



 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.: F2000756
Expiration date: 2022-11-22

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	F201400756	2022-11-22
CAL 2	4 vials	F201400756	2022-11-22
CAL 3	4 vials	F201400756	2022-11-22

Analytical Data	Specification	Result
Concentration	CAL 1 : < 20 ng/mL CAL 2 : 40 -60 ng/mL CAL 3 : 80 -120 ng/mL	0 66(*) 109
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	> 1.00 Measured values for controls in acceptance ranges

(*) Accepted under waiver (NCI No 1849)

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

Date of Approval: 2020-06-29

Quality Control Manager: S. LECOURT