DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 19, 2017

RONALD DUNN,
VICE PRESIDENT GLOBAL REGULATORY AND CLINICAL AFFAIRS
LUMINEX CORPORATION
12212 TECHNOLOGY BLVD.,
AUSTIN, TX 78727 US

Re: EUA160015/A002
Trade/Device Name: xMAP® MultiFLEX™ Zika RNA Assay
Dated: May 15, 2017
Received: May 16, 2017

Dear Mr. Dunn:

This is to notify you that your request to modify the Instructions for Use labeling and the Fact Sheets authorized with the xMAP® MultiFLEX™ Zika RNA Assay with the minor updates and clarifications requested by FDA and the additional minor updates proposed by Luminex, has been granted. By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the xMAP® MultiFLEX™ Zika RNA Assay issued August 4, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure