



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ480D.02  
Att.04  
4874B0D.01

## F VIII Mangelplasma immunads, 50x1mL

REF      5154004  
LOT      4874B0D.01  
      2019-05-31

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 Negative	Negative Negative Negative OK
The testing methods applied were FDA-approved or CE marked.			
Kontrollwiederfindung FVIII am Ceveron® Alpha	Control N LOT 1P71B00	74.3 - 123.8 %	93.5 % OK
Recovery of controls FVIII on Ceveron® Alpha	Control A LOT 3P71B00	20.1 - 33.5 %	30.6 % OK

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06. DEZ. 2017

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