Declaration of Conformity

Doc. Nr.: DoC9J.01

Temp.: TF0484.04
Att. 01 to D00100

Manufacturer	Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH Brunner Str. 67 1230 Vienna Austria
SRN	**AT-MF-000024115**
Product(s)	Imidazole Buffer
Basic UDI-DI	912003686TC9J00000015V

UDI-DI (GTIN)	**Product name**		**REF**
09120036863675	Imidazole Buffer	6 x 25 mL	5410007
09120036860872	Imidazole Buffer	25 mL	5410008
09120036860889	Imidazole Buffer	50 mL	5410010
09120036860896	Imidazole Buffer	90 mL	5410012

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-Jän-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.