Dašk 28.7.2007 Ase

521 108 71
(NR 9484-3)

Iris
Sample Processing

EC Declaration of Conformity

Device Revision:	A
Manufacturer:	StatSpin, Inc. d/b/a Iris® Sample Processing
Address:	60 Glacier Drive Westwood, Massachusetts 02090 USA
In-vitro Diagnostics Medical Device:	ThermoBrite™
Device identification (Part No.):	ThermoBrite S500-12 • ThermoBrite S500-24
EDMA Classification:	26 02 09 Multiple Purpose Sample Processor
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.

The Conformity of the production quality assurance is certified with the notified body of:	The identification number of the notified body for implementation of the procedure set out in Annex IX of the Directive is:
Name: National Standards Authority of Ireland (NSAI)	Identification No: 0050
Address: Glasnevin	
Dublin 9, IRELAND	Certificate No. MD19.3349 | Date 2.DEC.2005

We hereby appoint mdi Europa GmbH, Wittekamp 30, D-30163 Hanover, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Quality Assurance & Regulatory Affairs Manager

Place and Date: Westwood, Massachusetts, USA | 30-Mar-2006	
Signature:	Printed Name: Louis J. Falcone

President

Place and Date: Westwood, Massachusetts, USA | 30-Mar-2006	
Signature:	Printed Name: Robert A. Mello

This manufacturer's declaration certifies the compliance with the EC Directive. Conditions of guarantee and liability are dealt within our General Conditions of Sale.

Mdi Europa use only!

The necessary pre-requisites for placing the CE mark on the above mentioned products and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this day 4th of May 2006

mdi Europa GmbH
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mdi Europa
THE MEDICAL DEVICE SERVICE-MANAGEMENT