



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ480D.02

Att.03

4802C0D.01

F VIII Mangelplasma immunads, 5x1mL

REF	5154002
LOT	4802C0D.01
⌚	2022-02-28

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 1P02C00	71.3 - 118.8 % 95.4 % OK
Recovery of controls FVIII on Ceveron® Alpha	Control A LOT 3P91B00	18.0 - 30.0 % 23.3 % OK

Durchgeführt von
Prepared by

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27. MAI 2020

Datum / Date:

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27. MAI 2020

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