Werfen Group | Instrumentation Laboratory

CE DECLARATION OF CONFORMITY

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**Instrumentation Laboratory Co** **180 Hartwell Road** **Bedford – MA 01730-2443 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 ι υμμορφούνται με την οδηγία της Ευρωπαϊκής Ενωι ης και τα πρότυπα που προι διορίζονται ι την παρούι α δήλωι η.

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

Critical Care

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

ISO 9001	*EN 375*
ISO 13485	*EN 591*
ISO 13612	*EN 980*
ISO 13641	*prEN ISO 17511*
ISO 14971	*21CFR Part 809, 812, 820*
ISO 15223	

Barbara A. Way 2011-09-28
Signature/Date (YYYY-MM-DD)

Barbara A. Way, Director of Quality Assurance
(Name/Title)

Critical Care

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*	*Inicio* *Gældende fra* *Fr o m* *Εναρξη*
P/N		**LOT / SN /CO**	
0002309	GEM Crit Check Multilevel	159	
00003310700	Zeroing Solution	N0347679	
00003311900	Critical Care Diluent	N1134700	
00003312250	Multi 4 CO-Oximeter Level 4	N0648620	
00003313250	Multi 4 CO-Oximeter Level 3	N0733213	
00003314250	Multi 4 CO-Oximeter Level 2	N0733210	
00003315050	CalDye Reference Standard	N0849764	
00003315250	Multi 4 CO-Oximeter Level 1	N0733177	
00003316200	Multi 4 CO-Oximeter Control	N0733274	
00003331350	Standard 140/5/1	N0347184	
00003510000	Urine Standard 100 mmol/L Na^+ /100 mmol/L K^+	N0448019	
00005133700	abc Artificial Blood Control Multipack	N0934501	
00005133800	abc Artificial Blood Control Acidosis	N1234754	
00005133900	abc Artificial Blood Control Normal	N1234755	
00005134000	abc Artificial Blood Control Alkalosis	N1234758	
00008468950	abc Artificial Blood Control High pO_2	N0146523	
00009751750	Standard 140/5	N0447729	
00009751850	Standard 120/2	N0649145	
00009751950	Standard 160/8	N0447717	
00009752900	Rinse Solution	N1242368	
00009755500	Etching Solution	N0548769	
00009756400	Internal Standard 1.5 mmol/L Cs	N1236106	
00009831300	6.840 pH Reference Buffer	N0347681	
00009831400	Flush Solution	N0146429	
00009831600	7.384 pH Reference Buffer	N0246983	
00009831700	Cleaning Solution	N0246981	
00009831800	Cal 1	N0146419	
00009832000	Flush Solution	N1236109	
00009832350	Hematocrit Check Low	N0632383	
00009832450	Hematocrit Check High	N0733211	

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P/N		**LOT / SN /CO**
00009832550	Hematocrit Calibrator	N0733277
00009832650	Balanced Heparin	I0104001
00009832700	Critical Care/HemosIL Cleaning Agent	N1134936
00009833100	Flush	N1236112
00009833200	Cal 1	N1236108
00009833300	Cal 2	N1236113
00009833400	Critical Care CO-Oximeter Cleaning Agent	N1134711
00009833650	ContrIL Spectrum Level II	N0331092
00009833750	ContrIL Spectrum Level I	N0331091
00009833850	ContrIL Spectrum Level III	N0331097
00009833900	CO-Oximeter Cleaning Agent	N1236107
00009834200	Cal 2	N0548755
00020423700	ContrIL Plus Level 4	505
00020450005	Lactate Linearity Check	N0649246
00024001380-1383	ContrIL 7	711
00024001418-1421	ContrIL 9	906
00024001587	CVP (Calibration Validation Product)	800
00024001811	CVP (Calibration Validation Product) Level 1	1801
00024001812	CVP (Calibration Validation Product) Level 2	2801
00024001813	CVP (Calibration Validation Product) Level 3	3801
00024001814	CVP (Calibration Validation Product) Level 4	4801
00025000145	GEM CVP 5 tBili	5850
00025000101	GEM SYSTEM EVALUATOR LEVEL 1	1500
00025000102	GEM SYSTEM EVALUATOR LEVEL 2	2500
00025000103	GEM SYSTEM EVALUATOR LEVEL 3	3500
00025000104	GEM HEMATOCRIT EVALUATOR LEVEL 1	1600
00025000105	GEM HEMATOCRIT EVALUATOR LEVEL 2	2600
00025000106	GEM HEMATOCRIT EVALUATOR LEVEL 3	3600

Critical Care