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Department:
Trade, Industry and Competition
REPUBLIC OF SOUTH AFRICA

FFP2 medical masks (also referred to N95 mask) clarification notice

South African Standards and Regulations – Respiratory Protective Devices

This note serves as a clarification notice regarding FFP2 medical masks and N95 medical masks confusion within the Republic of South Africa. Respiratory protective masks are commonly referred to as N95 masks but the FFP2 is also a respiratory mask.

- N95 is not the name of the masks, but refers to the United States of America's Federal Agency, the National Institute for Occupational Safety and Health (NIOSH), standard.
- The European Union uses filtering face piece (FFP) respirators score which comes from the European Norms (EN) standard 149:2001.
- This standard covers the P1, P2 and P3 ratings of the respiratory masks and the standard is maintained by CEN (European Committee for Standardisation).
- **The NIOSH requires a minimum of 95 and 99.97% efficiencies for N95 and P100 FFR, respectively; meanwhile, the EN requires 94 and 99% efficiencies for FFRs, class P2 (FFP2) and class P3 (FFP3), respectively.**
- **The Republic of South Africa has adopted the European Norms standard: EN149:2001 (FFP1/P2/P3) and the harmonised specification is SANS 50149:2003 - <https://store.sabs.co.za/covid-19-free-sans>**
- The Republic of South Africa has a similar system to that of the European Union CE mark, referred to as homologation where the legislated compulsory specifications and requirements are specified in government gazette VC8072 – <https://www.nrccs.org.za/siteimgs/vc/VC8072.pdf>



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- The National Regulator for Compulsory Specifications (NRCS) oversees this process in accordance with SANS 10338:2009

- <https://store.sabs.co.za/pdfpreview.php?hash=49e49e30e2cd5924f0c6706eeb7cb19f3ac672e4&preview=yes>

Masks manufacturers, responding to the COVID-19, Pandemic within the Republic of South Africa & contact details

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Country	Specification	Standard	Filter performance (must be \geq X% efficient)	Test Agent	Flow rate	Total Inward Leakage (TIL) ** (tested on human subjects)
South Africa	EN149:2001	FFP2	$\geq 94\%$	NaCl and paraffin oil	95 L/min	$\leq 8\%$ leakage (arithmetic mean)
Europe	EN149:2001	FFP2	$\geq 94\%$	NaCl and paraffin oil	95 L/min	$\leq 8\%$ leakage (arithmetic mean)
USA	NIOSH CFR	N95	$\geq 95\%$	NaCl	85 L/min	Not tested
China	GB2626-20 06	KN95	$\geq 95\%$	NaCl	85 L/min	$\leq 8\%$ leakage (arithmetic mean)
Japan	DS (Japan JMHLW-Notification 214, 2018)	DS	$\geq 95\%$	NaCl	85 L/min	Inward Leakage measured and included in User Instructions
Korea	Korea 1st Class (KMOEL-2017-64)	1st Class	$\geq 94\%$	NaCl and paraffin oil	95 L/min	$\leq 8\%$ leakage (arithmetic mean)
Australia & New Zealand	P2(AS/NZ 1716:2012)	FFP2	$\geq 94\%$	NaCl	95 L/min	$\leq 8\%$ leakage (arithmetic mean)

COMPARISON OF FILTERING FACEPIECE RESPIRATOR CLASSES

** Total inward leakage (TIL) is defined as the combination of contaminated air that leaks through a respirator from various sources, including face seal, valves and gaskets, and penetration through the filter.