



Declaration of Conformity



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Alt.: 01 to 000100

Manufacturer	Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH Brunner Str. 67 1230 Vienna Austria		
SRN	AT-MF-000024115		
Product(s)	Ceveron Wash Solution		
Basic UDI-DI	912003686TC990000001UA		
UDI-DI (GTIN)	Product name		REF
09120036862739	Ceveron Wash Solution	30 mL	9820320
09120036863293	Ceveron Wash Solution	6 x 30 mL	9820328
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	26-May-2022		
Valid until	25-May-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.