

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:

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)





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	Title: Addendum to Approved DoC		

1. Purpose

To provide recent changes to the original Declaration of Conformity (DoC) signed on 03/30/2022.

2. Scope

This memo covers Xpert BCR-ABL 0%IS, Catalog #: C13112-5.

3. Background

As per Article 110, **Maine Molecular Quality Controls, Inc.** can benefit from the transitional provisions if the Declaration of Conformity has been drawn up prior to May 26, 2022. Since **Maine Molecular Quality Controls, Inc.** is updating the DoC after this date, this addendum is provided to show the non-significant changes have been made to the original DoC. These changes do not impact the conformity status of the product; therefore, the original DoC issued before May 26, 2022, is still effective.

4. List of Changes

4.1. Name Change of European Authorized Representative (AR)

The AR for **Maine Molecular Quality Controls, Inc.** has changed their name and address from:

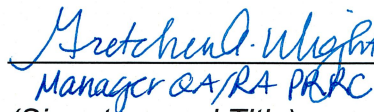
QARAD EC-REP BV
Pas 257
2440 Geel
Belgium

To:
QbD RepS BV
Groenenborgerlaan 16
2610 Wilrijk
Belgium

Approved By:

Saco, Maine USA / 2025-11-11

(Place and date of Issue)



Manager QA/RA PR/RC

(Signature and Title)