



A Company of Sysmex Group



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN Factor XIII  
**Product Code :** 227005  
**Lot No. :** FE21981J / FE20761C  
**Expiration date :** 2027-09-03

| Components             | Quantity | Lot                 | Expiration Date |
|------------------------|----------|---------------------|-----------------|
| R1 : Thrombin          | 3 vials  | FE2198bs1J-FE20761C | 2027-09-03      |
| R2 : Detection Reagent | 3 vials  | FE2198bt1J-FE20761C | 2027-09-13      |

| Analytical Data   | Specification  | Result                         |
|---|--|--------------------------------|
| Calibration curve : reactivity, slope, linearity and accuracy on CS | OD/min(100%) > 0.016<br>Delta OD/min (100-50%) ≥ 0.006<br>R <sup>2</sup> ≥ 0.98<br>Measured values for controls in acceptance ranges | 0.021<br>0.009<br>PASS<br>PASS |
| Detection Threshold   | ≤ 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 : **Quality Control Approval** Quality Control Manager :

10 AVR. 2025

S. LECOURT