FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR LICENSING OF PREMISES FOR THE STORAGE AND DISTRIBUTION OF MEDICAL DEVICES

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APPLICATION FORM FOR LICENSING OF PREMISES FOR THE STORAGE AND DISTRIBUTION OF MEDICAL DEVICES

APPLICANT'S CHECKLIST		FDA DOUBLE CHECKLIST
☐	Covering Letter	☐
☐	Fully completed Application Form	☐
☐	Signed Declaration	☐
☐	Certificate of Incorporation/Commencement of Business	☐
☐	Factory Layout/Floor Plan (*Where applicable)*	☐
☐	*Personnel Medical Test Certificate (Where applicable)*	☐

APPLICATION FORM FOR LICENSING OF PREMISES FOR THE STORAGE AND DISTRIBUTION OF MEDICAL DEVICES

TYPE OF APPLICATION:

☐ New Application ☐ Renewal Application

1.0 COVER LETTER

Addressed to:

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

NB: For extra information refer to Guidelines for the Registration and Licensing of Premises for the Storage and Distribution of Medical Devices – FDA/MCH/MID/GL-MD-GDP 2019/03

2.0 DETAILS OF APPLICANT (COMPANY)

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

3.0 STORAGE FACILITY LOCATION DETAILS

Name: ……………………………………………………………………………….
Location Address: ....
....
....
Digital Address:……………………………………………………………………..
Fax: ....
Tel. Nos.: ....
E-mail: ....
Website: ....
Contact Person: ....
Contact Person Designation: ……………………………………………………….
Contact Person Tel. Nos.: ....

4.0 TYPE OF STORAGE FACILITY
Indicate the type of storage facility/warehouse (*Tick as appropriate*)

☐ Custom-bonded warehouse/storage facility

☐ Non-Custom-bonded (ordinary) warehouse/storage facility

5.0 OWNERSHIP OF THE STORAGE FACILITY

(a) Indicate the ownership of the storage facility (Tick as appropriate)

☐ Owned by the Applicant

☐ Owned by a Third Party

☐ Joint Ownership with a third party

(b) If storage facility is owned by a third party/joint ownership with a third party, provide the following details on the third party

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

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

Fax: ....

Tel. Nos.: ....

E-mail: ....

Website: ....

Contact Person: ....

Contact Person Tel. Nos.: ....

6.0 CLASS OF MEDICAL DEVICES STORED/TO BE STORED
(a) Indicate the class of medical devices stored or to be stored/distributed
(Tick the appropriate box (es))

☐ Diapers and Sanitary Pads

☐ Class I Devices

☐ Class II-IV Devices

(b) State other products stored or to be stored at the same premises which do not fall within the categories listed in 6(a), if any.

- ……………………………………………………………………………………..........
- ………………………………………………………………………………………………
- ………………………………………………………………………………………………

(c) Indicate the device's medical specialty (Global Medical Device Nomenclature – GMDN). *(Tick the appropriate box (es))*

- ☐ Sanitary Devices
- ☐ Anesthesiology
- ☐ Cardiovascular
- ☐ Chemistry
- ☐ Dental Part
- ☐ Ear, Nose, and Throat
- ☐ Gastroenterology and Urology
- ☐ General and Plastic Surgery
- ☐ General Hospital
- ☐ Hematology
- ☐ Immunology
- ☐ Microbiology
- ☐ Neurology
- ☐ Obstetrical and Gynecological
- ☐ Ophthalmic
- ☐ Orthopedic
- ☐ Pathology
- ☐ Physical Medicine
- ☐ Radiology
- ☐ Toxicology
- ☐ Any Other (please specify…………………………………………………….

7.0. TYPE OF BUSINESS

(a) Which of the following types of businesses do you operate? *(Tick as appropriate)*

- ☐ Importer
- ☐ Exporter
- ☐ Wholesaler/Main Distributor
- ☐ Any other (Please specify) ……………………………………..…..……..
- ☐ Retailer
- ☐ User facility

(b) If an importer, state the name and country of origin of the manufacturing companies from where your products are imported

	Manufacturer/Open Market Source	**Country**
1		
2		
3		
4		

Attach if more

8.0 SOME SPECIFIC INFORMATION

(Tick where appropriate)

	Yes	No
(i) Are controlled/dangerous/hazardous/ products stored at this site?	☐	☐
(ii) Do the products stored require any special storage conditions?	☐	☐

9.0 DECLARATION

I/We hereby confirm that the information provided in this application form are true and correct to the best of my/our knowledge.

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

Position: …………………………………………………………………........……

Signature: ……………..

Date: ………………………………………………………………………………...

Official Stamp:

NB: Should there be any intentions/changes in the course of business to change any information provided, the FDA shall be notified.