July 20, 2004  
Date

Declaration Number: 107A

EC Certificate: CE 00500

Notified Body: BSI Product Services, 0086

Standards: UL544, EN980 EN55011, EN1441,  
EN60417, EN60878, EN(IEC)60601-1,  
EN(IEC)60601-1-2, EN(IEC)60601-2-2  
AAMI HF 18

Revision Date: July 20, 2004  
Supersedes: March 6, 2003

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# Annex 1

To Declaration of Conformity Number 107A  
Revision Date July 20, 2004

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

<u>CATALOG NUMBER</u>	<u>CLASS</u>	<u>MDD RULE</u>	<u>MDD CONFORMITY ASSESSMENT ROUTE</u>	<u>GMDN CODE</u>
Force 2-20PCH	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 300	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 10A	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 2-20CEM	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 2-20PC	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 2-8CEM	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 2-8PCH	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 20A	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 30	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 30A	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force 40AS	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force EZ	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force EZ-20	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force EZ-8	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force EZ-C	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force EZ-8C	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force FX-8	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force FX-8C	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force FX-8A	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.

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## Annex 1 To Declaration of Conformity Number 107A (Cont.)

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

<u>CATALOG NUMBER</u>	<u>CLASS</u>	<u>MDD RULE</u>	<u>MDD CONFORMITY ASSESSMENT ROUTE</u>	<u>GMDN CODE</u>
Force 40S	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
Force FX-8CA	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
SURGII-8	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
SURGII-8PE	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
SURGII-8ZD	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
SURGII-8ZE	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
SURGII-20	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
SURGII-20PE	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
SURGII-20ZD	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.
SURGII-20ZE	IIb	Rule 9	Annex II	Electrosurgical unit, general-purpose.

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