



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	Respirator Face Mask - KF94 Face Mask
<b>ESTABLISHMENT NAME</b>	RESPACK MEDICARE SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	MANUFACTURER
<b>REGISTRATION NO</b>	GA3151221-66724
<b>BRAND NAME</b>	RESPACK
<b>MEDICAL DEVICE CATEGORY</b>	SINGLE-USE DEVICES
<b>DEVICE GROUPING TYPE</b>	SINGLE
<b>DEVICE DESCRIPTION</b>	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.
<b>DEVICE INTENDED PURPOSE</b>	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.
<b>VALIDITY DATE OF REGISTRATION</b>	16/07/2021 - 15/07/2026

## LIST OF DEVICE

MEDICAL DEVICE AUTHORITY

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