PHARMACY BOARD OF SIERRALEONE

APPLICATION FORM FOR THE REGISTRATION OF A MEDICAL DEVICE

(FORM H)

CHECKLIST

Applicant's check list		**PBSL double check**
☐	**Signed Declaration**	☐
☐	**Covering Letter**	☐
☐	**Certificate of Analysis of Finished Product**	☐
☐	**Real-time and Accelerated Stability Data**	☐
☐	**Manufacturing Licence**	☐
☐	**Free Sale Certificate**	☐
☐	**Sterility Certificate**	☐

Applicant

Name:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Signature:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

PBSL Staff

Name:_ _ _ _ _ _ _ _ _ _ _ _

Signature:_ _ _ _ _ _ _ _ _

Date:_ _ _ _ _ _ _ _ _ _ _ _

APPLICATION FOR THE REGISTRATION OF A MEDICAL DEVICE

(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:……

……

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:……
Approved generic name(s)[INN]:……
……
……
……..
Strength(s) per dosage unit:……..……
……
Formulation:……
Applicant company:……..
……
is correct and true, and reflects the total information available.

Name:……

Position in company:……..

Signature:……

Date:…… Official Stamp:…….

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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……..……

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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

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 ☐

If YES, list the countries

…….....

……

…..……

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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……..……..……..

……..……

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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……
……
……..……
……
……..

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