SAPEMA
Southern African Protective Equipment Marketing Association

SAPEMA BULLETIN BOARD

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VOLUME 1: ISSUE 1

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Understanding the FFP2 Dust Mask vs N95

We see a lot of confusion in South Africa when it comes to the respiratory standards.

All respiratory products sold in South Africa are required to be homologated with the SABS (SANS 50149), as per VC8072 from the National Regulator for Compulsory Standards (NRCS).

For this reason, the "normal" NIOSH N95 products are not legally allowed in South Africa.

The European standards make provision for Health Care Particulate Respirators.

These products must be tested to EN 14683:2005 "Surgical masks – Requirements and test methods" and EN 149:2001+A1:2009 "Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking". CE approved to the Medical Device and PPE Directives. (See below extract of EN14683:2005).

This changes slightly when we refer to NIOSH approved, and FDA **cleared** "Surgical Masks".

In South Africa, these products will fall under SANS 1866-2:2018 (Medical devices Part 2: Medical Respirators).

As you know, this covers the material, classification and performance requirements for medical respirators, intended to limit the transmission of infective agents in the healthcare environment. The challenge (and contradiction to SANS 50149) is that it allows for both NIOSH and EN149 respiratory standards. For this reason, products that are classified as "N95 &

FDA Cleared for use as surgical mask" products are allowed in the country.

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Extract from EN14863: 2005

EN 14683:2005

This European Standard specifies construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements. This European Standard is not applicable to masks intended exclusively for the personal protection of staff.
This standard is intended to help facilitate the choice of surgical face masks in the European Market by standardizing the information and performance data required for the masks.
There are three test methods used to classify surgical masks:

1. Bacterial Filtration Efficiency in vitro (BFE) (ASTM F2101-07)
This test is used to determine the amount of infective agent that is retained by the surgical facemask, which is directly related to the amount of bacteria released through the mask into the air of the surgical theatre.
Classification:
BFE => 95% TYPE I
BFE => 98% TYPE II

2. Breathing Resistance (Delta P)
This test is used to determine the resistance airflow of the facemask.
Classification:
TYPE I & II (non splash resistant) = < 29.4 Pa/cm2
TYPE IR & IIR (splash resistant) = < 49.0 Pa/cm2

3. Splash Resistance (ASTM F1862-07)
This test is used to determine the resistance penetration of potentially contaminated fluid splashes.
Classification:
TYPE I & TYPE II not applicable
TYPE IR & TYPE IIR >120 mmHg
120 mmHg is a minimum value. It corresponds to the average systolic arterial blood pressure, and intends to protect against ruptures in small arteries causing small sprays of blood. Some products off protection even in excess of the 120 mmHg.

Minimum Performance Requirements According to the New Facemask Standard EN14683

EU Standard Class	Bacterial Filtration Efficiency	Breathing Resistance (Pa/cm2)	Splash Resistance (mmHg)
Type I	95%	< 29.4	NA
Type IR	95%	< 49.0	> 120
Type II	98%	< 29.4	NA
Type IIR	98%	< 49.0	> 120

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Current standard EN14863: 2014

The reason for referring to the 2005 standard is because the Medicines Council for SA has still not adopted the current standard – EN 14683:2014.

In respect to EN 14683:2005, the following changes have been made:

a) change/extension of title and scope to the more general and broader use for medical face masks;
b) adjustment to ISO 22609 concerning the request for resistance to liquid splashes;
c) addition of requirements for microbiological purity and general biocompatibility;
d) adjustment of Table 1 on performance requirements for medical face masks;
e) update of Annex A on user information;
f) complete revision of Annex B on method for in-vitro determination of the bacterial filter performance in particular with regard to the testing conditions and the structure of the test apparatus;
g) complete editorial revision, including update of all normative references, the Bibliography and Annex ZA on the relationships to the EU Directive 93/42/EEC. [Manufacturers of currently approved medical devices will have a transition time of three years until May 26th 2020 (date of application) to meet the requirements of the MDR. The new MDR provides an additional time after the date of application allowing to place new products under the MDD for max. 4 more years on the market. Additional requirements and limitations will apply for this extended transition period.]

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	Fitting Instructions of a dust mask
1 & 2:	re-stretch around entire length of each strap by pulling at 3cm intervals between both hands
3	Cup respirator in one hand with nosepiece at fingertips, allow headbands to hang freely below hand.
4	Hold respirator under chin, with nosepiece up.
5	Locate the upper strap across the crown of the head and the lower strap below the ears.
6	Straps must not be twisted.
7	Using both hands, mould nose clip to the shape of the lower part of the nose to ensure a close fit and good seal. Pinching the nose clip using only one hand may result in less effective respirator performance
8	The seal of the respirator on the face should be fit-checked before entering the workplace

Figure 1