



DEVICE DETAILS

NAME OF DEVICE	N95 RESPIRATOR PLUS (ANTI-VIRAL FACE MASK)
ESTABLISHMENT NAME	IDS MEDICAL SYSTEMS (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GMD94133439018A
BRAND NAME	RESPOKARE
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>This is a single use disposable N95 respirator with a hydrophilic plastic coating on the outer layer (citric acid 2% w/w, a pH-lowering agent), and a second inner layer treated with metal ions (copper 1.6% w/w and zinc 1.6% w/w). It inactivates 99.99% of tested influenza viruses on five minutes contact with the surface of the respirator in laboratory (in vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/04/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PuertoRico/8/34), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested. This is flat-folded and expands into a convex-shaped mask with polyamide/spandex elastic head-loops to secure the mask to the user's face, and a malleable aluminium strip positioned above the nose to improve seal around the nose and face. The device is intended to be worn during seasonal influenza A or influenza B, and influenza A or influenza B pandemic. It is intended for occupational use, to help reduce wearer exposure to pathogenic biological airborne particulates, and to protect against the transfer of micro-organisms, body fluids, and particulate material.</p>

DEVICE INTENDED PURPOSE	This is flat-folded and expands into a convex-shaped mask with polyamide/spandex elastic head-loops to secure the mask to the user's face, and a malleable aluminium strip positioned above the nose to improve seal around the nose and face. The device is intended to be worn during seasonal influenza A or influenza B, and influenza A or influenza B pandemic. It is intended for occupational use, to help reduce wearer exposure to pathogenic biological airborne particulates, and to protect against the transfer of micro-organisms, body fluids, and particulate material. It inactivates 99.99% of tested influenza viruses on five minutes contact with the surface of the respirator in laboratory (in vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/04/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PuertoRico/8/34), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.
VALIDITY DATE OF REGISTRATION	22/02/2023 - 21/02/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	N95 Respirator Plus (Anti-Viral Face Mask)-Small Size	RK-200-3040A
2	N95 Respirator Plus (Anti-Viral Face Mask)-Medium Size	RK-200-3041A
3	N95 Respirator Plus (Anti-Viral Face Mask)-Large Size	RK-200-3042A