



DEVICE DETAILS

NAME OF DEVICE	Respirator Face Mask - KF94 Face Mask
ESTABLISHMENT NAME	RESPACK MEDICARE SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA3151221-66724
BRAND NAME	RESPACK
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Respirator Face masks are made of 4-ply of water resistant outer layer, non woven filter to filter out the dust and germs, excellent filtering melt blown fabric with electrostatic charge, soft and fine inner non woven skin friendly and suitable for sensitive skin. They have bacterial filtration efficiency and particles filtration efficiency for use by humans in any situation such as pandemic, medical sectors and common use for health concern.
DEVICE INTENDED PURPOSE	Respirator Face Mask is intended to be worn by Medical Personnel during surgical or other Medical Procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluid and particulate material transfer.
VALIDITY DATE OF REGISTRATION	16/07/2021 - 15/07/2026



LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Respirator Face Mask - KF94 Face Mask	Class 1-Respack-Respirator Face Mask