



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQP000.02  
Att.19  
P881B01.01

## Technoview® Edoxaban CONT Medium 5x1mL

REF	5090252
LOT	P881B01.01
	2022-03-31

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
visuelle Kontrolle visual inspection	Cap color	red	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
	Batch table	present	confirmed	OK
	Appearance before reconstitution	buff colored plug of lyophilized material	confirmed	OK
	Appearance after reconstitution	buff colored liquid	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 am Ceveron® Alpha Recovery of controls on Ceveron® Alpha	Technochrom® anti-Xa LOT 0891B00	81.0 - 135.0 ng/mL	107.9 ng/mL	OK

Durchgeführt von  
Prepared by

Michael KAFKA

18. Okt. 2019

Datum / Date:

Freigabe von  
Approved by

Alessandro BENIGNI

18-Okt-2019

Datum / Date: