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|  |  **FOOD AND DRUGS AUTHORITY**      | **DOC. TYPE: FORM**   |
| **DOC NO.: FDA/MDD/FOR-03**  |
| **Page 1 of 8**   | **REV. NO.: 02**  |
| **TITLE:**  **APPLICATION FORM FOR THE REGISTRATION OF CLASS I MEDICAL DEVICES**  |

**APPLICATION FORM FOR THE**

**REGISTRATION OF CLASS I MEDICAL DEVICES**

# APPLICANT’S FDA’S CHECKLIST CHECKLIST



 **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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Fax: . ........................................................................................................................

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

 Email: …..............................................................................

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

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# C. DETAILS OF MANUFACTURER

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

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

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

Fax: … ........................................................................................................................

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

E-mail:…

....................................................................................................................... Website: ...................................................................................................................... Contact Person: ........................................................................................................... Tel. Nos. : .....................................................................................................................

# D. DETAILS OF LOCAL AGENT

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

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

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………………………………………………………………………………………………….. Fax: …………………………………………………………………………………………..... Tel. Nos.: ...................................................................................................................... Website: ......................................................................................................................

Email: ………………………………………………………………………………………….

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.

Size(s)…………………………….Colour(s)………………………………………………... iv. Model/Series (*If applicable*):

………………………………………………………………..

v. Family (*If applicable*): ………………………………………………………………………... vi. Commercial presentation:

…………………………………………………………………..

vii. Country of origin: …………………………………………………………………………… viii. Intended use of the device:

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#  APPENDIX I

Manufacturing Procedure and Related Controls of Medical Device

1 . Details of manufacturing procedure and documentation

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

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1. Attach the final analytical report and authorisation for the release of the finished product

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1. Provide 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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**APPENDIX II**

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

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| --- | --- |
|  |   |
|  |  |

 YESNO

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

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, state 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).