



**Declaration of Conformity**  
European Directive 98/79/EC

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

Dok.Nr.:TF0003.03

Ersetzt: TF0003.02

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

**Product:**

**valid from** **LOT** :

REF 5184004 Factor XI Deficient Plasma native, 5 x 1 ml

4E61000

**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-2027

  
V. Binder  
Company director

  
S. Schwingenschlöggl  
QM-Manager