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