

CERTIFICATE OF ANALYSIS
Factor IX native



Temp.: TP0326.07

Attachment 03 DQ4900.03
4933C00.03

REF	5164008-RUO
LOT	4933C00.03
⌚	2025-07-31

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 IX	Control N LOT 1P31C00	87.8 - 146.3 %	118.4 %	OK
	Control A LOT 3P42C00	16.5 - 27.5 %	19.6 %	OK

Prepared by	 _____ Mayja RAUSCHER	_____ 27. SEP. 2024 Date
Approved by	 _____ Lygia HOŁOWICZ	_____ 27. SEP. 2024 Date