



Declaration of Conformity



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Manufacturer	Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH Brunner Str. 67 1230 Vienna Austria		
SRN	AT-MF-000024115		
Product(s)	CaCl ₂ 50 mM		
Basic UDI-DI	912003686TC9C0000002ZP		
UDI-DI (GTIN)	Product name		REF
09120036860582	CaCl ₂ 50 mM	100 mL	5279025
09120036860599	CaCl ₂ 50 mM	25 mL	5279027
Classification	Class A according to Annex VIII rule 5(a)		
Common Standards	N/A		
Notified Body Involvement	N/A		
Conformity assessment route	Following article 48(10), the EU declaration of conformity is issued after drawing up the technical documentation set out in Annexes II and III (IVDR)		
Initial date of first declaration of conformity	21-Jul-2022		
Valid until	20-Jul-2025		

This declaration of conformity is issued under the sole responsibility of Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH. We hereby declare that the device(s) specified above meet the provision of the Regulation for *in vitro* diagnostic medical devices (EU) 2017/746 Annex I.

Name: Veronika Binder

Position: Chief Executive Officer

Signed:

Date: 01-Feb-2023

This declaration of conformity is issued in Vienna, Austria on behalf of Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH.