



DEVICE DETAILS

NAME OF DEVICE	KN95 PROTECTIVE FACE MASK
ESTABLISHMENT NAME	NEWSERA GLOBAL SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA9188722-83026
BRAND NAME	NEWSERA NEWSGUARD
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	A flexible, loose-fitting mask designed to be placed over the mouth and/or nose and chin fitted with the head harness which can be head or ears attachment of a wearer to permit normal breathing while protecting the wearer from the transfer of particles from the environment. This is a single use, non-sterile product. This product consists of non-woven fabric, melt-blown fabric, electrostatic cotton, nose clip and elastic ear belt.
DEVICE INTENDED PURPOSE	The Disposable folding mask is intended to be worn to protect personnel from the transfer of particulate material.. This mask is suitable for use in protection against the non-toxic solid and liquid aerosols. The length of time this mask can be used depends on contaminants present but should not exceed one shift. "NR" means this mask shall not be used for more than one shift. This mask may used for performing patient procedures, or when patients are in isolation (Clean Environments, sterile cores, processing departments, ER and ICU for bedside procedures, etc.) to reduce the risk of spread of infections. As it is comparable to FFP2 grade mask, it can be used for protection against SARS-Covid 19 as well.
VALIDITY DATE OF REGISTRATION	16/01/2022 - 15/01/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	KN95 PROTECTIVE FACE MASK	GB2626-2006 (2019) KN95