GUIDELINES ON REGISTRATION OF SURGICAL INSTRUMENTS AND APPLIANCES

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Citation

These guidelines shall be cited as the *"Professional Guidelines on Registration of Surgical Instruments and Appliances, Doc. No. DAR/GDL/028, Revision No. 0."*

Adoption and approval of these professional guidelines

In EXERCISE of the powers conferred upon the Drug Authority by Section 5(i) of the National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition), the Drug Authority hereby ADOPTS and ISSUES these Professional **"Guidelines on Registration of Surgical Instruments and Appliances,** Doc. No. DAR/GDL/028 Revision No.: 0", made this 6th day of August 2020, that take effect on 14th August 2020

Signature

Dr. Medard Bitekyerezo
CHAIRPERSON
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Table of Contents

1.0 INTRODUCTION

1.1 The Mandate

National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition). The Act established a National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

In pursuance of the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda this guideline is for information, guidance and to be followed for the purposes of procedure and requirements for registration of surgical instruments and appliances in Uganda. It applies to all surgical instruments and appliances for human and veterinary use, where applicable.

Surgical Instruments and appliances just like other pharmaceutical products play a crucial role and constitute a critical part/proportion of products for quality and effective health care delivery.

The control of surgical instruments and appliances will be based on risk assessment and risk management such that the level of regulatory control applied to them is proportional to the degree of perceived risk associated with the surgical instrument and appliance. The requirements of the review process differ for each class, type and technology of the appliance.

These guidelines must be read and used in conjunction with other relevant regulations and guidelines issued by the National Drug Authority.

1.2 Objectives of these Guidelines

a) To guide all those involved in the registration of surgical Instruments and appliances in order to meet minimum requirements.

b) To set out the requirements and procedure for application for approval of surgical instruments and appliances.

c) These guidelines are intended to provide a descriptive mechanism to persons involved in registration of surgical Instruments and appliances within the realm of legal and ethical provisions in Uganda.

1.3 Scope of these Guidelines

These guidelines apply to registration of surgical instruments and appliances in Uganda only.

These guidelines do not apply to surgical instruments and appliances for the purposes of an application for a patent or a donation / gift.

1.4 Policy

1.4.1 The National Drug Policy and Authority Act (Cap 206 of the laws of Uganda), Regulations, Sections 64(g) provides for regulating, restricting or prohibiting the importation, sale or advertising of surgical instruments and appliances;

1.4.2 The Statutory Instrument No-29, The National Drug Policy and Authority (Control of Surgical Instruments and appliances), Regulations, 2017, Section 25,(1) and (2) states that:

i. All surgical instruments and appliances shall be registered by the Authority before sale or distribution in Uganda.

ii. The Authority shall register the surgical instruments and appliances which meet the safety, quality and performance requirements determined by the Authority.

2.0 TERMS AND DEFINITIONS

For the purposes of these guidelines, unless the context otherwise requires, the following terms have the assigned meaning and definition:

Active implantable surgical appliance means any active appliance, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

Authority means the National Drug Authority, Uganda.

Body orifice means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

Certified Copy means a true copy of the original document certified by a person registered to practice law in the Manufacturer's country of origin and endorsed with the legal practitioner's official stamp and signature.

Conformity Assessment means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that a surgical Instrument / appliance is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Appliances.

Implantable appliance means any appliance, including those that are partially or wholly absorbed, which is intended:-

a) to be totally introduced into the human / animal body or,

b) to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure.

In addition, any appliance intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable appliance.

Intended purpose means the use for which the appliance is intended according to the data supplied by the manufacturer on the labelling, in the instructions and / or in promotional materials.

Invasive appliance means an appliance which, in whole or in part, penetrates inside the body, either through a natural body orifice or through the surface of the body.

Recognized Standards means National or International standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Re-usable surgical instrument means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical appliance and which can be reused after appropriate procedures have been carried out

Risk means a combination of the probability of occurrence of harm and the severity of that harm.

A **Surgical instrument and appliance** means a specialized tool or implement for performing specific actions or tasks during surgery or to relieve a particular medical condition.

Surgical operation used in this definition includes all clinical interventional procedures in which an appliance is placed into the body through the surface in the context of a surgical operation or other clinical procedure.

Surgically invasive appliance means an invasive appliance which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation other than those referred to above and which produce penetration other than through an established body orifice.

Technical Documentation means documented evidence, normally an output of the Quality Management System that demonstrates compliance of an appliance to the Essential Principles of Safety and Performance of Medical Appliances.

Time means duration of which;

a) **Transient** means normally intended for continuous use for less than 60 minutes.

b) **Short term** means normally intended for continuous use for not more than 30 days.

c) **Long term** means normally intended for continuous use for more than 30 days.

Validation means confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

3.0 CLASSIFICATION OF SURGICAL INSTRUMENTS AND APPLIANCES

3.1 Overview

The classification of the surgical instruments and appliances will be based on a risk assessment and risk management. The level of regulatory control applied to the surgical instruments and appliance will be proportional to the degree of perceived risk associated with the appliance. The requirements of the review process differ for each class, type and technology of the appliance.

3.2 Classification (Four Risk Classes A, B, C & D)

Surgical instruments and appliances are a section of medical appliances and have their classification applying under the classification rules set out in the Technical Rules for Classification of Medical Appliances.

The applicant or manufacturer must apply the classification rules **(Appendix VII)** to each surgical instrument/appliance/appliance according to its intended purpose.

The initial determination of class should be based on a set of rules derived from those features of appliances that create risk. The risk presented by a particular appliance depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use. There are four classes when considering risk. (Table 1)

Table 1 indicates the four risk classes. The classification levels are:

Classification	Level of risk	Example
Class A	Low risk	Surgical retractors / tongue depressors
Class B	Low–moderate risk	Hypodermic Needles / suction equipment
Class C	Moderate – high risk	Lung ventilator / bone fixation plate
Class D	High risk Where risk relates to the patient or to public health	Heart valves / implantable defibrillator

In these guidelines classification for surgical instruments and appliances shall be considered by taking into account the **category** of **Invasive appliances** using rules based system and the rules applied will be 5, 6, 7 and 8. (**Appendix VII).**

An important relative distinction, regarding surgical instruments, is the amount of bodily disruption or tissue trauma that their use might cause the patient. Terms relating to this issue are 'a traumatic' and minimally invasive.

Surgical appliance on the other hand is a specialized appliance used by somebody to relieve a particular medical condition.

Take into consideration all the rules that follow in order to establish the proper classification for the appliance, noting that where a surgical instrument or appliance has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated and also determine if the appliance is subject to special national rules that apply within a particular jurisdiction.
The following should be noted:

a) Once a rules-based system has been adopted, modifications may occasionally be required. For example, where through post-market experience, a level of risk for a type of surgical Instrument / appliance, classified using the criteria found in this guideline is no longer appropriate, consideration should be given to re-classification of the appliance type by a change to the rules.

b) Similarly, the historical knowledge of an appliance may necessitate a different class than the one assigned by the initial classification. Unlike the principle of re-classification after post-market experience with a surgical instrument or appliance, this principle of historical knowledge should be applied immediately when the initial classification yields an inappropriate result.

c) Where special national rules are applied, resulting in a class other than that suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such appliances for free movement in countries where these present rules have been adopted unless other, or additional, conformity assessment procedures are carried out.

4.0 REGISTRATION OF SURGICAL INSRUMENTS AND APPLIANCES

4.1 General Rules for Applications

Without prejudice to the other regulations for registration of medicinal products and other pharmaceutical product already set by the National Drug Authority, if a surgical instrument or appliance is placed on the market in such a way that the appliance and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by corresponding guidelines on submission of documentation for marketing

authorization of a pharmaceutical product for human use (PAR/GDL/004) set by the National Drug Authority.

4.2 Application Processing

All applicants shall be required to submit a dully filled application form (**Form 7- Appendix I)** accompanied with prescribed information as detailed in these guidelines. Other adduced evidence must be submitted to the National Drug Authority to support the placement of the surgical instrument and appliance or surgical appliance on the Ugandan market.

They should be typed in English and where original copies are in another language, they should be presented together with a certified English translation.

The company registration documents should be submitted at the same time with the registration files of its first product/s. Afterward files for the subsequent products from the same manufacturer could be submitted without the need for the company documents. Surgical appliances for the same company that are under the same category or family (carrying the same trade name) and which share one certification could be consolidated within one application and registration file.

The applications will be processed for either expedite registration and will be issued a notice as listed or for the review of the Technical Committee which upon approval will be granted a certificate.

The registration files should include all required documents and studies for products according to the presentation form and the class of surgical instrument / appliance

4.3 Product Registration Dossiers

4.3.1 Scope

Product Registration Dossiers in addition to the non-refundable application fees and the application form, need to include the “List of Surgical instruments/appliances” intended to be marketed in Uganda according to approved forms (soft copy) with labelling and artwork for each (soft copy). A representative label could be sufficient for those groups of more than 5 versions based on an undertaking letter that the labels will be identical for all those sections which are not related to the differentiating factor (unit size, pack size, software version) given that, the parts relevant to differentiation should be highlighted.

Along with labels, a representative sample for each product category should be provided with the company registration dossier as well as the required certificates for each appliance. The dossier for surgical instruments and appliances (whether for listing or registration) will differ in requirements, as these requirements are based on the class and labelling and not on the route of registration it will follow.

Companies can ask for exemption from sample submission for large appliances, or those that are extra expensive. In such a case, the product catalogue and / or sample viewing could be considered by NDA.

Once an application has been accepted, the processing of an application will involve evaluation of application, request for additional data / samples and clarification of some issues where applicable.

Once a query or a request has been raised, the processing shall halt until after the response to the query has been received. If no response to the query or request is received within six months from the written query notification date, the application could be subject to cancelation or rejection.

As part of evaluation of the surgical instrument / appliance, a pre-registration GMP inspection or Quality System audit may be conducted to verify compliance.

All applications and supporting documents shall be made in English and a declaration by the authorized local technical representative of the applicant should be submitted for all applications to declare that:

a) He / she will insure that all submitted documents are an accurate reflection of truth, by ensuring that these were collected and compiled through the right and legal channels, from the concerned responsible parties, are authenticated by signature and stamping of their source and by all possible means available.

b) He / she will be fully responsible for the product and post market plan submitted for complaint handling or recall.

c) Will fully comply with the requirements of the National Drug Authority after the placing the product in the market.

4.3.2 Surgical Instruments / appliances registration requirements

For surgical Instruments or appliances classified or considered high risk, the applicant for these products has to submit the following requirements based on their classification as Sterile or non-Sterile:

a) Filled application form (**Form 7 - Appendix I)**,

b) Details of the Surgical Instrument/appliance/appliance,

c) Legalized approval issued by a health authority in Country of origin to market the product in the relevant country (Certificate of conformity, or any equivalent).

d) All certificates / documents issued by an assessment body as evidence of regular approval or clearance of the surgical Instrument / appliance.

e) Manufacturing process (Master formula, manufacturing steps, sterilization method used, and manufacturing facilities with steps performed at each facility).

Flowchart for the manufacturing process along with the relevant manufacturing sites should be provided.

f) If the manufacturer(s) of any step are different from the legal manufacturer / authorized representative in country of origin, authenticated relationship letters from the contract manufacturer along with the technical agreement copy should be provided. The contract manufacturer should be registered and a separate file should be submitted by the Market Authorization Holder (MAH) for that purpose, site registration procedures will be followed for each site separately.

g) Stability study with shelf life specifications according to ICH guidelines for zone IV, covering full shelf life, as stipulated in the guidelines used for the stability studies (if applicable).

h) Laboratory Quality Control (QC) analysis files; after QC file submission, at a later stage, the applicant should expect to receive a formal request issued by the QC lab directorate for analysis requirements where applicable.

i) Performance & Safety clinical studies (where applicable, **upon request**)

j) Status of Surgical instrument / appliance distribution.

k) English leaflet and labelling artwork that conforms to Country Of Origin (COO) marketing approval (the Directorate of Product Assessment and Registration may ask for some changes, if this is the case the product will not get the marketing approval unless the Local Technical Representative in Uganda submits the new artwork with a sample from the first consignment that conforms to the approved labelling and packaging artwork where applicable.

4.3.3 Required Technical Documentation

The technical requirements should be submitted within the application for registration filed according to the surgical instrument or appliance class that is the required attachment for documents under each class type. In addition to the covering letter on the top, the requirements shall be attached within the application file.

4.3.3.1 Product Registration Dossier

A separate and complete dossier in electronic form for each surgical instrument and or appliance(s), group or family shall be submitted. Applicant is required to arrange application dossiers as follows:

<table>
<tr><th>CLASS A</th><th>CLASS B,C,D</th></tr>
<tr><td>The filled application form (Appendix I)</td><td>The filled application form (Appendix I)</td></tr>
<tr><td rowspan="2">Letter of authorization</td><td>Letter of authorization</td></tr>
<tr><td>Information on appliance details</td></tr>
<tr><td>IFU (Instructions for Use), patient information leaflet and promotion material (including brochures and catalogues)</td><td>Summary of technical documentation</td></tr>
</table>

CLASS A	CLASS B,C,D
Labeling information	Labeling information
Information on sterilization method(s) and validation standards used (where applicable)	Evidence of conformity to Essential Principles / Essential requirements checklist **(Appendix II)** of the dossier)
Proof of Quality Management System (QMS) e.g. ISO 13485 certificate	Proof of Quality Management System(QMS) e.g. ISO 13485 certificate

4.4 Labeling Requirements for Surgical Instrument / Appliance

The labeling information required shall be;

i. provided in English,
ii. in a permanent and prominent manner,
iii. legible and
iv. in terms that are easily understood by the intended user.

4.4.1 The applicant shall submit, along with the application for registration of a surgical instrument/appliance, a label which shall have the following:

a) The name of the surgical instrument/appliance;

b) The name and address of the manufacturer of the surgical instrument / appliance;

c) The identifier of the surgical instrument / appliance, including the identifier of any surgical instrument or appliance that is part of a system, kit or group;

d) Where the contents of the package of the surgical instrument / appliance are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the surgical instrument / appliance such as the size, net weight, length, volume or number of units;

e) The word “Sterile”, if the manufacturer intends for the appliance to be sold in a sterile condition;

f) The expiry date of the surgical instrument, appliance / surgical appliance where applicable, to be determined by the manufacturer on the basis of the component of the surgical instrument / appliance as the case may be, that has the shortest projected useful shelf life;

g) Unless self-evident to the intended user, the medical conditions, purposes and uses for which the surgical instrument / appliance is manufactured, sold or represented, including the performance specifications of the surgical

instrument / appliance where those specifications are necessary for proper use;

h) The directions for safe and effective use of the surgical instrument / appliance unless directions are not required; and

i) Any special storage conditions applicable to the surgical instrument / appliance

j) The batch number / lot number / identification number

4.4.2 Where a surgical instrument or appliance is intended to be sold to the general public, the information required shall:-

a) Be set out on the outside of the package that contains the surgical instrument or appliance; and

b) Be visible under the normal conditions of sale of the surgical instrument or appliance.

4.4.3 Where the package that contains the surgical instrument or appliance is too small to display all the information required on the outside of the package, the directions for the use of the surgical instrument or appliance shall accompany the surgical instrument / appliance.

4.5 Registration Certificate of the Surgical Instrument / Appliance

When an appliance is found to have complied with all the registration requirements, the applicant will be informed to that effect. A certificate of registration (**Appendix III)** or notice of listing shall be issued. The approved artwork and design shall be attached to the registration certificates, where applicable.

4.6 Register of Surgical Instruments / Appliances

The Authority shall maintain a register of the surgical instruments and appliances registered in the format specified **(Appendix IV).** The register shall be available on the NDA website.

4.7 Validity of Registration

The registration or listing of a surgical Instrument and appliance shall remain valid unless suspended or revoked or for that matter terminated.

The validity of registration shall be subject to:-

a) Submission of annual post-marketing surveillance reports for those products defined by the NDA to be of high risk or that require special attention.

b) Submission of adverse effects reports associated with the use of surgical instruments and appliances. (Applicable for products classified as class D)

4.8 Termination of Registration

i. The Authority may, by giving reasons in writing, suspend or revoke the registration of an appliance, or amend the conditions of its registration.

ii. The registrant may, by giving 30 days written notice and reasons to the Authority, terminate the registration of an instrument / appliance.

4.9 Appeals

Any objection to a decision of the registration in relation to any application for registration / listing of a surgical instrument / appliance can be submitted in writing to NDA.

After consideration of the representations, NDA may approve registration / listing of the surgical instrument / appliance and if not satisfied it may reject the application.

4.10 Application for Variation of A Registered Surgical Instrument and Appliance

Application for variation of a registered surgical instrument and appliance shall be made using **Appendix V**.

The National Drug Authority should be informed on any significant change(s) that could reasonably be expected to affect the safety or effectiveness or performance of a surgical instrument / appliance. Significant change(s) may include (but not limited to) any of the following:

a) The manufacturing process, facility or equipment;

b) The manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the appliance or of the materials used in its manufacture;

c) The design of the surgical instrument or appliance, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and

d) The intended use of the surgical instrument or appliance, including any new or extend use, any addition or deletion of a contraindication for the appliance and any change to the period used to establish its expiry date (where applicable), pack size, and storage conditions

e) A change in local technical representative, licence holder, manufacturer

The major changes mentioned above will require the National Drug Authority's approval before they can be implemented.

In case the manufacturer was not sure of the urgency to report a certain change, the subject of change should be communicated in writing to NDA with a detailed report of expected risk and impact. The manufacturer has to follow the decisions and instruction of NDA with regard to the change.

Any other minor change(s) should be notified immediately to NDA and may be implemented without prior approval. All applications for variation or amendment to a registered / listed surgical instrument or appliance shall be made in writing and shall be accompanied by the variation application fee.

4.11 Regulatory Approval Certificates

The surgical instrument or appliance approvals or clearance from a recognized regulatory authority can be used to abridge the evaluation process for surgical instruments / appliances to be marketed in Uganda. Evidence of regular approval or clearance of the appliance in the form of certification and relevant documents must be provided, as original authenticated documents.

Appliances not certified by any of the recognized countries below, will be examined and if appropriate may be exempted from recognized country certification given that they are of class A only. For other classes, the recognized country or CE certification is a must

a) USA: US Food and Drug Administration clearance / approval: Certification for Foreign Government the Certificate for Foreign Government is a written certification that a company or its appliances are in compliance with US law.

b) Canada: Trans-Pacific Partnership clearance / approval

c) Japan: MHLW clearance / approval: Medical appliances are regulated by the Pharmaceutical Affairs Law, which is enforced by the Japanese Ministry of Health, Labour and Welfare (MHLW).

d) Europe (see below): Types of required certificates (as mentioned in table below); EC Certification for quality System / GMP. The manufacturer must ensure application of a quality system approved for the design, manufacturer and final inspection of the products concerned.

For Class B & C: Full quality assurance / EC Type Examination Certificate. (EC Type Examination is a procedure whereby a notified body ascertains that a representative sample of the production covered fulfils the relevant provisions of the EU Medical Appliance Directive.) The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved.

For Class D: Full quality assurance / EC Design Examination Certificate. The certification must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the product.

Note: the notified body should be approved officially by health authorities in Europe, the committee shall ask for documented evidence regarding the Notified Body's registration or licensing that details Notified body's qualification.

4.12 Registration Tracks

4.12.1 Track 1 - Applications for appliances licensed in one of the International Medical Appliance Regulators Forum (IMDRF) Member countries should contain:

a) A covering letter containing the applicant's attestation that all information in the application is true and correct

b) Product details as listed in 4.3.2 above, **Appendix I** (no. 2. Parts a-k)

c) Manufacturer details as listed in 4.3.2 above, **Appendix I** (no. 3-4).

d) Notarized copy of a license in the IMDRF founding member country, **Table 2** below

e) Certificate of Analysis confirming compliance to a Quality System Standard in **Table 3** below

f) Evidence of repeat sales in country of manufacture. 4.3.2 above, **Appendix I** (no. 2. Part n)

g) Appropriate number product samples, where practicable 4.3.2 above, **Appendix I** (no. 2. Part l)

h) A filled application submission checklist, section 4.14 (**Appendix VI**)

Table 2 - Licensing requirements in the IMDRF founding member countries

	Australia	**Canada**	**European Union**	**Japan**	**United States**
Marketing permit/condition	GMPALS License or CE Mark	Appliance license	CE mark	Appliance license	510K appliance letter

Table 3 - Acceptable quality system standards in the five IMDRF founding member countries

Country	**Quality system standards for medical appliances**	**Certification body**
Australia	ISO 13485 or ISO 13488	Government or third party accredited by the government
Canada	ISO 13485 or ISO 13488	Third party accredited by the government
European Union	ISO 13485 or ISO 13488	Third party accredited by the EU

Country	Quality system standards for medical appliances	Certification body
Japan	GMP (QS Standard for medical appliances #1128)	Government
United States	QS (21 CFR part 820)	Government

4.12.2 Track 2 - Applications for appliances NOT licensed in one of the IMDRF Member Countries should contain:

a) A covering letter containing the applicant's attestation that all information in the application is true and correct.

b) Product details as described in 4.3.2 above, **Appendix I** (no. 2.Parts a-k)

c) Manufacturer details as listed in 4.3.2 above, **Appendix I** (no. 3 -4).

d) Documented evidence of conformity to a Quality System Standard in table 3 above, from a certification body accredited by a regulatory authority in one of the IMDRF founding member countries or WHO Prequalification or any other international organizations recognized by NDA

e) Certificate of Analysis confirming compliance to a Quality System Standard in table 3

f) Evidence of repeat sales in country of manufacture 4.3.2 above, **Appendix I** (no. 2. Part n)

g) Appropriate number of product samples, where practicable 4.3.2, **Appendix I** (no. 2. Part l)

h) A filled application submission checklist section 4.14, **Appendix VI**

4.12.3 Track 3 - Applications for appliances that do NOT have certification for any of the Quality System Standards listed in table 3 above should contain:

a) A covering letter containing the applicant's attestation that all information in the application is true and correct

b) Manufacturer's Declaration of Conformity (DOC) to IMDRF Essential Principles of Safety and Performance or that in **Appendix II**

c) Summary information on pre-clinical design verification and validation, **Appendix I** (no. 2 part p)

d) Product details as described in 4.3.2 above, **Appendix I** (no. 2. Parts a-k)

e) Manufacturer details as listed in 4.3.2 above, **Appendix I** (no. 3 -4).

f) Evidence of repeat sales in country of manufacture as 4.3.2 above, **Appendix I** (no. 2. Part n)

g) Appropriate number of product samples, where practicable 4.3.2 above, **Appendix I** (no. 2. Part l)

h) A filled application submission checklist, section 4.13 **(Appendix VI)**

4.13 Application Submission Checklist

The application submission checklist (**Appendix VI)** should be filled and submitted along with the application according to the track in which the product belongs. It should indicate the items included in the application and should be signed at the end confirming that all relevant information has been submitted as filled in the checklist.

4.14 Maintenance of Registration

Maintenance of registration status is subject to consistent quality and satisfactory performance of the surgical instrument or appliance on the market

The holder of a certificate of registration shall pay an annual retention fee prescribed by the Authority, for maintaining the surgical instrument on the Register.

5.0 REFERENCES

Australian regulatory guidelines for medical devices (ARGMD). https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd

China Food and Drug Administration (2014) Regulations for the Supervision and Administration of Medical Devices

EN ISO 13485:2016 Medical devices - Quality management systems

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices. http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf

European Union. http://europa.eu.int/comm/enterprise/medical_devices/index.htm .

Guidance documents – Medical devices. https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents.html#guidance_devices

International medical devices regulators forum. http://www.imdrf.org/documents/documents.asp

National Drug Authority & Policy Act (Registration) Regulations, 2014 (S.I. No. 29 of 2014)

Overview of Device Regulation. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation

Principles of Medical Devices Classification. http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n15-2006-guidance-classification-060627.pdf

Quality System (QS) Regulation/Medical Device Good Manufacturing Practices 21CFR part 820

Understanding Japanese Medical Device Requirements. https://www.pmda.go.jp/files/000164006.pdf

US FDA. www.fda.gov/cdrh/index.html

WHO, Geneva: 2003. Medical Devices and Regulations. Global overview and guiding principles; pp. 1–43.

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:.....

2. Particulars of the surgical instrument / Appliance

a) Proprietary / brand name:

.....

b) Brief description of the Surgical Instrument / appliance (Per GMDN or as applicable):
.....

c) Class of the appliance:
.....

d) Intended use and method of use:
.....

e) Medical specialty in which Surgical instrument / appliance is used:
.....

f) Contraindications, warnings, precautions, potential adverse effects:
.....

g) List of accessories and other appliances or equipment to be used in combination with the appliance:
.....

h) Variations in shape, style or size of the appliance, if applicable:
.....

i) Labelling description:
.....

j) Packaging description including pack sizes:
.....

k) Recommended storage condition:
.....

l) Two samples submitted when practicable (Yes/No):
.....

m) Certificate of analysis / Test Report or Certificate of conformity submitted (Yes/No):
.....

n) Evidence of repeat sales in country of manufacture submitted (Yes/No):
.....

o) Copy of a product license from the country of manufacture or evidence of conformity to standards from a certification body submitted (Yes/No):
.....

p) Summary information on pre-clinical design verification and validation submitted where applicable (Yes/No):
.....

3. 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			

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

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

c) 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:

.....

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

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ESSENTIAL PRINCIPLES CHECKLIST IN REGISTERING OF SURGICAL INTRUMENTS AND APPLICANCES

APPENDIX II: ESSENTIAL PRINCIPLES CHECKLIST IN REGISTERING OF SURGICAL INSTRUMENTS AND APPLIANCES

Product Owner Name:

Product Name/Brand where applicable:

Risk Class:

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
1.0	Surgical Instrument / Appliance should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			
2.0	The solutions adopted by the product owner for the design and manufacture of the appliances should conform to safety			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the product owner should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The product owner should apply the following principles in the priority order listed: identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, eliminate risks as far as reasonably practicable through inherently safe design and manufacture, reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, inform users of any residual risks.			
3.0	Appliances should achieve the performance intended by the product owner and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical appliance.			
4.0	The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the appliance, as indicated by the product owner, when the appliance is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the product owner's instructions.			
5.0	The appliances should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the product owner.			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
6.0	The benefits must be determined to outweigh any undesirable side effects for the performances intended.			
7.0	Every medical appliance requires clinical evidence, appropriate for the use and classification of the appliance, demonstrating that the appliance complies with the applicable provisions of the essential principles. A clinical evaluation should be conducted.			
Essential Principles – Design and Manufacturing Requirements				
8.1	The appliances should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1 to 6 of the 'General Requirements'. Particular attention should be paid to: the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the appliance, the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
8.2	The appliances should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the appliances and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.			
8.3	The appliances should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the appliances are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	restrictions governing these products and that their performance is maintained in accordance with the intended use.			
8.4	Where an appliance incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies and which is liable to act upon the body with action ancillary to that of the appliance, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the appliance.			
8.5	The appliances should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the appliance.			
8.6	Appliances should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the appliance taking into account the appliance and the nature of the environment in which it is intended to be used.			
9.1	The appliances and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: allow easy handling, and, where necessary reduce as far as reasonably practicable and appropriate any microbial leakage from the appliance and/or microbial exposure during use prevent microbial contamination of the appliance, or specimen where applicable, by the patient, user or other person.			
9.2	Where an appliance incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources,			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.			
9.3	Products incorporating non-viable tissues, cells and substances of animal origin falling within the definition of a medical appliance, should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. The product owner is required to retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
9.4	For products incorporating cells, tissues and derivatives of microbial or recombinant origin falling within the definition of a medical appliance, the selection of sources/donors, the processing, preservation, testing and handling of cells, tissues and derivatives of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
9.5	For products incorporating non-viable human tissues, cells and substances falling within the definition of a medical appliance, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	process.			
9.6	Appliances labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the product owner.			
9.7	Appliances delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and /or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the product owner, until the protective packaging is damaged or opened.			
9.8	Appliances labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilised by appropriate, validated methods.			
9.9	Appliances intended to be sterilised should be manufactured in appropriately controlled (e.g. environmental) conditions.			
9.10	Packaging systems for non-sterile appliances should keep the product without deterioration at the level of cleanliness stipulated and, if the appliances are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilisation indicated by the product owner.			
9.11	The packaging and /or label of the appliance should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
10.1	If the appliance is intended for use in combination with other appliances or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the appliances. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
10.2	Appliances should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration; the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; the risks of accidental penetration of substances into the appliance; the risk of incorrect identification of specimens; the risks of reciprocal interference with other appliances normally used in the investigations or for the treatment given; risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
10.3	Appliances should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to appliances whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
10.4	Appliances must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
11.1	Appliances with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the appliance. The limits of accuracy should be indicated by the product owner.			
11.2	Diagnostic appliances should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.			
11.3	Where the performance of appliances depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.			
11.4	Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the appliance.			
11.5	Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the appliance.			
12.1	Appliances should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.			
12.2.1	Where appliances are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	appliances should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
12.2.2	Where appliances are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.			
12.3	Appliances should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.			
12.4	The operating instructions for appliances emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.			
12.5.1	Appliances intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.			
12.5.2	Appliances emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.			
12.5.3	Appliances emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.			
13.1	Appliances incorporating electronic programmable systems,			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
13.2	Appliances where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.			
13.3	Appliances where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.			
13.4	Appliances intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.			
13.5	Appliances should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other appliances or equipment in the usual environment.			
13.6	Appliances should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.			
13.7	Appliances should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the appliances are installed and maintained as indicated by the product owner.			
14.1	Appliances should be designed and manufactured in such a way as to protect the patient and user against mechanical risks			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	connected with, for example, resistance to movement, instability and moving parts.			
14.2	Appliances should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the appliances, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.			
14.3	Appliances should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.			
14.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimise all possible risks.			
14.5	Accessible parts of the appliances (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.			
15.1	Appliances for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.			
15.2	Appliances should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Appliances should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.			
15.3	The function of the controls and indicators should be clearly specified on the appliances. Where an appliance bears			

No.	Essential Principles – General requirements	Applicable to the appliance?	Method of Conformity	Identity of Specific Documents
	instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.			
16.1	Such appliances should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the product owner should be easy for the user to understand and apply.			
16.2	Such appliances should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the appliance and, if applicable, the specimen, and also in the interpretation of results.			
16.3	Such appliances should, where reasonably possible, include a procedure by which the user can verify that, at the time of use that the product will perform as intended by the product owner.			
17.1	Users should be provided with the information needed to identify the product owner, to use the appliance safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.			
18.1	Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.			

APPENDIX III: FORM 8 – CERTIFICATE FOR REGISTRATION OF SURGICAL INSTRUMENTS

Regulation 30(2)

NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

Date of registration: _____ **Registration Number:**_____

Application No:_____ Expiry date of registration:_____

Class of Surgical Instrument / Appliance: ……..

Product Name: ……..

Description of product: …….

Manufacturer name and address: ……..

Country of Manufacture:……...

Components/parts/accessories/appliances/appliances for this Certificate

ID Number	*Model*	*Name*

The above Surgical Instrument/Appliance is registered in Uganda subject to conditions prescribed at the back of this certificate.

.....

SECRETARY TO THE AUTHORITY

APPENDIX IV: FORMAT OF REGISTER FOR SURGICAL INSTRUMENTS

Regulation 26

Name and particulars of applicant (patent holder, licensed person, manufacturer or agent.	Manufacturer	Name of Surgical Instrument/appliance	Pack sizes	Country of Manufacture	Registration No. of Authority

APPENDIX V: APPLICATION FORM FOR VARIATION / ALTERATION OF A REGISTERED SURGICAL INSTRUMENT/APPLIANCES

Regulation Section 39

File Number:_____	
Registration Number:_____	
Product Name:	
Risk Class of Surgical Instrument/Appliance:	
Category of Surgical Instrument/Appliance:	
Model/Series/System if applicable:	
Type of change(State type of variation/amendment)	

Other application(s): (Provide brief information on any ongoing variation / amendment or other variation(s) / amendment(s) / alterations submitted in parallel or renewal of applications or line extension(s)).	
Scope (Please specify scope of change(s)/ variations/amendment(s) in a concise way)	
Background for change and justification for consequential change(s) (If applicable), give brief background explanations for proposed changes to the authorized/registered product as well as justification in case of consequential changes.	
Present (Specify precise present wording)	**Proposed** (Specify precise proposed variation/amendment/alteration/change)
In case of change to the surgical instrument / appliance(s) detail, package leaflet, Instruction for use (IFU) or catalogue applications should always enclose a working model clearly showing the differences between the proposed new version and the current text, previous or reference text.	

Particulars of the applicant (Holder of registration Certificate)

Name: .....

Physical address: .....

Postal address (if different):

Phone: ……Fax: ……e-mail:.....

Declaration of the applicant:

I hereby submit an application of the above registered product to be amended/varied/altered in accordance to the proposals given above. I declare that (Please tick)

a) There are no other changes other than those identified in this application(s) except for those addressed in the variation/amendment submitted in parallel; such parallel variations/amendments have to be specified under other application(s)

b) Where applicable , variation fees have been paid;

c) Change will be implemented from next run/next printing

Name:

Qualification:

Position in the Company:

Signature:

Date

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APPLICATION SUBMISSION CHECKLIST FOR SURGICAL INSTRUMENTS AND APPLICANCES

APPENDIX VI: APPLICATION SUBMISSION CHECKLIST

	HAVE YOU INCLUDED THE FOLLOWING ITEMS IN YOUR APPLICATION? (INDICATE WITH A TICK)	Particulars to be filled by applicant	Yes	No	Remarks by assessor
	1. Details of the applicant Name Physical address Telephone Email				
ALL APPLICATIONS	(a) Soft copies of application				
	(b) Cover letter				
	(c) Correct application fees				
	2. Product details:				
	(a) Proprietary/brand name				
	(b) Brief description of the appliance				
	(c) Class/Category of the appliance				
	(d) Intended use and method of use				
	(e) Medical specialty in which appliance is used				
	(f) Contraindications, warnings, precautions, potential adverse effects				
	(g) List of accessories and other appliances or equipment to be				

	used in combination with the appliance				
	(h) Variations in shape, style or size of the appliance, if applicable				
	(i) Labelling details				
	(j) Packaging description including pack sizes.				
	(k) Recommended storage condition				
	(l) Two samples where practicable				
	(m) Certificate of analysis				
	2 Manufacturer details				
	(a) Site name, physical address, telephone, fax and e-mail				
	(b) Particulars of other sites, if applicable				
	(c) Copy of manufacturing license(s)				
	(d) Evidence of repeat sales in country of manufacture				
	(e) Manufacturer's declarations to essential principles of safety and performance				
	3 **LTR/Authorised agent in Uganda:** Name, physical address, telephone, fax and e-mail				
	4 NOTARIZED POWERS OF ATTORNEY in country of origin for the LTR/Authorised agent				
TRACK 1	6. If the appliance is licensed in one of the IMDRF founding member countries				
	a) Notarized copy of a license in a IMDRF member country				
TRACK 2	*7. If the appliance is NOT licensed in one of the IMDRF founding member countries*				
	a) Evidence of conformity to standards from a certification body accredited by a regulatory				

	authority in one of the IMDRF founding member countries or a recognized international organization				
TRACK 3	8. If the appliance does NOT have certification for any of the international quality system standards				
	(a) Manufacturer's Declaration of Conformity (DOC) to IMDRF Essential Principles of Safety and Performance or as in appendix II of NDA guidelines				
	(a) Summary information on pre-clinical design verification and validation				
	(c) Summaries or reports of tests and evaluations based on other standards, manufacturer rules and tests, or alternative ways of demonstrating compliance. The data may cover: i. engineering tests ii. laboratory tests (e.g.: sterility tests, metrology tests, etc) iii. biocompatibility tests where applicable				

Confirmation: I confirm that all the relevant information for my application has been submitted as filled out in this checklist

Name and designation of signatory: .....

Signature and date: .....

Tel: .....Email: .....

Name and designation of full-time contact person
(if different from signatory): .....

Tel: .....Email: .....

Note: In case there is a change in the contact person, NDA should be notified immediately.

Provide PDF OCR readable softcopy, a Microsoft word document along with application in USB/CD

Decision: Accept or Refuse to Accept

Reviewed by:

Name signature Date

Approved by:

Name signature Date

APPENDIX VII - CLASSIFICATION RULES FOR SURGICAL INSTRUMENTS AND APPLIANCES

What Classification rules apply?

The actual classification will depends on the claims made by the manufacturer and on its intended use. While the provision of illustrative examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasised that the actual classification of a particular surgical instrument and appliance must be considered individually, taking account of its design and intended use.

Classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the surgical instrument and appliance.

In these guidelines the category of the invasive surgical instruments and appliances will be considered using rules based system and the rules applied will be **5, 6, 7, and 8** as out lined in the table below:

i. Invasive appliance / instrument intended to be used to penetrate body orifices.

ii. Surgically invasive appliance / instrument intended for transient use.(less than 60 minutes)

iii. Surgically invasive appliance / instruments intended for short-term use.(between 60 minutes to 30 days)

iv. Surgically invasive appliance / instruments for long-term use and implantable devices.(more than 30 days)

RULE 5: INVASIVE APPLIANCES/INSTRUMENTS INTENDED TO BE USED TO PENETRATE BODY ORIFICES

This rule covers appliance/instruments that enter the body through existing body orifices (for example, ear, mouth, nose, eye) and surgically created stomas. Appliances / instruments covered by this rule tend to be for diagnostic and therapeutic use in particular specialties (ear, nose, and throat; ophthalmology; dentistry; proctology; urology; and gynaecology).

Rule 5	Description
5(a) Invasive appliance/instruments that are not connected to an active medical appliance, or are intended for connection to a Class A medical appliance only and are for transient use—Class A.	Examples: handheld dental mirrors, dental impression materials, exam gloves, prostatic balloon dilation catheters.
5(b) Invasive appliance/instruments that are not connected to an active medical appliance, or are intended for connection to a Class A medical appliance/instrument only and are for short-term use—Class B.	Examples: hard contact lenses, urinary catheters, tracheal tubes, stents, perineal reduction devices.
5(c) Invasive appliance/instrument that are for short-term use in the oral cavity as far as the pharynx, in an ear canal to the ear drum, or in a nasal cavity—Class A.	Examples: dressing for nose bleeds, dentures removable by the patient.
5(d) Invasive appliance/instrument that are not connected to an active medical appliance/instrument, or are intended for connection to a Class A medical appliance only and are for long-term use—Class C.	Examples: long-term urinary catheters, artificial eyes, urethral stents, contact lenses for long-term continuous use.
5(e) Invasive appliance/instrument for long-term use in the oral cavity as far as the pharynx or in an ear canal to the ear drum, or in a nasal cavity and are not liable to be absorbed by the mucous membrane—Class B.	Examples: orthodontic wire, fixed dental prostheses, fissures sealants.

Rule 5	Description
5(f) Invasive appliance/instrument with respect to body orifices, to be connected to an active medical appliance that is classified as Class B or higher—Class B.	Examples: tracheostomy tubes connected to a ventilator, powered nasal irrigators, nasopharyngeal airways, heat and moisture exchangers, suction catheters or tubes for stomach drainage. (Independent of the time for which they are invasive)

RULE 6: SURGICALLY INVASIVE APPLIANCES/INSTRUMENTS INTENDED FOR TRANSIENT USE

This rule covers appliance/instrument that are to be used continuously for less than 60 minutes and are used to create a conduit through the skin (needles, cannulae), surgical instruments (scalpels, saws) and various types of catheters, suckers

Rule 6	Description
6(a) Surgically invasive appliance/instrument for transient use—Class B.	Examples: suture needles, hypodermic needles and syringes, suckers, surgical swabs, surgical gloves.
6(b) A reusable surgical appliance/instrument —Class A.	Examples: scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes, chisels.
6(c) A surgically invasive appliance/instrument for transient use to supply energy in form of ionising radiation—Class C.	Examples: catheters containing or incorporating radioactive isotopes where the isotope is not intended to be released into the body.
6(d) A surgically invasive appliance/instrument for transient use to have a biological effect or be wholly or mainly absorbed—Class C.	Where the biological effect is an intended one rather than unintentional. e.g. bone wax “Absorption” refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body This rule does not apply for substances that are excreted without modification from the body *i.e.* insufflation gases for the abdominal cavity

Rule 6	Description
6(e) A surgically invasive appliance/instrument for transient use to administer medicine via a delivery system, and where the administration is potentially hazardous to the patient—Class C.	Devices for repeated self-application where the dose and the medicine are critical. Examples: personal insulin injectors (commonly referred to as 'pens').
6(f) Surgically invasive appliance/instrument intended for use in direct contact with the central nervous system – Class D	
6(g) Surgically invasive appliance/instrument for transient use to diagnose, monitor, control or correct a defect of the heart, or central circulatory system through direct contact—Class D.	Examples: cardiovascular catheters, angioplasty balloon catheters, coronary artery probes.

RULE 7: SURGICALLY INVASIVE APPLIANCES/INSTRUMENTS INTENDED FOR SHORT-TERM USE

This rule covers appliance/instrument to be used continuously for at least 60 minutes but not more than 30 days and are used in the context of surgery or post-operative care (for example, clamps and drains), infusion devices (cannulae and needles) and catheters of various types.

Rule 7	Description
7(a) Surgically invasive appliance/instrument for short-term use—Class B.	Examples: clamps, infusion cannulae, skin closure devices or temporary filling materials, some surgical retractors for example, chest retractors for cardiac surgery.

Rule 7	Description
7(b) A surgically invasive appliance/instrument for short-term use to administer medicine - Class C.	Examples: intravenous cannulae.
7(c) A surgically invasive appliance/instrument for short-term use to undergo a chemical change in a patient's body (except a appliance/instrument intended to be placed in the teeth) - Class C.	Examples: surgical / tissue adhesives.
7(d) A surgically invasive appliance/instrument for short-term use to supply energy in the form of ionising radiation - Class C.	Examples: bradytherapy devices.
7(e) A surgically invasive appliance/instrument for short-term use to have biological effect—Class D.	Examples: haemostatic sponge.
7(f) A surgically invasive appliance/instrument for short-term use to be wholly, or mostly, absorbed by a patient's body—Class D.	Examples: absorbable sutures.
7(g) A surgically invasive appliance/instrument for short-term use to be used in direct contact with the central nervous system—Class D.	Examples: neurological catheters, cortical electrodes, connonoid paddles.
7(h) A surgically invasive appliance/instrument for short-term use to be specifically used to diagnose, monitor, control or correct a defect of the heart, or central circulatory system, through direct contact with these parts of the body—Class D.	Examples: cardiovascular catheters, cardiac output probes and temporary pacemaker leads, thoracic catheters intended to drain the heart, including the pericardium and a carotid artery shunt.

Rule 7	Description
7(i) A surgically invasive appliance for short-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body—Class B. *Note: for this clause, a medical* appliance/instrument *to be placed in the teeth includes an* appliance/instrument *that is intended to penetrate a tooth but that does not enter the gum or bone beyond the tooth.*	Examples: dental adhesives used for root canal therapy.

RULE 8: SURGICALLY INVASIVE APPLIANCES/INSTRUMENTS FOR LONG-TERM USE AND IMPLANTABLE APPLIANCES/INSTRUMENTS

Appliances covered by this rule include implants used in orthopedic, dental, ophthalmic and cardiovascular fields. In addition, soft tissue implants used in plastic surgery are covered by this rule.

Rule 8	Description
8(a) All implantable appliances/instruments and surgically invasive appliances/instruments for long-term use and implantable appliances—Class C.	Examples: implantable joint replacements, shunts, stents, nails, plates and screws, intra-ocular lenses, infusion ports, peripheral vascular grafts, bone cements, maxillo-facial implants.
8(b) A surgically invasive appliance/instrument for long-term use to be placed in the teeth—Class B.	Examples: bridges and crowns.
8(c) A surgically invasive appliance/instrument for long-	Examples: prosthetic heart valves, aneurysm clips, vascular

Rule 8	Description
term use to be used in direct contact with the heart, the central circulatory system or the central nervous system—Class D.	prostheses, spinal stents, vascular stents, CNS electrodes, cardiovascular sutures.
8(d) A surgically invasive appliance/instrument intended to be life supporting or life sustaining—Class D	Example: pacemakers
8(e) A surgically invasive appliance/instrument intended to be active implantable medical device—Class D	
8(f) An *implantable* accessory to an active implantable medical appliance/instrument—Class D.	Example: electrode leads associated with pacemakers, defibrillators, nerve stimulators.
8(g) An active appliance/instrument to control, monitor or directly influence the performance of an active implantable medical appliance/instrument—Class D.	Example: clinician's programming device for pacemakers, patient control device for nerve stimulation devices.
8(h) A surgically invasive appliance/instrument for long-term use intended by the manufacturer to have a biological effect—Class D.	Implants claimed to be bioactive (Hydroxyapatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer)
8(i) A surgically invasive appliance/instrument for long-term use to be wholly, or mostly, absorbed by a patient's body—Class D.	Examples: absorbable sutures, bioactive adhesives and implants through the attachment of surface coatings such as phosphorylcholine.
8(j) A surgically invasive appliance/instrument for long-term use to administer medicine—Class D.	Examples: rechargeable non-active drug delivery systems.
8(k) A surgically invasive appliance/instrument for long-term use to undergo a chemical change in the patient's body (except an appliance/instrument that is to be placed in the teeth)—Class D.	Examples: surgical adhesive.
8(l) Breast Implants – Class D	

Rule 8	Description
8(m) A surgically invasive appliance/instrument for long-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body is Class B. *Note: for this rule a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but does not enter the gum or bone beyond the tooth.*	Examples: dentine adhesives.

5.0 DOCUMENT REVISION HISTORY

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
6 Aug 2020	0	DAR/GDL/028	*Authors* Brenda Kitimbo Lilian Mutesi *Reviewers* Mutyaba Michael Juliet Okecho	First Issue of document

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