



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4800.02

Att.03

4887B00.01

F VIII Mangelplasma nativ, 5x1mL

REF	5154007
LOT	4887B00.01
⌚	2020-11-30

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 Positive	Negative Negative Positive	OK
Kontrollwiederfindung FVIII am Ceveron® Alpha	Control N LOT 1P71B01	74.3 - 123.8 %	88.1 %	OK
Recovery of controls FVIII on Ceveron® Alpha	Control A LOT 3P71B01	20.1 - 33.5 %	30.3 %	OK

Durchgeführt von
Prepared by

Alessandro BENIGNI

13-Dez-2018

Datum / Date:

Freigabe von
Approved by

Suzana GRESAK PODAKAR

13-DEZ-2018

Datum / Date: