



EC Design Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV, section 4

Certificate No.:
DGM – 586

Reference:
artIVD4a2204v502f646

Date of issue:
2022-05-10

Valid Until:
2025-05-26

Initial date of issue:
2007-06-08

This is to certify that the design dossier relating to the devices manufactured by:

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015-1360
USA

have been approved in conformity with the requirements of

**Annex IV, section 4 - Examination of the design of the product, of
Council Directive 98/79/EC concerning in vitro diagnostic medical
devices as transposed into Danish law.**

The certificate covers the following devices:

**In vitro diagnostic medical devices for rapid
HIV testing according to Annex II, list A**

The Design Examination certificate is valid provided that no changes are made to the approved design that could affect conformity with the essential requirements or the conditions prescribed for use for the product without the approval of Presafe Denmark A/S. The EC-Design Examination certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 98/79/EC concerning medical devices. The certificate is based on successful evaluation of the device design dossier in accordance with the IVDD, Annex IV, section 4.

Presafe Denmark A/S

Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark



Zeshaan Sayd
Authorized person
For Presafe Denmark A/S

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The following devices from Annex II, List A, are covered by the certificate:

Product identifier	Product name
3001-1347	OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test, Single Device Unit
1001-0284	OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test, 25 count
1001-0285	OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test, 100 count
1001-0288	OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test Kit Controls
1001-0513	OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test, Algeria 25 count
1001-0514	OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test, Algeria 100 count
1001-0515	OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test, Egypt Department of Health 100 count
1001-0516	OraQuick <i>ADVANCE</i> ® Rapid HIV-1/2 Antibody Test, Egypt Department of Defense 100 count
1001-0600U	OraQuick® HIV Self-Test, Single Unit CE, UK
1001-0600	OraQuick® HIV Self-Test, CE, UK, 25 Count Kit
1001-0601U	OraQuick® HIV Self-Test, Single Unit, CE, Spain/Portugal
1001-0601	OraQuick® HIV Self-Test, CE, Spain/Portugal, 25 Count Kit
1001-0602U	OraQuick® HIV Self-Test, Single Unit, CE, Germany
1001-0602	OraQuick® HIV Self-Test, CE, Germany, 25 count kit
1001-0603U	OraQuick® HIV Self-Test, Single Unit, CE, France/Italy
1001-0603	OraQuick® HIV Self-Test, CE, France/Italy, 25 Count Kit

The authorized EC representative:

Qarad bvba
Cipalstraat 3
B-2440 GEEL
Belgium