



Declaration of Conformity
European Directive 98/79/EC

Dok.Nr.: TF0003.03

Ersetzt: TF0003.02

Attachment 3 of DO0081 i.t.c.v.

Manufacturer: Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
Brunner Str. 67
1230 Vienna
AUSTRIA

Product: **valid from** LOT :

REF 5164008	Factor IX Deficient Plasma native, 5 x 1 ml	4963000
REF 5164016	Factor IX Deficient Plasma native, 50 x 1 ml	4963000

Classification: IVD, "all other classes"

European directive: 98/79/EC

We declare that the above mentioned products meets all applicable requirements set out in Annex III (excluding section 6) of the Directive 98/79/EC and take sole responsibility of the these products. These products have been manufactured and classified as "all other classes" according to the European Directive 98/79/EC.



Date: 20-May-2022
Valid until: 25-May-2026


V. Binder
Company director


S. Schwingenschlögl
QM-Manager