Safe Drugs Save Lives

GUIDELINES ON QUALITY REQUIREMENTS FOR MEDICAL FACE MASKS

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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 the Quality Requirements for Medical Face Masks,** Doc. No. INS/GDL/040 Revision No.: 0", made this 7th day of April 2020, that take effect on 07th April 2020

Signature

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1.0 Introduction

National Drug Authority (NDA) is a regulatory body established by the National Drug Policy and Authority Act (Cap. 206) to ensure availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs. In line with the above mandate, NDA regulates the manufacture, importation, exportation and distribution of face masks within the provisions of the regulations on importation, sale or advertising of surgical instruments and appliances, S.I no. 77 (2019) and registration of drugs, S.I 29 (2014).

In the wake of the COVID-19 pandemic, there is a global surge in demand for face masks which are an important protective barrier between healthcare providers and patients. Therefore, this technical guidance document identifies the classification regulation and product codes for face masks. In addition, other sections of this guidance document provide additional information to manufacturers on addressing risks related to these devices in registration.

2.0 Definitions

Face masks may be categorized into two broad types, that is; **medical face masks** and **surgical respirators**.

Medical face mask: a medical device covering the mouth and nose providing a physical barrier to fluids and particulate material, minimizing the direct transmission of infective agents between staff and patient. The masks referenced in this document include masks that are labeled as a surgical, dental, isolation or medical procedure masks.

Surgical respirator: an appliance fitted to the user's face, forming a seal that provides a physical barrier to fluids, particulate materials, and aerosols. If you wish to label your device "N95 NIOSH Certified," please refer to the (NIOSH) website at http://www.cdc.gov/niosh/status.html for information about NIOSH's certification program support for respirator manufacturers.

3.0 General classification of face masks

Face masks specified in this guide are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided into types II and IIR according to whether or not the mask is splash resistant. The technical differences between these different classes of masks are detailed in table 3 below.

Note:

a) Type I medical face masks should only be used by patients and other members of the public so as to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

b) Type II and IIR should be of a minimum 3 Ply construction.

4.0 Overview of regulatory controls on face masks for the Ugandan Market

4.1 The face masks imported into Uganda shall be compliant with an internationally recognised standard.

4.2 The manufacturing facility shall have ISO 13485 certification for Quality Management Systems for Medical Devices. Each consignment shipped into the country shall be accompanied by a certificate/declaration of conformity.

5.0 Physical attributes of face masks

The face masks shall be:

a) latex free

b) fiber glass free

c) hypo-allergic

d) with ear loops and nose pieces.

6.0 Intended uses of masks

The requirement for and selection of appropriate mask is determined by a number of factors that involve a risk-assessment-based approach considering;

a) the task or procedure to be undertaken;

b) the suspected or known infectious status of the patient; and

c) the presenting symptoms of the patient.

Medical face masks are intended to be worn by medical personnel during surgical or other medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluid and particulate material transfer.

	Category of face masks / Respirator			
	Face mask (cloth or paper masks)	**Surgical mask**	**Surgical N95 Respirator**	**N95 Respirator**
Indication	Ideal as a comfortable substitute for ear loop face masks, this mask is a simple physical barrier ideal for exams and visitations or for dry, short procedures that do not produce fluid, spray or aerosols.	Type IIR-Ideal for procedures where heavy to moderate amounts of fluid spray and/or aerosols are produced. Type II are used where no fluids are generated Type I are used by patients and other persons.	Indicated for use when treating patients with airborne diseases such as TB or influenza	Most N95 respirators are manufactured for use in construction and other industrial type jobs that expose workers to dust and small particles.
Purpose	Prevents large particles expelled by you, the wearer, from reaching the environment.	Prevents large particles expelled by you, the wearer when you are ill, from reaching the environment. To be used as a physical barrier to protect you from large droplets of blood or body fluids.	Reduces your exposure to very small airborne particles or contaminants.	Reduces your exposure to very small airborne particles or contaminants. (only non -oil aerosols) May not protect against sprays and direct liquid splashes

7.0 Technical Specifications

7.1 Material Composition

The technical specification of the face mask shall be available, which shall include a description of the material composition, including the following:

a) Type of fabric:
   i. Polypropylene
   ii. spun bonded or melt blown, or wet laid.

b) Other materials:
   i. metals, for example, used in nose features
   ii. colorants
   iii. elastic materials, such as those used in ear loops
   iv. foam and other anti-fog materials, if any
   v. face shield materials, if any.

7.2 Design features

Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).

The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. The design features of the face mask, such as Tie-on or ear loops, Elastic materials and Face shield (if any) should be described. The style of the mask may be; duck bill, flat pleated, cone shaped, and pouch.

7.3 Performance

All tests on face masks shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state. The performance requirements for face masks are summarized in the table 3 below:

Table 2: Summary of tests to be performed on face masks:

Test	Description
Bacterial filtration efficiency (BFE)	When tested, the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 3 below.
Breathability	The differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 3 below.
Splash resistance	When tested in accordance with ISO 22609, the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 3 below.
Microbial cleanliness (Bioburden)	When tested according to ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 3 below). In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested. NOTE ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package.
Biocompatibility	The manufacturer shall complete the evaluation of the medical face mask and determine the applicable toxicology testing regime. The results of testing should be documented. The test results shall be available upon request.

Table 3: Summary of performance requirements for face masks

Test	Type I	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

7.4 Labelling

The label of the mask shall have the following minimum information:

a) Name and/or trademark of the manufacturer
b) Manufacturer's product reference
c) Type of mask and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging
d) Lot number or Batch number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable)
e) Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol) (if applicable)
f) The words "for single use" (or equivalent harmonized symbol)
g) The words "destroy after use" (if space allows)
h) Number of units per primary packaging (if applicable)
i) Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol)
j) Manufacturer's instruction for use

8.0 General Precautions

People with chronic respiratory, cardiac, or other medical conditions that make breathing difficult should check with their health care provider before using an N95 surgical respirators because the N95 respirator can make it more difficult for the wearer to breathe.

Some models have exhalation valves that can make breathing out easier and help reduce heat build-up.
Note that N95 respirators with exhalation valves should not be used when sterile conditions are needed.

10.0 References

a) European Standard EN14683:2019 "Medical face mask – requirements and test methods"

b) FDA Guidance Document for Surgical Masks – Premarket Notification [510(k)] Submissions

c) J.E, Coia et al, / Journal of Hospital Infection 85 (2013) 170-182 "Guidance on the use of respiratory and facial protection equipment"

d) The National Drug Policy and Authority Act (Cap. 206)

11.0 Document Revision History

Date of revision	Revision number	Document Number	Author(s)	Changes made and reasons for revision
07th April 2020	0	INS/GDL/040	*Authors:* Brenda Kitimbo Moses Akampurira *Reviewers:* Solomon Onen Denis Mwesigwa Peter Ssali	First issue

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