October 28, 2026

Keerthi Kumar M.Sc, RAC
Regulatory Affairs Program Manager
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Re: EUA260001/S001
Trade/Device Name: OraQuick Ebola 2.0 Rapid Antigen Test
Dated: September 28, 2026
Received: September 28, 2026

Dear Keerthi Kumar:

This is to notify you that your request to update the OraQuick Ebola 2.0 Rapid Antigen Test to; (1) extend the shelf-life expiration date to 10 months when stored at 15-40°C, and (2) provide in accordance with Condition of Authorization "W" in the July 21, 2026, Letter of Authorization information concerning OraSure Technologies, Inc.'s quality management system plan and timeline, is granted. Upon review, we concur that the data and information submitted in EUA260001/S001 supports the requested updates to the authorized labelling for the OraQuick Ebola 2.0 Rapid Antigen Test and fulfills Condition of Authorization "W" in the July 21, 2026, letter. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the OraQuick Ebola 2.0 Rapid Antigen Test issued on July 21, 2026.

Sincerely yours,

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Noel J. Gerald, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health