

## **CERTIFICATE OF ANALYSIS**

444

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

**BIOPHEN EDOXABAN CALIBRATOR** 

**Product Code:** 

226501

Lot No.:

FC19551D

Expiration date:

2026-03-03

| Components | Quantity | Lot        | Expiration Date |
|------------|----------|------------|-----------------|
| CAL 1      | 4 vials  | FC1955aa1D | 2026-03-03      |
| CAL 2      | 4 vials  | FC1955ab1D | 2026-03-03      |
| CAL 3      | 4 vials  | FC1955ac1D | 2026-03-03      |

| Analytical Data                                            | Specification                                                                   | Result                            |
|------------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------|
| Concentration                                              | CAL 1 : ≤ 40 ng/ml<br>CAL 2 : 200 -300 ng/ml<br>CAL 3 : 400 -600 ng/ml          | 0 mg/ml<br>244 mg/ml<br>495 mg/ml |
| Linearity and accuracy of calibration with values assigned | $\label{eq:R2} R^2 \geq 0.98$ 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: 2023-11-07

Quality Control Manager : S. LECOURT