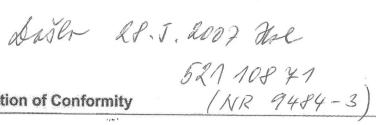


EC Declaration of Conformity



Device Revisi	ion:	A	
Manufacturer:	· ·	StatSpin, Inc. d/b/a Iris® Sample Proce	essing
Address:	•	60 Glacier Drive Westwood, Massachusetts 02090 US	A
In-vitro Diagno	ostics Medical Device:	ThermoŖrite™	
Device identifi	ication (Part No.):	ThermoBrite S500-12 • ThermoBrite St	500-24
EDMA Classif	fication:	26 02 09 Multiple Purpose Sample Prod	cessor
Classification	according to Annex III (98/79/EC):	General (Low Risk) IVD	
We declare with sole responsibility, that our products listed above meet the essential requirements of the In-vitro Diagnostics Medical Device Directive 98/79/EC of 27 October 1998. Any modification to the device, not authorized by us, will invalidate this declaration.			
certified with the	ty of the production quality assurance is he notified body of:	The identification number of the notified b implementation of the procedure set out in Directive is:	ody for n Annex IX of the
National Stan	ndards Authority of Ireland (NSAI)	Identification No: 0050	
Glasnevin	antanamenta antanamenta anta di manamenta antanamenta di manamenta di manamenta di manamenta di manamenta di m		
Dublin 9, IRE	LÁND	Certificatig No. MD19.3349	0ale 2.DEC 2005
We hereby app Representative	point mdi Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Dire	MD19.3349 63 Hanover, Germany to act as European	2.DEC.2005
We hereby app Representative Quality Assura	point mdi Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Dire ance & Regulatory Affairs Manager	MD19.3349 63 Hanover, Germany to act as European	2.DEC.2005
We hereby app Representative Quality Assura Place and Date Westwood, Mass	point mdi Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Dire	MD19.3349 63 Hanover, Germany to act as European Active 98/79/EEC.	2.DEC.2005
We hereby app Representative Quality Assura	point mdi Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Dire ance & Regulatory Affairs Manager	MD19.3349 63 Hanover, Germany to act as European	2.DEC.2005
We hereby apply Representative Quality Assurative Place and Date Westwood, Mass Signature President	point mdi Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Dire ance & Regulatory Affairs Manager	MD19.3349 63 Hanover, Germany to act as European Active 98/79/EEC.	2.DEC.2005
We hereby app Representative Quality Assura Place and Date Westwood, Mass Signature President Place and Date Westwood, Mass	point mdi Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Dire ance & Regulatory Affairs Manager	MD19.3349 63 Hanover, Germany to act as European Active 98/79/EEC.	2.DEC.2005
We hereby app Representative Quality Assura Place and Date Westwood, Mass Signature President Place and Date	point mdi Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Dire ance & Regulatory Affairs Manager sachusetts, USA 30-Mar-2006	MD19.3349 63 Hanover, Germany to act as European Active 98/79/EEC.	2.DEC.2005
We hereby app Representative Quality Assura Place and Date Westwood, Mass Signature President Place and Date Westwood, Mass Signature	point mdi Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Dire ance & Regulatory Affairs Manager sachusetts, USA 30-Mar-2006	MD19.3349 63 Hanover, Germany to act as European Active 98/79/EEC. Printed Name: Louis J. Falcone Printed Name: Robert A. Mello	Authorized
We hereby app Representative Quality Assura Place and Date Westwood, Mass Signature President Place and Date Westwood, Mass Signature This manufact dealt within ou	point mdl Europa GmbH, Wittekamp 30, D-301 e as explicitly defined in Article 1, § 2(g) of Directors ance & Regulatory Affairs Manager sachusetts, USA 30-Mar-2006 sachusetts, USA 30-Mar-2006 sachusetts, USA 30-Mar-2006 furer's declaration certifies the compliance with a General Conditions of Sale. Mdi Europe y pre-requisites for placing the softhe European Union, have thus been fulfilled.	MD19.3349 63 Hanover, Germany to act as European Active 98/79/EEC. Printed Name: Louis J. Falcone Printed Name: Robert A. Mello the EC Directive. Conditions of guarantee ause only! he above mentioned products and marketing.	2.DEC.2005 Authorized and liability are g them in all