APPLICATION FORM FOR THE INITIAL REGISTRATION OF IN VITRO DIAGNOSTIC DEVICE

MARIA CECILIA C. MATIENZO
Director IV
Center for Device Regulation, Radiation Health, and Research
Food and Drugs Administration
Department of Health

ATTENTION: Licensing and Registration Division

Sir/Madam:

In Accordance with R.A. 9711 and other related issuances, we wish to apply for the initial registration of our product.

Name of Medical Devices	
Brand Name (if any)	
Size/Product Code/Reference Number	
Primary Packaging (Market or Commercial Presentation)	

Enclosed are the documents stated in the Checklist of Requirements for Registration and representative samples of our product.

We categorically declare that all data and information submitted in connection with this application as well as other submission in the future are true and correct and reflect the total information available. We certify that we have examined the following statements and we attest to their accuracy:

1. The Current Good Manufacturing Practice Guidelines for Medical Device is applied in full in the manufacture of this product.
2. The formulation per dosage form is in agreement with the master formula and with the batch manufacturing record forms (if applicable).
3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing records.
4. Product covered by this declaration will not undergo any change in the formulation, size, reference number, use, manufacturer, manufacturing process, labeling or commercial presentation without prior approval of this office.
5. Each batch of the finished product is tested and certified to be fully compliant with the specifications in the accompanying documentation.
6. The person releasing the product for sale is an authorized and/or qualified person.
7. The procedures for control of the finished product have been validated.
8. The market authorization holder has a standard operating procedure for handling any adverse event related to the use of the device.
9. The market authorization holder has a standard operating procedure for handling batch recalls.
10. All the documentation referred to in this application is available for review during a GMP inspection.

11. We shall change the brand name so submitted should the proper authority decides with finality that we have no right to appropriate and utilize said brand name; and
12. We shall acknowledge and agree to indemnify and/or hold FDA free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with FDA.

For and in behalf of _____ (Name of Company):

QUALIFIED PERSON
Signature _____
Name (print or type) _____
Position (print or type) _____
Date _____

OWNER / GENERAL MANAGER
Signature _____
Name (print or type) _____
Position (print or type) _____
Date _____

ACKNOWLEDGMENT

SUBSCRIBED AND SWORN TO BEFORE ME this _____ at _____ personally appeared the following:

Name	Residence Certificate/Government Issued ID	Date Issued	Place Issued
1.			
2.			

Known to me and to me know to be the same persons who execute the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed.
WITNESS MAY HAND AND SEAL on the date and place first above written.

Doc. No. _____
Page No. _____
Book No. _____
Series of _____