



DEVICE DETAILS

NAME OF DEVICE	FACE MASK
ESTABLISHMENT NAME	ONE GOLD TRADING
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA8463021-53107
BRAND NAME	I-TEC
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Face Mask is intended to be worn by health professionals during surgery and certain health care procedures to catch microorganisms shed in liquid droplets and aerosols from the wearer's mouth and nose. The medical personnel are dressed with them in operation so that the blood, body fluid and exudation of patients, which has potential infection, can be obstructed effectively to prevent the bacteria infection. All parts of the products and processing materials are used to meet the requirements of medical materials, no pyrogen, convenient use, safety, etc.
DEVICE INTENDED PURPOSE	Face Mask is intended to be worn by health professionals during surgery and certain health care procedures to catch microorganisms shed in liquid droplets and aerosols from the wearer's mouth and nose. The medical personnel are dressed with them in operation so that the blood, body fluid and exudation of patients, which has potential infection, can be obstructed effectively to prevent the bacteria infection.
VALIDITY DATE OF REGISTRATION	22/01/2021 - 21/01/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	DISPOSABLE FACE MASK	ITM-D08
2	MEDICAL FACE MASK	ITM-M05
3	MEDICAL KIDS MASK	ITM-K09
4	SURGICAL MASK	ITM-S03
5	SURGICAL MASK	ITM-S09