



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ480D.02

Att.04

4883B0D.01

F VIII Mangelplasma immunads, 50x1mL

REF	5154004
LOT	4883B0D.01
	2020-04-30

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	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab The testing methods applied were FDA-approved or CE marked.	Negative Negative Negative	Negative Negative Negative	OK
Kontrollwiederfindung FVIII am Ceveron® Alpha	Control N LOT 1P71B01	74.3 - 123.8 %	78.5 %	OK
Recovery of controls FVIII on Ceveron® Alpha	Control A LOT 3P71B01	20.1 - 33.5 %	24.2 %	OK

Durchgeführt von
Prepared by

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20. AUG. 2018

Datum / Date:

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20. AUG. 2018

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