




A Company of Sysmex Group

 HYPHEN BioMed  
155 rue d'Eragny  
95000 Neuville-sur-Oise  
France

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN PROTHROMBIN  
**Product Code :** 221605  
**Lot No. :** F1900547  
**Expiration date :** 2023-04-19

Components	Quantity	Lot	Expiration Date
R1 : Ecarin	4 vials	F191100547	2023-05-29
R2 : Substrate	4 vials	F191100547	2023-04-19
R3: Buffer	4 vials	F191100547	2023-05-22

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	A405 (1:25) $\geq$ 1.50 Delta A405 (1:25 ; 1:50) $\geq$ 0.50 $R^2 \geq$ 0.98 Measured values for controls in acceptance ranges	2.118 0.960 0.99 Measured values for controls in acceptance range
Detection Threshold	$\leq$ 5%	< 1 %

*This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.*

Date of Approval : 2019-07-04

Quality Control Manager : **S.LECOURT**