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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 |