FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR THE REGISTRATION OF CLASS I 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	☐
☐	Contract Agreement	☐
☐	Other Documents (where 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

Name :.....
Postal Address :.....
Location Address:.....

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

D. DETAILS OF LOCAL AGENT

Name :.....
Business Address :.....
.....
.....
.....

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. 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 device……..

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

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c. 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, 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).