EC Declaration of Conformity

Manufacturer/ Supplier Information:	**Maine Molecular Quality Controls, Inc.** 23 Mill Brook Road Saco, Maine 04072 USA Phone: 1-207-885-1072 Email: info@mmqci.com Website: www.mmqci.com
European Representative	**QARAD EC-REP BV** Pas 257 2440 Geel, Belgium

We, Maine Molecular Quality Controls Inc., declare under our sole responsibility, that the product:

Product name: Xpert FII & FV Genotype Panel G109

Catalog #: G109

meets the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices. The device is classified as a General In Vitro Diagnostic (IVD) Device. The MMQCI quality system is registered to EN ISO 13485:2016. Conformity Assessment Method: General IVD Annex III.

The undersigned declares that the device listed above conforms to the essential requirements described in ANNEX I of the European Directive 98/79/EC. Technical documentation demonstrating compliance as described in Annex I is kept by the manufacturer and can be made available by the authorized representative in Europe - QARAD EC-REP BV, Pas 257, 2440 Geel, Belgium.

Saco, Maine USA / 04/14/2022

(Place and date of Issue)

Gretchen A. Wright
QA/RA Manager

(Signature and Title)

MMQCI
MAINE MOLECULAR QUALITY CONTROLS, INC.