



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) CaCl₂ 25 mM

Basic UDI-DI 912003686TC9C0000001ZM

UDI-DI (GTIN)	Product name		REF
09120036860568	CaCl ₂ 25 mM	100 mL	5277015
09120036860575	CaCl ₂ 25 mM	25 mL	5277017
09120036863682	CaCl ₂ 25 mM	6 x 25 mL	5277020

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.