



DNV

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
10000512970-PA-MDSAP-DNK

Initial certification date:  
2019-06-04

Expiry Date:  
2028-06-03

This is to certify that the management system of

**OraSure Technologies, Inc.**

220 East First Street Bethlehem, Pennsylvania 18015 USA  
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

**Canada:**

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

**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

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 HIV-1/2, 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:  
2025-06-04



DNV is an MDSAP  
Recognized Auditing Organization



For the issuing office:

DNV Product Assurance AS  
Veritasveien 1, 1363 Høvik, Norway

**Tone Kolpus**

Management Representative

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](http://www.dnv.com)

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.

## 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, Manufacturing
OraSure Technologies, Inc. (F005909)	1745 Eaton Avenue Bethlehem, Pennsylvania 18018 USA	Manufacturing and QC, QA
OraSure Technologies, Inc. (F006977)	2685 Opus Way, Bethlehem, Pennsylvania 18020 USA	Warehouse, shipping, and inspection, manufacturing, engineering, QA & QC

