



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4800.02

Att.04

4803C00.01

## F VIII Mangelplasma nativ, 50x1mL

REF	5154016
LOT	4803C00.01
⌚	2022-05-31

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
visuelle Kontrolle 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	buff colored liquid without visible particles	confirmed	OK
Virologie / Virology	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Positive	Negative Negative Positive	OK
The testing methods applied were FDA-approved or CE marked.				
Kontrollwiederfindung FVIII am Ceveron® Alpha	Control N LOT 1P02C00	71.3 - 118.8 %	79.2 %	OK
Recovery of controls FVIII on Ceveron® Alpha	Control A LOT 3P91B00	18.0 - 30.0 %	24.0 %	OK

Durchgeführt von

Prepared by

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18. JUNI 2020

Datum / Date:

Freigabe von

Approved by

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18. JUNI 2020

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