

DEVICE DETAILS		
NAME OF DEVICE	Surgical Face Mask	
ESTABLISHMENT NAME	RESPACK MEDICARE SDN BHD	
ROLE OF ESTABLISHMENT	MANUFACTURER	
REGISTRATION NO	GA6148221-63080	
BRAND NAME	RESPACK	
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES	
DEVICE GROUPING TYPE	SINGLE	
DEVICE DESCRIPTION	Surgical Face Masks are made of non-woven fabric, melt-blown, nose bending and ear strap. 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	Surgical 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 REGISTRATIO	N 08/06/2021 - 07/06/2026	

LIST OF DEVICE		
NO	NAME OF DEVICE	IDENTIFIER
1	Surgical Face Mask	Class 1-Respack-Surgical Face Mask