|  |  |  |
| --- | --- | --- |
|    |  **FOOD AND DRUGS AUTHORITY**     | **DOC. TYPE: FORM**   |
| **DOC NO.: FDA/MDD/FOR-04**  |
|  **Page 1 of 7**   | **REV. NO.: 02**  |
| **TITLE: APPLICATION FORM FOR THE REGISTRATION OF** **CLASSES II-IV MEDICAL DEVICES**  |

 **APPLICANT’S**  **FDA’S**

 **CHECKLIST CHECKLIST**  **CHECKLIST**

 Cover Letter

 Signed Declaration

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 (where applicable)

 Other Documents (where applicable)

**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: .............................................................................................................

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......... .............................................................................................................................

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Fax: .............................................................................................................................

Tel. No.: ........................................................................................................................

 E -mail: ........................................................................................................................

 Website: .......................................................................................................................

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

Name: …………………………………………………………………………………………

Postal Address: ............................................................................................................

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Location Address: .........................................................................................................

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Fax: ..............................................................................................................................

Tel. No.: .....................................................................................................................

E -mail: .........................................................................................................................

Website: .......................................................................................................................

Contact Person: ...........................................................................................................

Tel. Nos.: .....................................................................................................................

# D. DETAILS OF LOCAL AGENT

Name: ……………………………………………………………………………………………… ...

Business Address: …………………………………………………………………………….............................

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......................................................................................................................................

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*): ………………………………………….

1. Commercial presentation: ……………………………………...
2. Country of origin: ………………………………………………

vii. Any special storage condition applicable to the device:

 ..….………………………………………….………………………………………………….

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

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x. Select Global Medical Device Nomenclature(GMDN) Categories

1. Active implantable device
2. Anaesthetic and respiratory devices
3. Dental devices
4. Electro mechanical devices
5. Hospital hardware
6. In vitro diagnostic devices
7. Non-active implantable devices
8. Ophthalmic and optical devices
9. 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

………………………………………………………………………........................................

 ……………………………………………………………………………………………………

 ……………………………………………………………………………………………………

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**APPENDIX I**

 1. Details of manufacturing procedure and documentation

1. Give a brief summary of the manufacturing process...................................................

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

1. Attach relevant Certificates for the quality of the finished products (sensitivity,

 specificity, sterility, pyrogen test, etc)

...................................................................................................................................

1. 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   |     |     |     |

1. State the estimated shelf-life of the Medical Device

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1. Attach stability data and justification on which shelf-life has been predicated

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1. Provide details of the source of starting material and characterization of the antigen used in the manufacture of the diagnostic test kit if the device

 is a rapid diagnostic test (RDT).

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**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

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1. 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.

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

 YES NO

If YES, provide details.

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

 YES NO

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

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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).