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**MEDICINES CONTROL AGENCY**

Kairaba Avenue, K.S.M.D. Pipeline, The Gambia. Telephone: (+220)4380632, [www.mca.gm](http://www.mca.gm)

**Related Product Registration Application**

**Medical Device  In-vitro Diagnostic  Household Chemical Substance**

**Cosmetic  Other  (**Specify)

**Renewal  MCA Product Registration Number**

|  |
| --- |
| Name of Product |
| Description of Product |

**MANUFACTURER**

|  |
| --- |
| Name. |
| Premises/Business Address    Tel Email Website |

**Responsible Person**

|  |
| --- |
| Name. |
| Premises/Business Address    Tel Email Website |

**APPLICANT**

|  |
| --- |
| Name |
| Address + Full Contact Details    Tel Email Website |

**STATUS OF APPLICANT**

|  |
| --- |
| Manufacturer Responsible Person Importer National Representative |
| Other  (please specify) |

**If Medical Device: NA**

|  |
| --- |
| General Medical Device  Medical Equipment  Implantable Medical Device  (Specify) |

**Intended Use / INDICATIONS:**

|  |
| --- |
|  |

**If In-Vitro Diagnostic: NA**

|  |
| --- |
| Kit  Reagent  Other  (Specify) |

**Test Purpose**

|  |
| --- |
|  |

**If Cosmetic or Houshold chemical substance NA**

|  |
| --- |
| Ingredients: |

**Claim(s)**

|  |
| --- |
|  |

**PACKAGE SIZE/net weight/length/volume/number of units**

|  |
| --- |
|  |

**MISCELLANEOUS (Special Conditions, etc.)**

|  |
| --- |
|  |

**ENCLOSURES (mark as X)**

|  |
| --- |
| Instructions for use  Technical documentation Labels |
| Declaration of Conformity Product Verification and Validation Documents |
| Registration certificate(s) from country of origin and others, where applicable |
| Other Documents |

**DECLARATION:**

I, the undersigned certify that the information in the accompanying documentation concerning the application for registration of the medicine indicated herein is true and reflects the total information available.

I also agree that I am obliged to comply with the requirements of the Agency related to the stated products at any time in the future.

Name of Applicant:

Position/Designation:

Address and Contact Details:

Signature of Applicant: Date:

**OFFICIAL USE**

|  |
| --- |
| Application no: |
| Comments |