



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN DABIGATRAN PLASMA CALIBRATOR LOW  
**Product Code :** 222901  
**Lot No. :** FC009418  
**Expiration date :** 2025-06-28

| Components | Quantity | Lot        | Expiration Date |
|------------|----------|------------|-----------------|
| CAL 1      | 4 vials  | FC0094DA18 | 2025-06-28      |
| CAL 2      | 4 vials  | FC0094DB18 | 2025-06-28      |
| CAL 3      | 4 vials  | FC0094DC18 | 2025-06-28      |

| Analytical Data  | Specification  | Result                           |
|--|--|----------------------------------|
| Concentration  | CAL 1 : < 20 ng/ml<br>CAL 2 : 40 -60 ng/ml<br>CAL 3 : 80 -110 ng/ml  | 0 ng/mL<br>52 ng/mL<br>102 ng/mL |
| Linearity and accuracy of calibration with values assigned | $R^2 \geq 0.98$<br>Measured values for controls in acceptance ranges | PASS                             |

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

Date of Approval : 2023-03-14

Quality Control Manager :

S.LECOURT