OraSure Technologies, Inc.

**Manufacturer's Declaration of Conformity**

We, OraSure Technologies Inc., 220 East First Street, Bethlehem, Pennsylvania 18015, United States, hereby declare under our sole responsibility that the product

**OraQuick® HIV Self-Test**

meets the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices.

Variants:

1001-0600U OraQuick® HIV Self-Test, Single Unit
1001-0600 OraQuick® HIV Self-Test, CE, 25 Count Kit
1001-0601U OraQuick® HIV Self-Test, Single Unit, Spain/Portugal
1001-0601 OraQuick® HIV Self-Test, CE, 25 Count Kit, Spain/Portugal
1001-0602U OraQuick® HIV Self-Test, Single Unit, Germany
1001-0602 OraQuick® HIV Self-Test, CE, 25 Count Kit, Germany
1001-0603U OraQuick® HIV Self-Test, Single Unit, France/Italy
1001-0603 OraQuick® HIV Self-Test, CE, 25 Count Kit, France/Italy

The conformity with the requirements of the Directive has been assessed following the procedures outlined in the following annexes of the Directive: Annex IV

(EC) Certificate numbers DGM-585 and DGM-586 have been issued by:

Presafe
Tuborg Parkvej 8
2900 Hellerup
Denmark
Notified Body ID Number 0543

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

QARAD b.v.b.a.
Cipalstraat 3
B-2440 GEEL
Belgium

Rebecca Rader
Sr. Manager, Regulatory Affairs

24 Sep 2021
Date