

# EC Declaration of Conformity

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

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

## Xpert BCR-ABL 0%IS, Catalog #: C13112-5

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 / 03/30/2022

(Place and date of Issue)

Gretchen D. Wright  
Manager QA/RS  
(Signature and Title)

