Werfen Group | Instrumentation Laboratory

CE DECLARATION OF CONFORMITY
IL ACL AcuStar Instrument

Manufacturer: *Hersteller* *Fabricante* *Fabricante* *Producent* *Fabricant* *Tillverkare* *Produttore* *Κατασκευαστής*	**Instrumentation Laboratory Co** **180 Hartwell Road** **Bedford, MA 01730-2443 U.S.A**
EU Authorized Representative: *EU-Bevollmächtigte* *Representante Autorizado na UE* *Representante Autorizado por la UE* *EU-autoriseret repræsentant* *Mandataire* *EU Auktoriserad representant* *Rappresentante Autorizzato in Eu* *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 9001 Quality Management Systems
- ISO 13485 Medical Devices - Quality Management Systems
- 21CFR Part 809.10, 812.5, 820.130-820.160(a), 820.30, 820.70
- ISO 14971 Medical Devices - Application of risk management to medical devices
- EN 61010-1 (2ed Edition),(IEC 1010-1) : Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- EN 61010-2-101 Part 2: Particular Requirements for in-vitro diagnostic (IVD) medical equipment .
- EN 61010-2-081 Particular Requirements for automatic and semi-automatic laboratory equipment,
- EN 61326-1, Electrical equipment for measurement, control and laboratory use – EMC requirements, Part 1 General Equipment
- ISO 15223 Medical Devices – Symbols to be used with medical devices, labelling and information to be supplied
- EN 591 Instruction for use for in vitro diagnostic instruments for professional use.
- ISTA 2b Partial Simulation Performance Test Procedure (over 150 lbs)
- EN 1658:1997 Requirements for marking of in vitro diagnostic instruments.

William Wood

William Wood
Director of Quality Assurance

February, 2013

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Product(s) Produkt(e) Producto(s) Produit(s Prodotto(i)	Produto(s) Produkt(er) Produkt(er) Προϊόντα	Beginning zu beginnen von A partir de Première id. A partire da	Dec.12, 2008 Inicio Gældende fra Fr o m Εναρξη

P/N	Product	GMDN Term	EDMA Code
0009801000	ACL AcuStar	56689	23 02 10 01
0009801200	AcuStar, Waste Bottle	14189	23 02 10 01
0009801030	AcuStar, Cuvette Waste Bin	14189	23 02 10 01
0009801012	AcuStar, Sample Rack	47832	23 02 10 01
0009801020	AcuStar, Sample Rack Adapters	47832	23 02 10 01
0009801100	ACL AcuStar Cuvettes, 1400 / box	14189	23 02 10 01
0009802200	HemosIL AcuStar System Rinse	58208	13 02 80 90
0009802201	HemosIL AcuStar Triggers	47832	23 02 10 01
0009802204	HemosIL AcuStar Cleaning Solution	58207	13 02 80 90