



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	KN95 PROTECTIVE FACE MASK
<b>ESTABLISHMENT NAME</b>	NEWSERA GLOBAL SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	MANUFACTURER
<b>REGISTRATION NO</b>	GA9188722-83026
<b>BRAND NAME</b>	NEWSERA NEWSGUARD
<b>MEDICAL DEVICE CATEGORY</b>	SINGLE-USE DEVICES
<b>DEVICE GROUPING TYPE</b>	SINGLE
<b>DEVICE DESCRIPTION</b>	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.
<b>DEVICE INTENDED PURPOSE</b>	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.
<b>VALIDITY DATE OF REGISTRATION</b>	16/01/2022 - 15/01/2027

## LIST OF DEVICE

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