# APPLICATION FORM FOR THE REGISTRATION OF CLASS I MEDICAL DEVICES

| APPLICANT'S CHECKLIST | | FDA'S CHECKLIST |
|---|---|---|
| ☐ | Signed Declaration | ☐ |
| ☐ | Cover Letter | ☐ |
| ☐ | Certificate of Analysis of Finished Product | ☐ |
| ☐ | Real/Accelerated Stability Data | ☐ |
| ☐ | Manufacturing License | ☐ |
| ☐ | Free Sale Certificate | ☐ |
| ☐ | 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: ……..
..... .....
..... .....
.....
Fax: . .....
Tel. Nos. :.....
Email: …..
..... Website:
.....

## 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

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

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

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c. Provide the estimated shelf-life of the Medical Device

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d. 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?

YES☐ ☐NO

If YES, list the countries

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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.

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c. 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).