



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	SMARTOPTZ PLT
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC10537221-68594
BRAND NAME	MBH
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	The Fingertip Pulse Oximeter determines functional oxygen saturation of arterial hemoglobin (SpO ₂) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.
DEVICE INTENDED PURPOSE	The Fingertip Pulse Oximeter is indicated for use in measuring oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate. It is intended for patients during no-motion condition. The patients are limited to adults and children (weight above 40kg or 88lb). The device is indicated for non-invasive spot checking.
VALIDITY DATE OF REGISTRATION	07/08/2021 - 06/08/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	FINGERTIP PULSE OXIMETER	TD-8255