



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ480D.02

Att.04

4894B0D.01

## F VIII Mangelplasma immunads, 50x1mL

REF	5154004
LOT	4894B0D.01
	2021-06-30

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  The testing methods applied were FDA-approved or CE marked.	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab  Negative Negative Negative	Negative Negative Negative  OK
Kontrollwiederfindung FVIII am Ceveron® Alpha	Control N LOT 1P71B01	74.3 - 123.8 % 87.0 % OK
Recovery of controls FVIII on Ceveron® Alpha	Control A LOT 3P71B01	20.1 - 33.5 % 30.7 % OK

Durchgeführt von  
Prepared by

**Alessandro BENIGNI**

03-Dez-2019  
Datum / Date:

Freigabe von  
Approved by

**Michael KAFKA**

04.02.2019

Datum / Date: