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Declaration of Conformity

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Att. 01 to DO0100

Manufacturer	Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH Brunner Str. 67 1230 Vienna Austria
SRN	**AT-MF-000024115**
Product(s)	Ceveron m series
Basic UDI-DI	912003686TCCEVm00001KG

UDI-DI (GTIN)	**Product name**	**REF**
09120036863989	Ceveron m1	9830021
09120036863996	Ceveron m2	9830022
09120036864009	Ceveron m4	9830024

Intended use	The Ceveron m series systems are semi-automated instruments for analyzing in-vitro diagnostic coagulation tests including clotting, chromogenic and turbidimetric methods. Analysis is performed in human plasma or whole blood, depending on the specific device model. 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: DocuSigned by: 4C42B6165E52418... **Date:** 25-May-2025

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