

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

Authorized Representative:	Name:	Cell Solutions Europe Ltd.
	Address:	Hurst Bourne Cottage, Cornwells Bank Newick, East Sussex BN8 4RJ
	Telephone:	(44) 18257223000

Products/Model Numbers:

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

Cell Solution Slide Preparation Device	<input type="checkbox"/> REF	Model 120
General Cytology Preservative	<input type="checkbox"/> REF	C-101
GluCyte™ Cell Adherent	<input type="checkbox"/> REF	GC-100

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

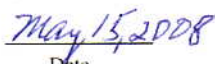
** In order to affix the **CE** marking, Synermed International Inc. has followed the procedure relating to the EC Declaration of Conformity set out in Annex III of the IVDD 98/79/EC. The full Quality System of Synermed International Inc. under ISO 13485:2003 has been certified by SGS United Kingdom 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; AAMI/ANSI/EC 60601-1-2 2001 Devices with energy source; EN928:1995 In vitro diagnostic system - Guidance on the application of EN 46001 for IVDMD; EN 980:2003 Graphical symbols for use in the labelling 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


Date