Instrumentation Laboratory

CE

DECLARATION OF CONFORMITY

IL ACL TOP Instrument

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**Instrumentation Laboratory Co** **113 Hartwell Avenue** **Lexington – MA 02421 U.S.A.**
EU Authorized Representative: *EU-Bevollmächtigte* *Representante Autorizado por la UE* *Mandataire* *Rappresentante Autorizzato in Eu*	*Representante Autorizado na UE* *EU-autoriseret repræsentant* *EU Auktoriserad representant* *Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ*	**Instrumentation Laboratory SpA** **Viale Monza, 338** **20128 – Milano, Italy**

Instrumentation Laboratory hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Instrumentation Laboratory erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Instrumentation Laboratory declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Instrumentation Laboratory déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Instrumentation Laboratory dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Instrumentation Laboratory declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Instrumentation Laboratory erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Instrumentation Laboratory bekräftar härmed att produkt(er) listade nedan, vara förenlig(a) med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

Η Instrumentation Laboratory με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ενωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:
EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) – Annex I and III

Standard(s):
Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπα

- **ISO 13485:1996**, Quality systems – Medical Devices
- **21CFR** Part 809.10, 812.5, 820.130-820.160(a), 820.30, 820.70
- **EN 1441:1997**, Medical Devices - Risk Analysis
- **ISO 14971:2000**, Medical Devices - Application of risk management to medical devices
- **EN 61010-1:2001 (2cd Edition)**,(IEC 1010-1) : Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- **EN 61326:2002**, Group 1, Class A , Electrical equipment for measurement, control and laboratory use – EMC requirements, + Amendment 1:1998 – Immunity ; Industrial
- **EN55011**, 1991 Limits and Methods of Measurement of Radio Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment, Group 1, Class A
- **ISO 15223:2000**, Medical Devices – Symbols to be used with medical devices, labelling and information to be supplied
- **EN 375:2000**, Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
- **EN 591:2001** , Instruction for use for in vitro diagnostic instruments for professional use
- **EN 980** Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices.

William Wood
Quality Assurance Director

Claire E. Theobald
A True Copy Attest 3/25/04
CLAIRE E. THEOBALD
NOTARY PUBLIC
My commission expires Aug. 29, 2008

Lexington, December, 2003

Instrumentation Laboratory

Product(s)		Beginning	
Produkt(e)	Produto(s)	zu beginnen von	Inicio
Producto(s)	Produkt(er)	A partir de	Gældende fra
Produit(s	Produkt(er)	Première id.	Fr o m
Prodotto(i)	Προϊόντα	A partire da	Εναρξη

P/N	Product	LOT / SN
0000280000	ACL TOP	Lots after December 1, 2003
0009831704	IL Test Cleaning Solution (Clean A) (common part)	
0009832700	IL Test Cleaning Agent (Clean B) (common part)	
0009757600	Factor Diluent (common part)	
0020009700	Rinse 1 x 4000 mL	
0028525200	Barcode labels for Factor Diluent, Clean B, Diluted Clean B	
0018902000	Bottles, Plastic, 30 mL (with cap), 10/pack	
0019085463	Bottles, Glass, 20 mL, 10/package	
0018924100	Bottles, Glass, 10mL, 10/package	
0018924104	Bottles, Glass, 4mL, 10/package	
0005575100	Sample Cups 2 mL (common part)	
0029400100	Cuvettes, 2400 cuvettes – 600 strips (4 cuvettes/strip)	
0029401100	Cuvette Waste Liner, 10/package	
0009746606	Magnetic stirrer (common part)	
0028911600	Syringe Tips, 250 uL	
0028741600	Pump/Probe Tubing Assembly	
0028713400	Rinse Aspirator Assembly, 4 L (Tubing connecting ACL TOP System to the Rinse Bottle	
0028713200	Clean Aspirator Assembly, (Tube connecting ACL TOP to the Clean Bottle	
0019006300	Stylet Kit (common part)	
0028739800	Syringe Assembly, 250 uL (common part)	
0018794300	Syringe Tip Installation Tool	
0028762900	Waste Sensor Assembly	
0028520500	4 mL Reagent Bottle Adaptor	
0028520900	10 mL Reagent Bottle Adaptor	
0029400601	Reagent Rack Set, RA - RF	
0029400602	Reagent Rack Set, RG - RM	
0029400701	Diluent Rack Set, DA - DC	
0029400702	Diluent Rack Set, DD - DF	
0029400501	Sample Rack Set, 01 - 12	
0029400502	Sample Rack Set, 13 - 24	
0029400503	Sample Rack Set, 25 - 36	
0029400504	Sample Rack Set, 37 - 48	
0029400505	Sample Rack Set, 49 - 60	
0029400506	Sample Rack Set, 61 - 72	
0029400507	Sample Rack Set, 73 - 84	
0029400508	Sample Rack Set, 85 - 96	

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