

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:

TechnoLEIA® D-Dimer Calibrator 0 ng/ml, 2 x 1 ml REF 4847236

K391A00

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

Company director

S. Schwingenschlög

QM-Manager