
	APPLICATION FORM FOR THE REGISTRATION OF A MEDICAL DEVICE	
	PBSL-F-73/02	

Checklist

**Applicant's
check list**

**PBSL
double check**

- | | | |
|--------------------------|--|--------------------------|
| <input type="checkbox"/> | Signed Declaration | <input type="checkbox"/> |
| <input type="checkbox"/> | Covering Letter | <input type="checkbox"/> |
| <input type="checkbox"/> | Certificate of Analysis of Finished Product | <input type="checkbox"/> |
| <input type="checkbox"/> | Real-time and Accelerated Stability Data | <input type="checkbox"/> |
| <input type="checkbox"/> | Manufacturing Licence | <input type="checkbox"/> |
| <input type="checkbox"/> | Free Sale Certificate | <input type="checkbox"/> |
| <input type="checkbox"/> | Sterility Certificate | <input type="checkbox"/> |

Applicant

PBSL Staff

Name: _____

Name: _____

Signature: _____

Signature: _____

Date: _____

Date: _____

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(To be submitted in duplicate)

Cover letter addressed to:

**THE REGISTRAR
PHARMACY BOARD OF SIERRA LEONE
CENTRAL MEDICAL STORES
NEW ENGLAND VILLE
FREETOWN
SIERRA LEONE
P.M.B. 322**

Samples and printed matter to be forwarded to the Board through the local agent; customs duty and clearance to be effected by the applicant in all instances.

A. PARTICULARS OF PRODUCT

Proprietary Name.....

Approved Name.....

Colour.....

Commercial Presentation (s)..... Country of Origin.....

B. PARTICULARS OF APPLICANT

Name of Applicant/License Holder:.....

Business Address:.....

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Phone:..... Fax:.....

E-mail:.....

C. PARTICULARS OF MANUFACTURER

Name of Manufacturer:.....

Full Premises Address of Manufacturer:.....

Phone:.....Fax.....

E-mail:.....

D. PARTICULARS OF LOCAL AGENT

Name of Local Agent:.....

Business Address:

Phone:.....Fax.....

E-mail:.....

Type of Medical Device

Intended Use:



Application Fee Paid..... Date.....

E. CERTIFICATION BY A RESPONSIBLE PERSON IN THE APPLICANT COMPANY

Certification

I the undersigned certify that all the information in the accompanying documentation concerning this application for registration for:

Proprietary name:.....

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Approved generic name(s) [INN]:.....

.....

.....

.....

Strength(s) per dosage unit:.....

.....

Formulation:.....

Applicant company:.....

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is correct and true, and reflects the total information available.

Name:.....

Position in company:.....

Signature:.....

Date:..... Official Stamp:.....

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APPENDIX I
Manufacturing Procedures and Related Controls

Name of Medical Device

Name of Applicant

Type of medical device

Size Colour

1. Details of manufacturing procedure and documentation.

a. Give a brief summary of the manufacturing procedure

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b. Attach documents showing analytical control procedures performed during the manufacturing process



c. Attach relevant Certificates for the Quality of the finished products (sensitivity, specificity, sterility, pyrogen test, etc)

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d. Attach the final analytical report and authorization for release of the finished product:

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.....

e. Indicate name(s), address (es), and qualification(s) of authorized person(s) in charge of product quality control, packaging and release of product

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SECTION	PERSON NAME OF AUTHORISED	ADDRESS	QUALIFICATION
Quality Control			
Product Packaging			
Product Release			

f. Estimated shelf-life of the Medical Device

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g. Stability data and justification on which shelf-life has been predicted

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APPENDIX II
Administrative Status of the Product

Name of Medical Device:.....

Name of Applicant:.....

Classification:.....

Size:.....Colour:.....

1.

a. Has an application for the registration of the device been made in any other country?

YES

NO

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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 Device in the country.

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

YES NO

If YES, state details

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2. Is the device manufactured in other countries?

YES NO

If YES, state details and list manufacturing plants from which import can be made



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APPENDIX III

List of Attached Documents and Materials

Name of Medical Device:.....

Name of Applicant:.....

Classification

Size.....Colour.....

Attach 4 (four) copies of labels, package inserts and packaging materials
proposed for marketing the product in PBSL.....

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*** The text of labels and written material should conform to existing
labelling regulations of the Pharmacy Board of Sierra Leone.**