

EU Declaration of Conformity (EU DoC)

in accordance with Art. 17 and Annex IV

Manufacturer Name: ViennaLab Diagnostics GmbH
Manufacturer Address: Gaudenzdorfer Guertel 43-45
1120 Vienna, Austria

SRN (Single Registration Number): AT-MF-000010341

Basic-UDI-DI: 912003421SA_FMF-SAA1A7

Product Code: 4-390, 4-390-TRIAL, 4-390-A

Name of the Device (s): FMF-SAA1 StripAssay[®]

Classification: Class C, rule 3i
Common specifications used: GHTF/SG5/N7:2012

Notified Body name: TÜV Süd Product Service GmbH
Notified Body Address: Ridlerstraße 65
80339 München, Germany

Notified Body Identification Number: 0123

Conformity assessment route: ViennaLab Diagnostics GmbH uses the following procedure for the CE-labelling of their products according to the Regulation IVDR 2017/746:
Quality Management System, Annex IX Chapters I and III including assessment of the technical documentation

This EU declaration of conformity is issued under the sole responsibility of ViennaLab Diagnostics GmbH. We hereby declare the *in vitro* Diagnostic(s) specified above meet the provision of the Regulation (EU) IVDR 2017/746 for in vitro diagnostics and with other union legislation, if applicable. This declaration is supported by the EU Quality Management System certificate (IVDR) No V12 104688 0002 Rev. 01 issued by TÜV Süd Product Service GmbH.

All supporting documentation is retained at the premises of the manufacturer.



Vienna, 16.10.2023

Julia Polzin - PRRC