

IVD



EC DECLARATION OF CONFORMITY

This declaration is in conformity to In Vitro Diagnostic Medical Devices(98/79/EC)article 16.

Manufacturer:	Name:	Synermed International Inc.
	Address:	17408 Tiller Court Suite 1900 Westfield, Indiana, 46074 USA
<hr/>		
Authorized Representative:	Name:	Woodley Equipment Ltd.
	Address:	Old Station Park Buildings, St. Johns Street Horwich Bolton, Lancashire BL6 7NY UK
	Telephone:	4+44 (0) 1204 669033

Products/Model Numbers:

We herewith confirm the following designated products which will bear the **CE** mark:

UV 185 ALT/GPT	IR 750 Direct Bilirubin 70	IR 170 Magnesium
UV 085 AST/GOT	IR 240 Calcium	IR 110 Phosphorus
IR 010 Albumin	IR 060 Cholesterol	IR 325 Serum Iron
VI 120 Alkaline Phosphatase	UV 310 Creatine kinase (CK)	VI 135 Protein
VI 400 Amylase	VI 560 Creatinine,	IR 140 Triglycerides
UV 380 Total CO2	IR 070 Glucose	IR 460 Uric Acid
UV190 BUN	VI 410 GGT	IR 150 UIBC
IR 700 Total Bilirubin 700	UV 340 LDH	

to which this declaration relates are in conformance with harmonized standards required by the directive **98/79/EEC article 9.1 annex III, IVD-general products for professional use**

Declaration:

We, Synermed® International Inc., being the manufacturer, declare on our own responsibility that the designated products listed above to which this Declaration relates, are in conformance with the harmonized standards required by the directive 98/79/EC article 9.1 annex III, IVD-general products for professional use.

****** In order to affix the **CE** marking, Synermed International Inc. has followed the procedure relating to the EC Declaration of Conformity set out in Annex III of the IVDD 98/79/EC. The full Quality System of Synermed International Inc. under ISO 13485:2003 has been certified by SGS United Kingdom Ltd. Systems and Services Certification. The harmonized standards used were: ISO 13485:2003 Quality Management System; ISO 14971:2000 Risk Management; EN375:2001 Information supplied by the manufacturer with IVD reagents for professional use; EN928:1995 In vitro diagnostic system - Guidance on the application of EN 46001 for IVDMD; EN 980:2003 Graphical symbols for use in the labeling of medical devices.

Place of Issue:	Name:	Synermed International Inc.
	Address:	17408 Tiller Court Suite 1900 Westfield, Indiana, 46074 USA

Approved by:

Jerry W. Denney
Director, Regulatory Affairs
Synermed International Inc.

 Signature

January 1, 2009

 Date