



STATEMENT LETTER

To Whom It May Concern,

We, **Instrumentation Laboratory Company**, located at 180 Hartwell Road, Bedford, MA 01730, USA, hereby certify that:

The warranty service is not applicable to our IVD medical devices listed below which are test kits, reagents, calibrators, controls, wash, rinse, cleaning, diluent products, and other auxiliary reagents and consumables for use with the Hemostasis (Coagulation) Analyzers.

Products' list:

No.	Product Code	Product Name
1	0009831700	HemosIL Cleaning solution
2	0009757600	HemosIL Factor diluent
3	0020302400	HemosIL Rinse solution
4	0009832700	Critical Care/ HemosIL Cleaning agent
5	0097579000	HemosIL Chromogenic Optic Test 160 µmol/L
6	0009832700	HemosIL Cleaning agent
7	0009802200	HemosIL AcuStar System Rinse
8	0009802204	HemosIL AcuStar Cleaning Solution
9	0020002400	HemosIL Wash-R Emulsion
10	0009802201	HemosIL AcuStar Triggers
11	0020004800	HemosIL Silica Clotting Time
12	0020301500	HemosIL dRVVT Screen
13	0020301600	HemosIL dRVVT Confirm

No.	Product Code	Product Name
14	0020002300	HemosIL vWF:Ag
15	0020301100	HemosIL Fibrinogen C
16	0020003900	HemosIL Fibrinogen-C XL
17	0020012200	HemosIL Factor II deficient plasma
18	0020011500	HemosIL Factor V deficient plasma
19	0020010000	HemosIL Factor X deficient plasma
20	0020011700	HemosIL Factor VII deficient plasma
21	0020300500	HemosIL Protein C
22	0020302000	HemosIL Protein S Activity
23	0020030100	HemosIL Liquid Antithrombin
24	0020011900	HemosIL Factor IX deficient plasma
25	0020011300	HemosIL Factor XI deficient plasma
26	0020011200	HemosIL Factor XII deficient plasma
27	0020012800	HemosIL Factor VIII deficient plasma
28	0020300900	HemosIL vWF:RCo
29	0020500100	HemosIL D-Dimer HS 500
30	0020013100	HemosIL D-Dimer HS 500 Controls
31	0020201300	HemosIL Factor XIII Antigen
32	0020002700	HemosIL Free Protein S
33	0020013400	HemosIL Dabigatran Calibrators
34	0020013500	HemosIL Dabigatran Controls

No.	Product Code	Product Name
35	0020302800	HemosIL Direct Thrombin Inhibitor Assay
36	0020007800	HemosIL Homocysteine
37	0020007900	HemosIL Homocysteine Controls
38	0020012500	HemosIL LA Positive Control
39	0020012600	HemosIL LA Negative Control
40	0020009000	HemosIL Plasminogen
41	0020009200	HemosIL Plasmin Inhibitor
42	0020004700	HemosIL vWF Activity
43	0020301800	HemosIL Q.F.A. Thrombin (Bovine)
44	0020301700	HemosIL Q.F.A. Thrombin (Bovine)
45	0020008700	HemosIL Factor V Leiden (APC Resistance V)
46	0020302700	HemosIL HIT-Ab(PF4-H)
47	0020013300	HemosIL HIT-Ab(PF4-H) Controls
48	0020009900	HemosIL FDP
49	0020009910	HemosIL FDP Calibrator
50	0020009920	HemosIL FDP Controls
51	00009800003	HemosIL AcuStar Multi-Ab Controls
52	0009802000	HemosIL AcuStar D-Dimer
53	0009802100	HemosIL AcuStar D-Dimer Controls
54	0009802004	HemosIL AcuStar Anti-Cardiolipin IgG
55	0009802008	HemosIL AcuStar Anti-Cardiolipin IgM

No.	Product Code	Product Name
56	0009802012	HemosIL AcuStar Anti-β2-Glycoprotein-I IgG
57	0009802016	HemosIL AcuStar Anti-β2-Glycoprotein-I IgM
58	0009802024	HemosIL AcuStar VWF:RCo
59	0009802020	HemosIL AcuStar VWF:Ag
60	0009802028	HemosIL AcuStar HIT-IgG (PF4-H)
61	0009801000	ACL AcuStar
62	0009802044	HemosIL AcuStar VWF:CB
63	0009802048	HemosIL AcuStar ADAMTS13 Activity
64	0020301000	HemosIL D-Dimer 500
65	0020013000	HemosIL D-Dimer Controls
66	0009802119	HemosIL AcuStar VWF Controls
67	00009800015	HemosIL AcuStar Anti-β ₂ GP1 Domain 1
68	00009800022	HemosIL AcuStar Anti-β ₂ GP1 Domain 1 Controls
69	0020301400	HemosIL ReadiPlasTin
70	0020006300	HemosIL APTT-SP (liquid)
71	0019741910	HemosIL Calcium Chloride 0.025 M
72	0009758515	HemosIL Thrombin Time
73	0020003050	HemosIL RecombiPlasTin 2G
74	0020002950	HemosIL RecombiPlasTin 2G
75	0020006800	HemosIL SynthASil
76	0008469810	HemosIL PT-Fibrinogen HS PLUS

No.	Product Code	Product Name
77	0020007400	HemosIL SynthAFax
78	0020302601	HemosIL Liquid Anti-Xa
79	0020300600	HemosIL Heparin Calibrators
80	0020300200	HemosIL LMW Heparin Controls
81	0020300300	HemosIL UF Heparin Controls
82	0020013600	HemosIL Rivaroxaban Calibrators
83	0020013700	HemosIL Rivaroxaban Controls
84	0020014200	HemosIL Apixaban Calibrators
85	0020014300	HemosIL Apixaban Controls
86	0020009400	HemosIL Heparin
87	0020003700	HemosIL Calibration plasma
88	0020003110	HemosIL Normal Control ASSAYED
89	0020003210	HemosIL Low Abnormal Control ASSAYED
90	0020003310	HemosIL High Abnormal Control ASSAYED
91	0020004200	HemosIL Low Fibrinogen Control
92	0020010500	HemosIL INR Validate
93	0020010600	HemosIL ISI Calibrate

Authorized Signatory:



Date: 15 July 2022

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Regulatory Affairs Manager II
Instrumentation Laboratory Co.
A Werfen Company