



DEVICE DETAILS

NAME OF DEVICE	KN95 MEDICAL FACE MASK
ESTABLISHMENT NAME	ONEWORLD CORPORATE (M) SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA7339621-75836
BRAND NAME	SURGIPLUS
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	KN95 Medical face mask is to be use by healthcare professional during procedures to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. - BFE >95% FFP2 5 -layers surgical & protective mask - Barrier layer: Non-woven fabric blocking large particles - Filtration layer:Melt-blown layer adsorb small particles - Filtration layer: Electrostatic capture of PM0.3 particles
DEVICE INTENDED PURPOSE	This KN95 Medical Face Mask effectively filters to serve as barrier to potential air pollutants that can be harmful to patient /surgeon and healthcare personnel. The face mask's filtration efficiency of 5 layers is intended to prevent air pollutants like allergens, virus, bacteria, dust, droplets and other harmful non-oil based particles in the air. The Face mask is Suitable to be used in Surgical Room , Medical Clinic and Hospitals
VALIDITY DATE OF REGISTRATION	13/10/2021 - 12/10/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	KN95 MEDICAL FACE MASK	KN95 Mask (5ply)