



DEVICE DETAILS

NAME OF DEVICE	Surgical Face Mask
ESTABLISHMENT NAME	U CARE PROTECTION INDUSTRIES SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA3523522-94730
BRAND NAME	Surgical Face Mask / Daxxo
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	A single use non sterile and latex free device made of 2 layer of non woven and 1 layer of melt blown. Adjustable to fit faces of various shapes and sizes. The middle layer of face mask (Melt blown) which tested for Bacterial Filtration Efficiency that has sufficient protection against haze particles, dust and harmful droplets. It also high breathability, hypoallergenic, soft and lightweight. This device is appropriate to be use by healthcare professional during surgical procedures to protect both the patient and healthcare personnel.
DEVICE INTENDED PURPOSE	A disposable single use surgical face mask is to be used as a barrier to prevent air-borne transfer of infectious, large particle droplets and various micro-organisms. It is designed to be used in hospital, clinic, operating theatre, dental, cleanroom and critical environment.
VALIDITY DATE OF REGISTRATION	16/06/2022 - 15/06/2027



LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	KF99+ Surgical Mask	DX99101
2	KF99+ Surgical Mask	DX99103
3	KF99+ Surgical Mask	DX99104