FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR THE REGISTRATION OF DIAPERS (BABY & ADULT), SANITARY PADS AND MOP-UP TOWELS

FDA/MCH/MDD/AP1-RMD/2016/03

APPLICANTS'S CHECKLIST		FDA DOUBLE CHECKLIST
☐	Signed Declaration	☐
☐	Covering Letter	☐
☐	Certificate of Analysis of Finished Product	☐
☐	Manufacturing License	☐
☐	Free Sale Certificate	☐
☐	Contract Agreement	☐

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).....
iii. Country of origin:.....
iv. Commercial presentation:.....
v. Intended use of the device.....
.....
vi. Estimated shelf-life of the MedicalDevice.....

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

YES ☐ ☐ NO

If YES, details.

.....
.....

b. 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).