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| **SRI LANKA STANDARDS INSTITUTION**    **APPLICATION FOR GOOD MANUFACTURING PRACTICES (GMP) CERTIFICATION SCHEME** |

**For office use only**

|  |  |
| --- | --- |
| **DATE RECEIVED** |  |
| **REFERENCE NUMBER** |  |
| **NEW CERTIFICATION** |  |
| **RE-CERTIFICATION** |  |
| **APPLICABLE STANDARD/ S** |  |

# The Director General

# SRI LANKA STANDARDS INSTITUTION

# No. 17, Victoria Place

# Elvitigala Mawatha

# COLOMBO 08

I/We hereby apply for Good Manufacturing Practices (GMP) Certification Scheme established in

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[Registered name of the Applicant Organization]

The particulars of my/our organization are given below:

# 1. GENERAL

1.1. Address (Head Office)

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…………………………………………………………………………………………………………………………………………………………….

Telephone: ................................................... Fax: ............................................. E-mail: .........................................

1.2. Legal status of the organization

1. Registration authority: ........................................................................................................................................
2. Registration number: .............................................................................. Date: .................................................

* 1. VAT registration number: .........................................................................................................................................
  2. SVAT registration number: …………………………………………………………………………………………………………………….

# 2. APPLICABLE LOCATION(S) FOR THE CERTIFICATION

[Please indicate the permanent physical locations (subsidiaries, branches, warehouses etc.) registered under the Applicant Organization, which are to be included in the GMP certification. Attach a separate sheet for temporary locations]

|  |  |
| --- | --- |
| Name & Address | Telephone/Fax/E-mail |
| ……………………………………………………………………………  ……………………………………………………………………………  ……………………………………………………………………………  ……………………………………………………………………………  ……………………………………………………………………………  ……………………………………………………………………………  ……………………………………………………………………………  ……………………………………………………………………………  ……………………………………………………………………………  ……………………………………………………………………………  …………………………………………..………………………………. | …………………………………………………………………………………  …………………………………………………………………………………  …………………………………………………………………………………  …………………………………………………………………………………  ……………………………………………………………….…………………  …………………………………………………………………………………  …………………………………………………………………………………  …….……………………………………………………………………………  …….…………………………………………………………………………… ………………………………………………………………………………….  …………………………………………………………………………………. |

[If required please attach a separate sheet]

# 3. DEPARTMENTS/DIVISIONS APPLICABLE AND NUMBER OF EMPLOYEES

|  |  |  |
| --- | --- | --- |
| Departments/Divisions  *(eg.: Management, Design, Production,*  *Quality Assurance, Human Resources, etc.)* | Total effective number of employees**\*** | |
| Head Office | Location 1 |
| ………………………………………………………………..........  ……………………………………………………………….......... ……………………………………………………………….........  ………………………………………………………………..........  ………………………………………………………………..........  ……………………………………………………………….......... ..................................................................................  .................................................................................. | ……...……………………  ……………………………  ……………………………  ……………………………  …………………………… …………………………… ……………………………  …………………………… | ……...………………………  ………………………………  ………………………………  ………………………………  ………………………………  ………………………………  ………………………………  ……………………………… |
| Total |  |  |

[If required please attach a separate sheet]

\* *The effective number of employees consists of all full time employees involved within the scope of certification including those working on each shift. Non-permanent (seasonal, temporary and contracted employees) and part time employees who will be present at the time of the audit shall be included in this number.*

3.1. Whether product or service realization processes operate on a shift basis,

1. No. of shifts available per day: …………………
2. No. of employees working in a shift: ………………………

**4. CATEGORY OF ORGANIZATION**

Category of organization in terms of value of fixed assets. (This information will be treated strictly confidential and will not be divulged to any person or institution)

|  |  |  |
| --- | --- | --- |
| Type of Organization | Value of fixed assets  (Excluding land and building) | Tick in relevant box  √ |
| Category 1 | Below LKR 1.0 million |  |
| Category 11 | Above LKR 1.0 million &  Below LKR 5.0 million |  |
| Category 111 | Above LKR 5.0 million & Up to LKR 10 million |  |
| Category 1V | Above LKR 10 million |  |

# 5. LIAISON OFFICER

5.1. Chief Executive Officer of the Applicant Organization

a) Name: …………………………………………………………………

Designation: ………………….……..……………………….…..

Telephone: ................................................. Fax: .......................................... E-mail: .........................................

5.2. Contact person of the organization

1. Nominee 1 [Name]: …………………..……………………………………

Designation: ………………….….……..…………………

Telephone: ................................................. Fax: .......................................... E-mail: ........................................

1. Nominee 2 [Name]:…………………………………………………………… Designation: ………………….………………...……..

Telephone: ................................................. Fax: .......................................... E-mail: ........................................

# 6. LEGAL OBLIGATIONS

[Please indicate the legal obligations to be abide by the Applicant Organization] *(eg.: Food Regulations, CEA Regulations, NMRA*

*Regulations, CDA Regulations, CAA Regulations, Industry Specific Regulations, compulsory product certifications etc.)*

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# 7. GOOD MANUFACTURING PRACTICES (GMP) CERTIFICATION SCHEME

7.1. Good Manufacturing Practices (GMP) Certification Scheme of the organization is developed by:

……………………………….……………………………………………………………………………………………………………………………

[outside consultant(s) and/or organization itself]

*7.2.* Type of certification [New Certification *or* Re-certification]: …………………………………………..…..……………..………..…

7.3. Description of products manufactured and / or services offered:

…………………………………………………………………………………………………………………………………………………………..…

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7.4. Description of manufacturing processes and/ or services which has been outsourced to the external party:

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7.5. Description of products manufactured and/ or services offered which are to be excluded from the scope of the certification:

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7.6. Desired scope of the certification:

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7.7. If Re-certification;

1. Date of first certification: …….…………………………………………………………….…………….
2. Validity period of previous certification: *From* ………….………………….. *to* ………………………… c) Scope of previous certification:

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d) Major changes done in the GMP System during the previous year [if any]:

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# 8. DOCUMENTED INFORMATION

1. Process flow diagrams
2. Quality Plan

# 9. DECLARATION BY APPLICANT

9.1 I am/We are fully informed and agree with the contents of the following documents of the Good Manufacturing Practices (GMP) Certification Scheme of the Sri Lanka Standards Institution; Rules and Procedures, Guidelines for Applicants, Fee Schedule, Certification Agreement and Conditions For Use of the Good Manufacturing Practices (GMP) Certification Mark.

9.2 Should any initial enquiry be made by the Certifying Authority, I/ We agree to extend to the Certifying Authority all required facilities at my/our command and I/ We agree to pay all costs involved prior to the grant of the Certificate.

9.3 I/ We will not hold liable either the Sri Lanka Standards Institution or those having a function in its activities for damages resulting from the consideration of the application for certification, including the possible rejection.

Signed at …………………..…………………………………………………..………….…………………………………………………..…...… on this ………………………… day of ……………………..…20……..…

Signature : …………………………………………………

Name : …………………………………………………

Designation : …………………………………………………

For and on behalf of ……………………………………………………………………………………………………………………..………

[Name of the Applicant Organization]