FDA/MCH/MDD/AP3-RMD/2016/03

FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR THE REGISTRATION OF CLASSES II – IV MEDICAL DEVICES

APPLICANTS'S CHECKLIST		FDA DOUBLE CHECKLIST
☐	Signed Declaration	☐
☐	Covering Letter	☐
☐	Certificate of Analysis of Finished Product	☐
☐	Real/Accelerated Stability Data	☐
☐	Manufacturing License	☐
☐	Free Sale Certificate	☐
☐	Sterility Certificate	☐
☐	Device Description and Features	☐
☐	Device Verification and validation	☐
☐	Software Verification and Validation	☐
☐	Pre and Post Clinical Study Reports	☐
☐	Risk Analysis Report	☐
☐	Biocompatibility Study Report	☐
☐	Contract Agreement (if applicable)	☐
☐	Other Documents (if applicable)	☐

FOOD AND DRUGS AUTHORITY

APPLICATION FOR THE REGISTRATION OF A MEDICAL DEVICE
(*TO BE SUBMITTED IN ONE HARD COPY, ONE SOFT COPY*)

A. COVER LETTER

Addressed to: THE CHIEF EXECUTIVE OFFICER
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS,ACCRA,GHANA.

B. DETAILS OF APPLICANT

Name :.....
Postal Address :.....
.....
.....
.....
.....
Fax: .....
Tel. Nos. : .....
E-mail: .....
Website: .....

C. DETAILS OF MANUFACTURER (*FOR AUDIT PURPOSES)*

Name:.....
Postal Address:.....
.....
.....
.....
Location Address:.....
.....
.....
Fax : .....
Tel. Nos. : .....
E-mail : .....
Website : .....
Contact Person : .....
Tel. Nos. : .....

D. DETAILS OF LOCAL AGENT

Name :..... .....
BusinessAddress:.....
.....
.....
Fax : ....
Tel. Nos. : .....
E-mail : ....
Website : .....
Contact Person: ....
Tel. Nos. : .....

Certified Copy of Power of Attorney (where applicable, to be attached)

E. DECLARATION

I/We, the undersigned, hereby declare that all the information contained herein is correct and true.
Name:.....
Position:.....
Signature:..... Date:.....

Official Stamp:

F. DETAILS OF THE MEDICAL DEVICE

i. Generic name:.....
ii. Brand name:.....
iii. Model/Series (*If applicable*):.....
iv. Family (*If applicable*):.....
v. Commercial presentation:.....
vi. Country of origin:.....

vii. Any special storage condition applicable to the device.....
.....
.....

ix. Intended use of the device
.....
.....
.....
.....

x. Select Global Medical Device Nomenclature(GMDN) Categories

01 Active implantable device
02 Anaesthetic and respiratory devices
03 Dental devices
04 Electro mechanical devices
05 Hospital hardware
06 In vitro diagnostic devices
07 Non-active implantable devices
08 Ophthalmic and optical devices
09 Reusable instruments
10 Single use devices
11 Technical aids for disabled persons
12 Diagnostic and therapeutic radiation devices
13 Complimentary therapy devices
14 Biologically derived devices
15 Healthcare facility products and adaptations
16 Laboratory equipment
17 Others

xi. Description of the device. (Applicable GMDN description. Otherwise, provide a short description of the device).....
.....
.....
.....

xii. Class of the medical device:

Class I .....
Class II .....
Class III .....
Class IV .....

xiii. Basis of classification of device.....
.....
.....
.....

APPENDIX I

1. Details of manufacturing procedure and documentation
a. Give a brief summary of the manufacturing process .....
.....
.....
....

b. Attach documents showing analytical control procedures performed during the manufacturing process.....

c. Attach relevant Certificates for the quality of the finished products (sensitivity, specificity, sterility, pyrogen test, etc)
....

d. Attach the final analytical report and authorization for the release of the finished product
.....

SECTION	NAME OF AUTHORISED PERSON	ADDRESS	QUALIFICATION
QUALITY CONTROL			
PRODUCT PACKAGING			
PRODUCT RELEASE			

f. Estimated shelf-life of the Medical Device

.....

g. Stability data and justification on which shelf-life has been predicated

.....

h. The source of starting material and characterization of the antigen used in the manufacture of the diagnostic test kit

.....

.....

APPENDIX II

1. a. Has an application for the registration of the device been made in any other country?

YES ☐ NO ☐

If YES, list the countries

.....

.....

.....

b. Has the device been registered in the country of origin?

YES ☐ NO ☐

If YES, attach a copy of certificates of registration in respect of such a device issued by the appropriate authority established for the registration of Medical Devices in the country.

.....

.....

.....

c. Has the registration of the device been rejected, refused, deferred or cancelled in any country?

YES ☐ NO ☐

If YES, details.

.....

.....

.....

2. Is the device manufactured in countries other than the country of origin?

YES ☐ NO ☐

If YES, state details and list manufacturing plants from which imports can be made.

.....

.....

.....

Attach 4 (four) copies of labels*, package inserts and packaging materials proposed for marketing the product in Ghana.

* The text of labels and written material should conform to the existing labeling regulations (LI 1541).