

CERTIFICATE OF ANALYSIS

Factor XI native



Attachment 03

DQ4E00.05

Temp.: TP0326.07

4E53C00.02

REF 5184004-RUO
 LOT 4E53C00.02
 2027-05-31

| Analytical Procedures | | Requirement | Result | |
|--|----------------------------------|---|----------------------------------|----|
| visual inspection | Cap color | blue | confirmed | OK |
| | Vial type | clear glass vial | confirmed | OK |
| | Vial label | according to packaging SOP | confirmed | OK |
| | Vial barcode | according to packaging SOP | confirmed | OK |
| | Box label | according to packaging SOP | confirmed | OK |
| | Box barcode | according to packaging SOP | confirmed | OK |
| | Package insert | present | confirmed | OK |
| | Appearance before reconstitution | buff colored plug of lyophilized material | confirmed | OK |
| | Appearance after reconstitution | amber colored liquid | confirmed | OK |
| Virology HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab The testing methods applied were FDA-approved or CE marked. | | Negative Negative Positive | Negative Negative Positive | OK |
| Recovery of controls F XI | Control N | | | |
| | LOT 1P42C00 | 75.8 - 126.3 % | 105.8 % | OK |
| | Control A | | | |
| | LOT 3P51C00 | 32.3 - 53.8 % | 48.8 % | OK |

Prepared by

Lavdrin NASUFI

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Date

Approved by

Lukas GRUBELNIG

17. SEP. 2025

Date