

# **Bản tiêu chuẩn chủ sở hữu công bố áp dụng**

*Tài liệu được xác nhận bằng chữ ký số*

*Hà Nội, ngày 07 tháng 9 năm 2022*

**Người đại diện hợp pháp của cơ sở**

**GIÁM ĐỐC**

**Nguyễn Thị Minh Phương**



To whom it may concern

**Declaration Letter**

**Technical Specification**

We, Instrumentation Laboratory Company, located at 180 Hartwell Road, Bedford MA 01730 USA, hereby declare that IL Labeled product technical specification information is documented in the Quality Control Monograph (QCM) and on the Certificate of Analysis (CoA) of each specific product.

Date: 07 March 2022

A handwritten signature in blue ink, reading 'Reba Daoust', is written over a horizontal line.

Reba Daoust  
Regulatory Affairs Manager II  
Instrumentation Laboratory Co

**Certificate of Analysis**

**Instrumentation  
Laboratory**

A Werten Company

PRODUCT: <u>HemosIL AcuStar Von Willebrand Factor Controls</u>		PRODUCT #: <u>0009802119</u>	
EXP. DATE: <u>2022-08-16</u>		LOT #: <u>B33738</u>	
VENDOR: <u>INSTRUMENTATION LABORATORY</u>			
TEST DESCRIPTION	SPECIFICATIONS	RESULTS	PASS/FAIL
<b>Chemical/Physical Characteristics</b>			
<b>Low and Normal Controls</b>			
Physical Form	Lyophilized	Lyophilized	Pass
Color	Colorless/Ochre	Ochre	Pass
<b>Functional Characteristics – ACL AcuStar System</b>			
Control Value HemosIL AcuStar VWF:Antigen	Low Control (%)	21.2 - 42.2	31.0
	Normal Control (%)	71.1 - 141.1	102.8
Control Value HemosIL AcuStar VWF:Ristocetin Cofactor	Low Control (%)	18.8 - 37.4	28.2
	Normal Control (%)	63.9 - 126.9	95.8
Control Value HemosIL AcuStar VWF:Collagen Binding Activity	Low Control (%)	20.4 - 40.6	26.4
	Normal Control (%)	64.9 - 128.7	79.9
Control Value HemosIL AcuStar ADAMTS13 Activity	Low Control (%)	23.1 - 45.9	35.2
	Normal Control (%)	63.5 - 126.1	86.6
Packaging meets specifications		( X ) YES	( ) NO

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: Kareame Smith *K Smith* DATE: 2/4/21  
Print Signature

TITLE: Sr. Quality Engineer

APPROVAL SIGNATURE: Andrew Chizmadia *Andrew Chizmadia* DATE: 02/04/2021  
Print Signature

TITLE: Manager Quality Engineering