



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4800.02

Att.04

4891B00.01

## F VIII Mangelplasma nativ, 50x1mL

REF	5154016
LOT	4891B00.01
⌚	2021-01-31

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  The testing methods applied were FDA-approved or CE marked.	Negative Negative Positive  Negative Negative Positive  OK
Kontrollwiederfindung FVIII am Ceveron® Alpha	Control N LOT 1P71B01	74.3 - 123.8 % 91.8 % OK
Recovery of controls FVIII on Ceveron® Alpha	Control A LOT 3P71B01	20.1 - 33.5 % 30.6 % OK

Durchgeführt von  
Prepared by

**Alessandro BENIGNI**

**21. FEB. 2019**

Datum / Date:

Freigabe von  
Approved by

**Stefan STEINER**

**22. FEB. 2019**

Datum / Date: