ANNEX A

Legal Requirements for Application for the Notification of IVD under Class A and Registration of IVD under Class B, C and D

1. Notarized Application Form
   - Shall be completely filled-out
   - Model / reference number / sizes / codes must be properly identified
   - Refrain from indicating the brand name (if applicable) on the name of the product and vice versa
   - For kits/sets, identify the complete contents/inclusions on the space provided for IVD name
   - For multiple models / reference number / size / codes, an annex page may be attached
   - For multiple models / reference number / size / codes; a Word copy must be submitted
   - Shall be signed by the proper authority as indicated on the form
   - Re-used/Altered forms is not acceptable since this is a legal document
2. Payment
3. Copy of Letter of Authorization. For imported IVD, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
   - Shall be valid
   - Shall be authenticated/apostilled by the territorial Philippine Consulate
   - The product being applied shall be indicated.
   - For imported IVD but the agreements are signed by both the principal and importer in the Philippines, it shall be notarized locally, with passport and record of arrival and departure of the principal to and from the Philippines.
   - For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a re-issued agreement/authorization shall be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect.
   - For locally manufactured IVD with exclusive distributors, the agreement shall be duly notarized.
   - For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer shall be duly notarized.
4. A government issued certificate attesting to the status of the manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported IVD, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
5. For imported IVD, the CIVDN or CIVDR or any equivalent document attesting to the safety, quality and effectiveness of the IVD issued by the National Regulatory Agency or accredited notified body in the country of origin. The copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
   - Shall be valid
   - Shall be authenticated/apostilled by the territorial Philippine Consulate
   - For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from.
   - The product being applied shall be indicated in the scope.
6. Colored picture of the device from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.