



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)	Ceveron 100 series	
Basic UDI-DI	912003686TCCEV100001VF	
UDI-DI (GTIN)	Product name	REF
09120036863958	Ceveron c100	9822010
09120036863965	Ceveron t100	9822110
09120036863972	Ceveron s100	9822210
Intended use	The Ceveron 100 series comprises three types of fully automatic measuring instruments used to perform in-vitro diagnostic coagulation tests in human plasma. The detection methods include clotting, chromogenic, turbidimetric, fluorogenic, and FRET quenching methods. The devices are intended for professional use by qualified personnel in laboratories or clinical environments.	
Classification	Class A according to Regulation (EU) 2017/746 Annex VIII rule 5(b)	
Common Standards	N/A	
Notified Body Involvement	N/A	
Conformity Assessment Procedure	Regulation (EU) 2017/746 Annex II and III	
Date of initial declaration of conformity	26-May-2022	

This declaration of conformity is issued under the sole responsibility of Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH. The device(s) covered by the present declaration is/are in conformity with the provisions of Regulation (EU) 2017/746 on in vitro diagnostic medical devices and Directive (EU) 2011/65 on the restriction of the use of certain hazardous substances in electrical and electronic equipment including the amendment of Directive (EU) 2015/863.

Name: Veronika Binder **Position:** Chief Executive Officer

Signed:  **Date:** 25-May-2025

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