December 27, 2018

SANDRA ZIMNIEWICZ,
REGULATORY SPECIALIST
DIASORIN INCORPORATED
1951 NORTHWESTERN AVENUE,
STILLWATER, MN 55082, US

Re: EUA170003/A002
Trade/Device Name: LIAISON XL Zika Capture IgM Assay
Dated: December 18, 2018
Received: December 20, 2018

Dear Ms. Zimniewicz:

This is to notify you that your request to modify the LIAISON XL Zika Capture IgM assay to (1) replace the original ZIKV-M conjugate with an updated version of the reagent, (2) change the ZIKV-M calibrators from liquid to lyophilized form, (3) update the calibrator target values, (4) update the unopened kit shelf life stability claim, (5) update in-use stability claim for the ZIKV-M calibrators, (6) increase the number of vials included in the assay kit for each ZIKV-M calibrator to two to facilitate kit calibration over the existing 21 day reagent open-use stability claim, and (7) extend re-calibration frequency of the LIAISON XL Zika Capture IgM assay from 7 to 14 days has been granted. Your request to modify the name from LIAISON XL Zika Capture IgM to LIAISON XL Zika Capture IgM II has also been granted.

Upon review, we concur that the clinical and analytical data submitted in EUA170003/A002 supports the modifications to the LIAISON XL Zika Capture IgM as outlined above. We also concur with the related updates of the Instructions for Use and the Fact Sheets for the LIAISON XL Zika Capture IgM II that reflect the modifications granted in this letter.

By submitting this amendment 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 LIAISON XL Zika Capture IgM Assay issued April 5, 2017.

Sincerely yours,

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