



DEVICE DETAILS

NAME OF DEVICE	RH 3 PLY DISPOSABLE MEDICAL FACE MASK
ESTABLISHMENT NAME	PECCA LEATHER SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA3557320-47913
BRAND NAME	RH
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Elastic earlobe for comfortable wear, adjustable nose bar for perfect fitting, soft and breathable material
DEVICE INTENDED PURPOSE	It is intended for single use by operating room personnel, other general healthcare and public users to protect against transfer of microorganisms, blood, body fluid and airborne particulates. Justification: Manufacturer follows the USFDA Guidance Document on Surgical Masks - Premarket Notifications [510(k)] Submissions. This document and the results of laboratory tests conducted are attached with "Any Additional Information".
VALIDITY DATE OF REGISTRATION	08/10/2020 - 07/10/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	RH 3 PLY DISPOSABLE MEDICAL FACE MASK	PH-102