



 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. : F2001290
Expiration date : 2023-03-21

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	F201501290	2023-03-21
CAL 2	4 vials	F201501290	2023-03-21
CAL 3	4 vials	F201501290	2023-03-21

Analytical Data	Specification	Result
Concentration	CAL 1 : < 20 ng/ml CAL 2 : 40 -60 ng/ml CAL 3 : 80 -120 ng/ml	0 48 94
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	0.99 Controls in acceptance ranges

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

Date of Approval : 2020-10-26

Quality Control Manager :

S.LECOURT