# APPENDIX I: FORM 7 – APPLICATION FORM FOR THE REGISTRATION OF SURGICAL INSTRUMENTS

***Regulation 27(2)***

**NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206**

1. **Particulars of the applicant**

Name:.................................................................................................................................

Physical address:.....................................................................................................................

Postal address (if different):

Phone: …………………………….Fax:………………….e-mail:..........................................

1. **Particulars of the surgical instrument / Appliance**
2. Proprietary / brand name: ...............................................................................................................................
3. Brief description of the Surgical Instrument / appliance (Per GMDN or as applicable): ..............................................................................................................................
4. Class of the appliance: ..............................................................................................................................
5. Intended use and method of use: ..............................................................................................................................
6. Medical specialty in which Surgical instrument / appliance is used: ..............................................................................................................................
7. Contraindications, warnings, precautions, potential adverse effects: ..............................................................................................................................
8. List of accessories and other appliances or equipment to be used in combination with the appliance: ...............................................................................................................................
9. Variations in shape, style or size of the appliance, if applicable: ..............................................................................................................................
10. Labelling description: ..............................................................................................................................
11. Packaging description including pack sizes: ..............................................................................................................................
12. Recommended storage condition: ..............................................................................................................................
13. Two samples submitted when practicable (Yes/No): ..............................................................................................................................
14. Certificate of analysis / Test Report or Certificate of conformity submitted (Yes/No): ..............................................................................................................................
15. Evidence of repeat sales in country of manufacture submitted (Yes/No): ..............................................................................................................................
16. Copy of a product license from the country of manufacture or evidence of conformity to standards from a certification body submitted (Yes/No): .............................................................................................................................
17. Summary information on pre-clinical design verification and validation submitted where applicable (Yes/No): ..............................................................................................................................
18. **Particulars of the manufacturer and activities of the manufacturer**

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Name*  | *Address of manufacturing plant (Include Physical Address and email*  | *Activity undertaken at the manufacturing plant*  |
| 1  |  |  |  |
| 2  |  |  |  |
| 3  |  |  |  |

1. Copy of manufacturing license(s) submitted (Yes/No):

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1. Evidence of repeat sales in country of manufacture provided (Yes/No):

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1. Manufacturer’s declaration of conformity to essential principles of safety and performance submitted (Yes/No): ..............................................................................................................................

**4. Authorized agent in Uganda:**

Name of the authorized agent:

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I, the undersigned hereby apply for registration of the appliance detailed above and declare that all the information herein and in the appendices is correct and true.

Fee enclosed: ......................................................Signed: ...................................
Date:......................................................................................................................
Full name of signatory:
..............................................................................................................................
Designation and qualifications:....................................................................…...

NB:

***GMDN (****Global Medical Appliance Nomenclatures)*

*Classification as per rules in the NDA guidelines*