African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

Africa Centres for Disease Control and Prevention (Africa CDC)

Advisory on Respiratory Protective Equipment

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Respiratory protective equipment (RPE) includes close fitting masks such as N95 and FFP2 respirators, reusable half masks and powered air purifying respirators. Disposable RPE (N95 or FFP2) is most commonly used by healthcare workers in medical settings. When used correctly RPE can filter small particles, including aerosol-borne pathogens, which may be created during aerosol generating procedures, or naturally occurring for specific pathogens. are an essential part of the personal protective equipment (PPE) required to protect healthcare workers.[1]

The COVID-19 pandemic has increased global demand for PPE, including RPE, resulting in large scale procurement by national and international organisations and increased competition for PPE. This has encouraged new manufacturers without experience in PPE production to join the market and made experienced producers to rapidly upscale production.

There is increased pressure on regulatory and quality management systems. Hence, the regulatory landscape has become complicated by a plethora of regional and national standards and there is no global regulatory system or post-market surveillance of PPE standards. There are currently concerns about the authenticity of certificates of test reports or national regulatory clearances2,3 and there is limited third party testing capability. This has increased the risks of substandard respiratory protective equipment that may not adequately protect healthcare workers reaching the frontline.

This advisory highlights the current situation and offers recommendations to ensure that healthcare workers remain protected.

International standards and descriptions for RPE

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st class (KMOEL-2017-64)	DS2 (Japan JMHLW notification	Description of test
Origin of standard	US standard	European standard	Chinese standard	Australian standard	Korean standard	Japanese standard	
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%	Level of filtration efficiency, the filter fabric is evaluated to measure the reduction in concentrations of specific aerosols
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl	The content of the aerosol generated for the filter performance test, oil is more challenging to pass than NaCl
Inhalation resistance – max pressure drop	≤ 343 Pa (85 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa (at 85 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/ valve) ≤ 50 Pa (no valve) (at 40 L/ min)	How hard is breathing in through the mask. Lower Pa indicates less work of breathing. Higher flow rates reflect higher breathing rates.
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%	Dead space behind the mask, a lower number indicates less rebreathed air

[1]WHO: Mask use in the context of COVID-19 01 Dec 2020; Available at ; https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak [Cited on 23 Dec 2020]

More details and additional tests at: Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf

WHO: Technical specifications of personal protective equipment for COVID-19 [Internet]. [cited 2020 Dec 23]. Available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1

Recommendations

- Member States are encouraged to direct any concerns or uncertainties about the quality of RPE to the New Partnership for Africa's Development (AUDA NEPAD) or refer to reference 4 for more details. (Also refer to African Union COVID-19; Occupational Safety and Health GUIDELINES SERIES; Available at;https://www.nepad.org/publication/african-union-covid-19-occupational-safety-and-health-guidelines-series for additional Occupational Health and Safety advice and recommendations.
- Regulatory bodies in Member States should increase testing capacity so that they can provide temporary certificates of conformity.
- Approved suppliers should be encouraged to strengthen their quality management system (e.g. though conformity with ISO 9001).
- New suppliers or procurement should be supported to develop a strong quality assurance system.
- Member States should consider diversifying accepted standards where there is equivalence between different regional standards.
- Sourcing of PPE, including RPE, should be diversified to reduce competition from the same manufacturers and suppliers.

References

Africa CDC;2020; COVID-19 Guidance on use of personal protective equipment for different clinical settings and activities; https://africacdc.org/download/covid-19-guidance-on-use-of-personal-protective-equipment-for-different-clinical-settings-and-activities/

US Food and Drug Administration; 2020;Personal Protective Equipment EUAs; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas

UK Health and Safety Executive; Use of face masks designated KN95; https://www.hse.gov.uk/safetybulletins/use-of-face-masks-designated-kn95.htm

British Occupational Hygiene Society: Spotting a Fake Respirator; https://www.bohs.org/covid-19-hub/

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