KENYA PUBLICLY AVAILABLE SPECIFICATION

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First Edition

Personal Protective Equipment — Face shield — Specification

TECHNICAL COMMITTEE REPRESENTATION

The following organizations were represented on the Technical Committee:

Alpha Medical Manufacturers Limited
Association of Medical Engineers of Kenya (AMEK)
Christian Health Association of Kenya (CHAK)
Diverse Management Consultancy Ltd.
Equra Health Kenya
Gertrude's Children's Hospital
Jads Diagnostics EA Ltd.
Kenya Medical Supplies Agency (KEMSA)
Kenya Accreditation Service (KENAS)
Kenya National Chamber of Commerce and Industry (KNCCI)
Medtronics Kenya
Ministry of Health
Physicist Society of Kenya
Nairobi County — Sub County Health Services, Kamukunji
Kenya Bureau of Standards — Secretariat

REVISION OF KENYA STANDARDS

In order to keep abreast of progress in industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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Foreword

This Kenya Publicly Available Specification was prepared by the Hospital Devices, Tools and Equipment Technical Committee under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards

This document gives the minimum specifications of a face shield as an additional protective gear to be used by health care service providers during the current COVID-19 pandemic or any other emergency declared by the Cabinet Secretary of Health at the time. It sets out minimum requirements of what is 'minimally acceptable for face shields'. Face shields shall be used in addition to donning of facemasks, which are most likely to confer protective benefit on the user while protecting the patient during emergency medical services. A face shield with lower specifications than this is likely to provide no protective benefit and might lead to increased harm, which would be unacceptable.

This document is intended to guide manufacturers and distributors in the process of meeting the key requirements of a face shield and does not attempt to provide a comprehensive list of requirements as the manufacturer is expected to be familiar with the concepts of face protection devices.

Some users may be wearing spectacles or protective goggles which is a whole system of protection and face shields shall be safely used with all other devices without discomfort or requiring ocular correction. Compliance with the essential safety standards and dimensions shall be demonstrated.

Usability testing at production stages will be required. This should be done along the lines of clinical trials that entails the user wearing complex protective clothing with hood including: Eye goggles (in addition to spectacles, if worn). Face shield, shall not elicit any form of discomfort.

In the process of preparing this standard, clinical acceptance of functionality, safety and performance by relevant stakeholders and their consensus was sought.

During the preparation of this standard, reference was made to the following documents:

ISO 18526, Eye and face protection — Test methods — Part 4: Headforms.

ISO 4007, Personal protective equipment — Eye and face protection — Vocabulary.

ASTM D1003-13, Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics.

Acknowledgement is hereby made for the assistance derived from these sources.

Personal Protective Equipment — Face shield — Specification

1 Scope

This Kenya Publicly Available Specification prescribes the minimum requirements, test methods and use of locally manufactured face shield for use by health care service providers during the COVID-19 pandemic or any other emergency declared by the Cabinet Secretary concerned with Health at the time.

2 Normative references

The following referenced documents referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM D1003-13, *Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics*

KS ISO 4007, *Personal protective equipment — Eye and face protection — Vocabulary*

KS ISO 18526, *Eye and face protection — Test methods — Part 4: Headforms*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in KS ISO 4007 and the following apply.

3.1
face shield
personal protective equipment covering the eyes and all, or a substantial part, of the face, which can be mounted directly on the head using a frame or headband and/or straps for use by health care workers in Kenya during the COVID-19 pandemic or any other emergency declared by the Cabinet Secretary concerned with Health at the time.

3.2
frame
structure of the face shield on which the oculars/lens(s) are mounted

3.3
lens/visor/screen
a protective component of the face shield through which the wearer sees

3.4
plano lens
lens that does not incorporate a corrective prescription; this lens is not necessarily flat

4 Requirements

4.1 General

4.1.1 Face shield manufacturers shall have a risk management system in place, including policy and risk management file.

4.1.2 Face shields shall satisfy all applicable requirements and unless otherwise stated, all values for measurements shall be considered as nominal.

4.1.3 The face shield shall either be single-use or reusable. Reusable face shields shall be made of material that can be cleaned and disinfected, and if single-use, the material shall be disposable.

4.2 Construction

Face shields shall be constructed such that either it has a non-removable visor/lens or removable ones.

The non-removable type of construction shall have a homogeneous and continuous lens or visor and frame and the lens/visor shall not be removed from the frame/headband without damage to the device.

Removable type of construction shall be fabricated to have lens/visor removed and all shall fit a single frame or head-harness. When won, the face shield shall fit on the head snugly.

4.3 Optical requirements

4.3.1 Optical quality

Face shields shall be free of striae, bubbles, waves and other visible defects which would impair the wearer's vision**.**

The visor/lens/shield shall have a minimum thickness of 0.25 mm sheets of acetate, Mylar, PETm-polycarbonate, or any type of clear plastic film.

The surface of the visor/lens shall be scratch resistant and should not be prone to scuff marks.

4.3.2 Haze and luminance transmittance

When tested in accordance with ASTM D1003-13, clear plano lenses/visor/ocular shield shall not exhibit more than 3% haze.

4.4 Physical requirements

Face shields shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.

4.4.1 Minimum coverage area

Completely covers the sides and length of the face.

The minimum overall width and length of the face shield shall be 290 mm and 210 mm, respectively.

The shields, including the frame and/or lens/visors shall cover in plain view an area of not less than 40 mm in width and 33 mm in height (elliptical) in front of each eye, centred on the pupil centres of the test headform as shown in Figure 1 (a) and (b).

Headforms shall conform to the requirements of KS ISO 18526.

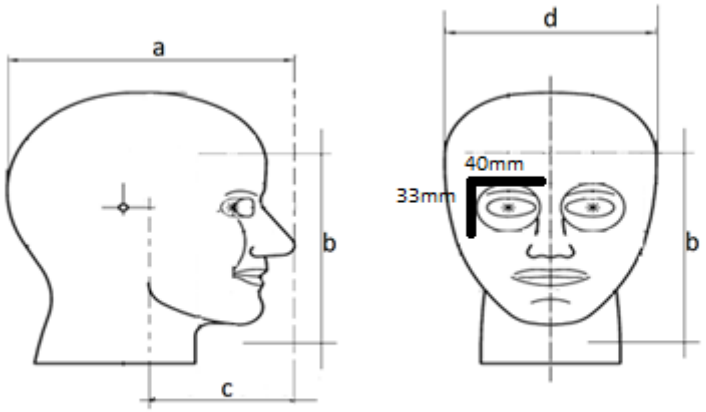

Figure 1 — Head form showing measurements

4.4.2 Frame/headband

The frame and/or headband shall be made of suitable materials capable of being cleaned and/or disinfected.

The frame/headband shall be made of good materials that is not sensitive to the skin of the wearer and shall allow good fit around the head and snug fit against the forehead.

Headbands may be elastic with at least 0.96 cm - 1.3 cm width and strap.

NOTE Components of the frame can be the holders, support straps, connecting elements and extension pieces.

5 Droplet and splash protection requirements

When tested in accordance with Annex A, the droplets and/or liquid splash shall not cause a red coloration within either of the two circles described in the test method.

6 Equipment identification, marking and documents

6.1 Labelling and packaging

The following information shall be indelibly and legibly put on the package:

a) Name and physical address of the manufacturer;

b) Trade name, if any;

c) the name of the product e.g. “Face Shield”;

d) The phrase “Single-use” or “Reusable”;

e) Instruction for use and cleaning/disinfection;

NOTE Manufacturers shall provide these instructions, if applicable, to each end user facility (e.g., each hospital) that receives the authorized face shield.

f) The statement, “Fog-resistant” if anti-fog material has been applied to the face-shield;

g) Number of pieces in the package;

h) Instructions for assembly, if they are packed as separate parts;

i) Instruction for disinfection, if required; and

j) Recommendations for disposal after use.

Annex A
(normative)

Droplet and splash test

B.1 Purpose

This test is intended to determine the capability of the face shield to prevent liquid splashes or sprays from penetrating the face shield. This is not intended to evaluate the fit of the face shield to the wearer's face.

B.2 Apparatus

A spray solution, 0.1 ml solution of sodium carbonate in water, shall be prepared and placed in a hand-operated atomizer, capable of producing fine droplets (not mist).

The detection/test area on the headform shall be defined by white blotting paper of sufficient size to cover the lens area and extend at least 20 mm (0.79 in.) beyond the periphery of the protector to be tested and marked with two circles of 40 mm diameter centred over the pupillary centre.

For this test, a detection solution, prepared by dissolving 5.0 g ± 0.5 g phenol-phthalein in 500 ml ± 50 ml ethanol and adding 500 ml ± 50 ml water, shall be prepared and stirred constantly (filter if precipitate forms) to obtain 1.0 l ± 0.1 l of solution.

B.3 Procedure

Cover the lens region of the headform with layers of cotton lint. Dip the blotting paper in the detection solution described above and shake off excess. Place the moist blotting paper over the lint, centring the circles over each eye.

Fit the face shield onto the headform in the normal wearing position so that the blotting paper protrudes all around its periphery by at least 20 mm (0.79 in.). Adjust the headband to a normal degree of tension. Adjust the number of layers of lint, as necessary, to ensure a good seal between the face shield and the headform.

Spray the mounted face shield with approximately 5 ml to 10 ml of the spray solution, holding the atomizer at a distance of approximately 600 mm from the headform and spraying from all directions. All the blotting paper around the periphery should turn a uniform crimson colour. The blotting paper shall not be over-wetted such that it drips. Examine the blotting paper for intrusion of colour into the circles. One complete device shall be tested.

Annex B
(informative)

Fog test

B.1 Purpose

The purpose of the testing is to assist material manufacturers and the companies that use their products in identifying and developing products that outgas SVOC's at a reduced rate.

B.2 Equipment and accessories

B.2.1 A specialized heating bath, with a means to hold the required beakers and cooling plates.

B.2.2 A cooling system, to keep the cooling plates at the desired temperature.

B.2.3 The required accessories, to perform the desired test method.

B.2.4 Glass beakers (6 needed), the 1000 ml flat-bottom beakers fit into the holes of the sealed frame. They are made from heat-resistant glass and hold the samples during testing.

B.2.5 Beaker sealing, fluoroelastomer sealing rings (6 needed). These O-rings form a seal between the top of the beakers and the glass plates so that the VOC vapours released from the sample do not escape from the beaker.

NOTE The sealing rings have a limited life and should be replaced as needed.

B.2.6 Beaker sealing, support rings (6 needed). The support rings are mounted inside the sealing rings. This helps stabilize the sealing ring when placed on top on the beaker.

B.2.7 Cooling plates (6 needed), these are made of a stainless steel top with an aluminium contact surface. They have an internal passage through which the temperature controlled water flows. Their purpose is to maintain the square glass plates or aluminium foil discs at the prescribed cooler temperature causing the VOC vapour to condense onto them.

B.2.8 FOG 150, heat transfer liquid FOG 150 (4 x 10-litre containers necessary); This is used as the heat transfer fluid in the fogging bath. It is normal for the fluid to vary in colour. It is soluble in water and can be used up to temperatures of 150 ºC.

B.2.9 Metal cutters, metal rings (6 needed), made from chrome-plated steel. These are placed on top of the test sample to secure the sample against the base of the beaker.

B.3 Method 1: Reflectometric/photometric/fogging/gloss methods

B.3.1 Principle

A prepared sample is placed in a beaker that is then covered with a glass plate. For a period of 3 h, the sample is heated to 100 ºC, while the glass plate is cooled to 21 ºC (note that there may be differing temperature requirements depending on the standard used).

The heat causes the sample to release SVOC gasses that condense on the cooled glass plate creating a "Fog" (*F*). The Reflective Index (R_1) of the clean glass is known before the test and the fogged glass R_1 is measured and recorded using a hand held Reflectometer. Fogging value (F_v) is expressed as a percent of change in the 60Reflective Index of a glass plate that has been fogged in accordance with the procedures (R_1) to a clean glass plate (R_2);

$$F_v = (R_2 \times 100)/R_1, \text{ where } F_v \text{ is expressed in \%}$$

NOTE 1 DIN specifies the maximum value for F_v in this test at 90%, a perfect value of a glass plate with no fog is 100.

NOTE 2 An alternative method known as the Haze Method uses the same procedure except that actual light transmittal (corrected for narrow angle scatter) rather than light reflection is measured using a Haze Meter. The Haze method is not the reciprocal of the gloss method; the measurements have no scientific connection to each other. A perfect value with no haze is zero. A measurement of 4-5 is too high (Honda uses 2 as the maximum value).

B.5 Method 2: Gravimetric method

B.5.1 Principle

A prepared sample is placed in a beaker that is then covered with an aluminium foil disk. For a period of 16 h the sample is heated to 100 ºC, while the aluminium foil disk is cooled to 21 ºC (not that there may be temperature variations depending on the standard used).

The heat causes the sample to release SVOC gasses that condense on the cooled aluminium foil disk creating a "Fog" (*F*) that has a measurable mass (*m*). The amount of fogging condensate is determined by weighing the aluminium foil disk before (m_1) and after the test (m_2) and subtracting the known mass of the same aluminium foil disk before fogging.

$$mF = m_2 - m_1$$

where

mF is the mass of the fog condensate collected during the test (milligrams).

Bibliography

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ISO 18526, *Eye and face protection — Test methods — Part 4: Headforms*

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