**APPLICATION FORM FOR THE**

**REGISTRATION OF DIAPERS (BABY &**

**ADULT), SANITARY PADS AND MOP-**

**UP TOWELS**



 **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. : ...................................................................................... .................................

E -mail: ............................................................................................................................. Website: ..........................................................................................................................

# C. DETAILS OF MANUFACTURER

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

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

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

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 ............ Fax:

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

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

YES NO

If YES, details.

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1. 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).