EU Declaration of Conformity (EU DoC)

in accordance with Art. 17 and Annex IV

Manufacturer Name: Manufacturer Address:	ViennaLab Diagnostics GmbH Gaudenzdorfer Guertel 43-45 1120 Vienna, Austria
SRN (Single Registration Number):	AT-MF-000010341
Basic-UDI-DI:	912003421RF_HLA-B27KX
Product Code:	7-620, 7-620-TRIAL, 7-623
Name of the Device (s):	HLA-B27 RealFast™ Assay
Classification: Common specifications used:	Class C, rule 3i GHTF/SG5/N7:2012
Notified Body name: Notified Body Address:	TÜV Süd Product Service GmbH 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.

J. Polzin

Vienna, 16.10.2023 Julia Polzin - PRRC