



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)	NaCl 0.9%	
Basic UDI-DI	912003686TC950000001RW	
UDI-DI (GTIN)	Product name	REF
09120036861503	NaCl 0.9 %	4847127
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	01-Feb-2023	
Valid until	31-Jan-2026	

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.