Instrumentation Laboratory
A Werfen Company

CERTIFICATE OF ANALYSIS

PRODUCT NAME:	HemosIL Calibration Plasma	EXPIRATION DATE:	2024-08
PRODUCT NUMBER:	0020003700		
LOT NUMBER:	N0815332		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		PASS / FAIL
PRODUCT DESCRIPTION	PER MONOGRAPH		---	PASS	PASS
FIBRIN	PER MONOGRAPH		---	PASS	PASS
CONTENT UNIFORMITY (TOP)					
PT SD	0	0.35	---	0.08	PASS
PT CV	0	3.0	%	0.7	PASS
APTT SD	0	0.9	---	0.3	PASS
APTT CV	0	3.0	%	0.9	PASS
FVIII (ACL Classic)	80	130	%	99	PASS
PT-FIBRINOGEN (TOP)	11.2	14.2	SEC	12.2	PASS
FIBRINOGEN (TOP)	250	400	mg/dL	327	PASS
APTT-SP (TOP)	28.0	32	SEC	29.4	PASS
SYNTHASIL (TOP)	26.8	32.0	SEC	30.3	PASS
24 HR. RECON. STABILITY 2-8°C					
PT-FIBRINOGEN (TOP)	-10	10	%	-3	PASS
APTT-SP (TOP)	-10	10	%	6	PASS

The human plasma used to manufacture this product has been tested at the source and has been found negative for HIV-1 antigen, HIV, and HCV Antibody, and non-reactive for HbsAg by FDA required tests.

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: Andrew Billington (Print) A. Billington (Signature) **DATE:** 10/13/21

TITLE: QC Analyst

APPROVED BY: Wei Wang (Print) (Signature) **DATE:** 10/13/21

TITLE: Production Manager

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