



DEVICE DETAILS

NAME OF DEVICE	KF94 3D 4PLY FACE MASK
ESTABLISHMENT NAME	CONCEPT HERO SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA9609922-89331
BRAND NAME	W+MEDTRONIC
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The 4 ply surgical mask with an added extra layer with one more filtering layer. They also have adjustable nose strip to give maximum protection and comfort to the user. With an added extra layer ensuring that you remain protected with 98% bacterial and particle filtration. A melt blown layer is critical as a filter because it provides a layer that contains droplets by electrostatically absorbing them on the surface. This makes it so that dust, particles, and bacteria cannot infiltrate the mask.
DEVICE INTENDED PURPOSE	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions. To be used as a barrier to prevent air-borne transfer of bacteria and particles. It is designed to be use in hospital, dental clinic, operating theater and etc especially by the surgeon / doctors / Nurse and the patient.
VALIDITY DATE OF REGISTRATION	04/04/2022 - 03/04/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	KF94 Disposable 3D 4ply Face Mask	FM-KF94-W+-M-200
2	KF94 Disposable 3D 4ply Face Mask	FM-KF94-W+-M-220