Instrumentation Laboratory

CÔNG TY TRÁCH NHIỆM HỮU HẠN CÔNG NGHỆ Y TẾ PMES

CE

DECLARATION OF CONFORMITY

ILyte Analyzers

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 III

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

- EN 1441 Medical Devices - Risk Analysis
- ISO 14971 Medical Devices - Application of risk management to medical devices
- EN 61326:1997+A1:1998, Class A (CISPR 11:1997) Group 1: Class A - Electrical Equipment For Measurement, Control And Laboratory Use
- EN 61326-1:1998+Amendment 1:1998 Immunity
- EN 61010-1:1993+A2:1995 (IEC1010-1) Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use
- EN 980 Graphical symbols for use in the labeling of medical devices
- EN 375 Information supplied by the manufacturer with *in vitro* diagnostic reagents for professional use
- EN 591 Instructions for use for *in vitro* diagnostic instruments for professional use
- EN 13612 Performance Evaluation of *in vitro* diagnostic medical devices
- EN 13640 Stability Testing of *in vitro* diagnostic medical devices
- FDA 21 CFR Part 820.30

Lexington, February 2004

William Wood
Quality Assurance Director