



DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000512970-PA-MDSAP-DNK

Initial certification date:
2019-06-04

Expiration:
2025-06-03

This is to certify that the management system of
OraSure Technologies, Inc.
220 East First Street Bethlehem, Pennsylvania 18015 USA

REP F005905

and the sites as mentioned in the appendix accompanying this certificate
has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 820

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

This certificate is valid for the following scope:

Design, development and manufacture of in-vitro diagnostic test kits used in the detection of drugs of abuse as well as rapid in vitro diagnostic test kits used for the detection of HIV1/2, HCV antibodies and Ebola antigen including near patient in-vitro diagnostic devices. Design, development, manufacture and distribution of oral specimen Collection Kits.

Place
Høvik

Effective Date:
2023-10-12



DNV is an MDSAP authorised
auditing organization



For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Yury Sumtsov
Certificate Authorizer

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

All our Certificates are in blockchain system and as a first step you can validate the certificate details by scanning the QR code on the Certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.



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Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
OraSure Technologies, Inc. F005905	1. 220 East First Street Bethlehem, Pennsylvania 18015 USA 2. 150 Webster Street Bethlehem, Pennsylvania 18015 USA	1. Management, sales, purchasing, manufacturing, engineering, warehouse, QA & QC. 2. Design and Development, RA, QA, HR, Sales and Marketing
OraSure Technologies, Inc. F005909	1745 Eaton Avenue Bethlehem, Pennsylvania 18018 USA	Manufacturing and QC, QA
OraSure Technologies, Inc. F005910	2500 Emrick Boulevard Suite 100 Bethlehem, Pennsylvania 18020 USA	Warehouse, shipping, and inspection.
OraSure Technologies, Inc. F006977	2685 Opus Way, Bethlehem, Pennsylvania 18020 USA	Warehouse, shipping, and inspection, manufacturing, engineering, QA & QC