

Tiêu chuẩn chủ sở hữu TTBYT công bố áp dụng

Tài liệu được xác nhận bằng chữ ký số và có hiệu lực kể từ ngày ký.

Hà Nội, ngày 02 tháng 01 năm 2020

Người đại diện hợp pháp của cơ sở

Giám đốc
Nguyễn Thị Minh Phương



DECLARATION OF CONFORMITY

Manufacturer:		Instrumentation Laboratory Co. 180 Hartwell Road Bedford - MA 01730-2443 U.S.A.
<i>Hersteller</i> <i>Fabricante</i> <i>Fabricant</i> <i>Produttore</i>	<i>Fabricante</i> <i>Producent</i> <i>Tillverkare</i> <i>Κατασκευαστής</i>	
EU Authorized Representative:		Instrumentation Laboratory SpA Viale Monza, 338 20128 - Milano, Italy
<i>EU-Bevollmächtigte</i> <i>Representante Autorizado por la UE</i> <i>Mandataire</i> <i>Rappresentante Autorizzato in Eu</i>	<i>Representante Autorizado na UE</i> <i>EU-autoriseret repræsentant</i> <i>EU Auktoriserad representant</i> <i>Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ</i>	

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

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

Instrumentation Laboratory declara por la presente que los producto(s) abajo mencionados, están conformes con la directiva identificada en esta declaración.

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

Instrumentation Laboratory dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conforme alla direttiva specificata in questa dichiarazione.

Instrumentation Laboratory declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva especificada nesta declaração.

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

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

Η εταιρεία instrumentation laboratory δηλώνει με το παρόν ότι τα προϊόντα που απαριθμούνται παρακάτω συμμορφωνονται πλήρως με την Οδηγία της Ευρωπαϊκής Ένωσης που αναφέρεται 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



Carol Marble
Regulatory Affairs Director

2016-03-23
Date (YYYY-MM-DD)



DECLARATION OF CONFORMITY

Product(s) <i>Produkt(e)</i> <i>Producto(s)</i> <i>Produit(s)</i> <i>Prodotto(i)</i>		<i>Produto(s)</i> <i>Produkt(er)</i> <i>Produkt(er)</i> <i>Προϊόντα</i>	Beginning <i>zu beginnen</i> <i>von</i> <i>A partir de</i> <i>Première id.</i> <i>A partire da</i>	<i>Inicio</i> <i>Gældende fra</i> <i>From</i> <i>Έναρξη</i>
P/N		LOT / SN		
00008468310	HemosIL Proclot		N1035090	
00008468600	HemosIL ProClot Diluent		N0548766	
00008469600	HemosIL HPX/PCX Diluent		N0448022	
00008469810	HemosIL PT-Fibrinogen HS PLUS		N0734168	
00009756710	HemosIL PT-Fibrinogen		N0331845	
00009756800	HemosIL Sample Diluent		N1034672	
00009756900	HemosIL Reference Emulsion		N0934448	
00009757600	HemosIL Factor Diluent		N0934667	
00009757950	HemosIL Chromogenic Optics Test		N1034577	
00009757980	HemosIL Chromogenic Optics Test Futura		N1034736	
00009758050	HemosIL Coagulometric Optic Test Kit		N0447733	
00009758080	HemosIL Coagulimetric Optic Test Kit		N0146999	
00009758515	HemosIL Thrombin Time		N0633247	
00009758710	HemosIL Hepatocomplex		N1242290	
00009758810	HemosIL Pro-IL-Complex		N1035665	
00009800003	HemosIL AcuStar Multi-Ab Controls		B24044	
00009831700	HemosIL Cleaning Solution		N0246981	
00009832700	Critical Care/HemosIL Cleaning Agent		N1134936	
00019741910	HemosIL Calcium Chloride 0.025 M		N0934690	
00020002300	HemosIL von Willebrand Factor Antigen		B30101	
00020002400	HemosIL Wash-R Emulsion		N1134712	
00020002500	HemosIL Liquid Antithrombin		N0834151	
00020002600	HemosIL Liquid Antithrombin Substrate		N1035328	
00020002700	HemosIL Free Protein S		B30069	
00020002800	HemosIL ProS		N0740043	
00020002950	HemosIL RecombiPlasTin 2G (5 x 8 mL)		N0573983	
00020003050	HemosIL RecombiPlasTin 2G (5 x 20 mL)		N0273477	
00020003110	HemosIL Normal Control ASSAYED		N0124808	
00020003120	HemosIL Normal Control 1 UNASSAYED		N1237086	
00020003210	HemosIL Low Abnormal Control ASSAYED		N0627385	
00020003220	HemosIL Low Abnormal Control 2 UNASSAYED		N0347747	
00020003310	HemosIL High Abnormal Control ASSAYED		N1029697	



DECLARATION OF CONFORMITY

Product(s) <i>Produkt(e)</i> <i>Producto(s)</i> <i>Produit(s)</i> <i>Prodotto(i)</i>		Beginning <i>zu beginnen</i> <i>von</i> <i>A partir de</i> <i>Première id.</i> <i>A partire da</i>	
<i>Produto(s)</i> <i>Produkt(er)</i> <i>Produkt(er)</i> <i>Προϊόντα</i>		<i>Inicio</i> <i>Gældende fra</i> <i>From</i> <i>Έναρξη</i>	
P/N		LOT / SN	
00020003320	HemosIL High Abnormal Control 3 UNASSAYED	N1237087	
00020003500	HemosIL FII & FV DNA Control	C01MAY08	
00020003700	HemosIL Calibration Plasma	N0734087	
00020003900	HemosIL Fibrinogen-C XL	N0348099	
00020004200	HemosIL Low Fibrinogen Control	N0247416	
00020004700	HemosIL von Willebrand Factor Activity	B40169	
00020004800	HemosIL Silica Clotting Time	N0261041	
00020005000	HemosIL PT-Fibrinogen Recombinant	N0733811	
00020005500	HemosIL ThromboPath	N0361308	
00020006300	HemosIL APTT-SP	N0834169	
00020006800	HemosIL SynthASil	N0325507	
00020006900	HemosIL Calcium Chloride 0.020 M	N0425956	
00020007400	HemosIL SynthAFax	N0130880	
00020007700	HemosIL D-Dimer HS	B50292	
00020007800	HemosIL Homocysteine	B60443	
00020007900	HemosIL Homocysteine Controls	B60459	
00020008000	HemosIL LAC Screen	H4A023AA	
00020008200	HemosIL LAC Confirm	H4B021AA	
00020008500	HemosIL D-Dimer	B30084	
00020008610	HemosIL D-Dimer Controls	B30065	
00020008700	HemosIL Factor V Leiden (APC Resistance V)	N1135821	
00020008800	HemosIL Factor V Reagent Plasma (for APC R V)	N0147188	
00020008900	HemosIL Antithrombin	N1135683	
00020009000	HemosIL Plasminogen	N1035591	
00020009200	HemosIL Plasmin Inhibitor	N1035592	
00020009320	HemosIL Rinse Solution (ACL Futura/Advance)	N0934422	
00020009400	HemosIL Heparin	N1136159	
00020009700	HemosIL Rinse Solution (ACL TOP Family)	N1236175	
00020010000	HemosIL Factor X Deficient Plasma	N0990149	
00020010500	HemosIL INR Validate	N0185665	
00020010600	HemosIL ISI Calibrate	N0185662	
00020010700	HemosIL Plasma Coagulation Control Level 1 (Super)	N1087617	


DECLARATION OF CONFORMITY

Product(s) <i>Produkt(e)</i> <i>Produto(s)</i> <i>Producto(s)</i> <i>Produkt(er)</i> <i>Produit(s)</i> <i>Produkt(er)</i> <i>Prodotto(i)</i> <i>Προϊόντα</i>		Beginning <i>zu beginnen</i> <i>Inicio</i> <i>von</i> <i>Gældende fra</i> <i>A partir de</i> <i>Fr o m</i> <i>Première id.</i> <i>Εναρξη</i> <i>A partire da</i>
P/N		LOT / SN
00020010800	HemosIL Plasma Coagulation Control Level 2 (Duper)	N1087616
00020011000	HemosIL Special Test Control Level I	N0473904
00020011200	HemosIL Factor XII Deficient Plasma	N1090383
00020011300	HemosIL Factor XI Deficient Plasma	N1290944
00020011500	HemosIL Factor V Deficient Plasma	N0799853
00020011700	HemosIL Factor VII Deficient Plasma	N0990158
00020011800	HemosIL Factor VIII Deficient Plasma	N0599279
00020011900	HemosIL Factor IX Deficient Plasma	N0499097
00020012000	HemosIL Special Test Control Level 2	N0473905
00020012200	HemosIL Factor II Deficient Plasma	N0799724
00020012500	HemosIL LA Positive Control	N0702894
00020012600	HemosIL LA Negative Control	N0702891
00020012800	HemosIL Factor VIII Deficient Plasma (normal VWF)	N0620475
00020013000	HemosIL D-Dimer Controls (Liquid)	B21892
00020013100	HemosIL D-Dimer HS 500 Controls (Liquid)	B23148
00020013200	HemosIL HIT-Ab(PF4-H) Controls	B01268
00020013400	HemosIL Dabigatran Calibrators	N0248653
00020013500	HemosIL Dabigatran Controls	N0248890
00020030100	HemosIL Liquid Antithrombin	N0757163
00020201300	HemosIL Factor XIII Antigen	B50303
00020300100	HemosIL Liquid Heparin	N0398798
00020300200	HemosIL LMW Heparin Controls	N0398799
00020300300	HemosIL UF Heparin Controls	N0398800
00020300400	HemosIL Liquid Antithrombin	N0273484
00020300500	HemosIL Protein C	N0473896
00020300600	HemosIL Heparin Calibrators	N0398801
00020300900	HemosIL VWF:RCo	B11509
00020301000	HemosIL D-Dimer 500	B11546
00020301100	HemosIL Fibrinogen-C (10x2ml)	N0599176
00020301200	HemosIL HIT-Ab(PF4-H)	B01267
00020301400	HemosIL ReadiPlasTin	N0836114
00020301500	HemosIL dRVVT Screen	N0805471



DECLARATION OF CONFORMITY

Product(s) <i>Produkt(e) Producto(s) Produit(s) Prodotto(i)</i>		Beginning <i>zu beginnen von A partir de Première id. A partire da</i>	<i>Inicio Gældende fra Fr o m</i> <u>Εναρξη</u>
<i>Producto(s) Produkt(er) Produkt(er) Προϊόντα</i>		LOT / SN	
00020301600	HemosIL dRVVT Confirm	N0505472	
00020301700	HemosIL QFA Thrombin (5 ml)	N1090513	
00020301800	HemosIL QFA Thrombin (2ml)	N1090514	
00020302000	HemosIL Protein S Activity	N0515735	
00020302400	HemosIL Rinse, 4 Liters	E0315329	
00020302500	HemosIL Rinse, 2 Liters	N0917234	
00020302600	HemosIL Liquid Anti-Xa	N0429735	
00020302800	HemosIL Direct Thrombin Inhibitor Assay	N0248656	
00020500100	HemosIL D-Dimer HS 500	B80816	
00020500200	HemosIL D-Dimer HS 500 Controls	B80825	
0009802000	HemosIL Acustar D-Dimer	B80786	
0009802004	HemosIL AcuStar Anti-Cardiolipin IgG	B80792	
0009802008	HemosIL AcuStar Anti-Cardiolipin IgM	B80793	
0009802012	HemosIL AcuStar Anti-β2 Glycoprotein I IgG	B80788	
0009802016	HemosIL AcuStar Anti-β2 Glycoprotein I IgM	B80789	
0009802119	HemosIL AcuStar von Willebrand Factor Controls	B11798	
0009802020	HemosIL AcuStar von Willebrand Factor Antigen	B21898	
0009802024	HemosIL AcuStar von Willebrand Factor Ristocetin Cofactor Activity	B22059	
0009802028	HemosIL AcuStar HIT-IgG(PF4-H)	B11611	
0009802032	HemosIL AcuStar HIT-Ab(PF4-H)	B11610	
0009802100	HemosIL Acustar D-Dimer Controls	B80787	
0009802104	HemosIL AcuStar Anti-Cardiolipin IgG Controls	B80835	
0009802108	HemosIL AcuStar Anti-Cardiolipin IgM Controls	B80836	
0009802112	HemosIL AcuStar Anti-β2 Glycoprotein I IgG Controls	B80790	
0009802116	HemosIL AcuStar Anti-β2 Glycoprotein I IgM Controls	B80811	
0009802122	HemosIL AcuStar HIT Controls	B11612	
049730503	Electrachrome Factor VIII	N0247557	
049738960	Hemoliance Dimertest	BX075A	
00020013900	HemosIL Normal Control 1	N0841796	
00020014000	HemosIL Abnormal Control 2	N0841798	
00020014100	HemosIL Abnormal Control 3	N0841800	
00020302601	HemosIL Liquid Anti-Xa	N0656778	


DECLARATION OF CONFORMITY

Product(s)		Beginning
<i>Produkt(e)</i>	<i>Produto(s)</i>	<i>zu beginnen</i>
<i>Producto(s)</i>	<i>Produkt(er)</i>	<i>von</i>
<i>Produit(s)</i>	<i>Produkt(er)</i>	<i>A partir de</i>
<i>Prodotto(i)</i>	<i>Προϊόντα</i>	<i>Première id.</i>
		<i>Inicio</i>
		<i>Gældende fra</i>
		<i>From</i>
		<i>Εναρξη</i>
		<i>A partire da</i>
P/N		LOT / SN
00020013600	HemosIL Rivaroxaban Calibrators	N0741129
00020013700	HemosIL Rivaroxaban Controls	N0741139
00020301300	HemosIL ReadIPlasTin	N0958719
00020014200	HemosIL Apixaban Calibrators	N0857952
00020014300	HemosIL Apixaban Controls	N0858051