



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	K-ONE MEDITECH SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC8924622-95826
BRAND NAME	MEDKAIRE
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Fingertip Pulse Oximeter for single use, Brand name: "Medkaire" and model is PC060B1. The intended use and indication in its label as show instruction for use of the Fingertip Pulse Oximeter. Mark with CE with certification and the label-used language must be in accordance with the EC requirements.
DEVICE INTENDED PURPOSE	This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through a patient's finger. It is applicable for spot-checking SpO2 and pulse rate of adult and pediatric patients in homes and medical clinics. The Fingertip Oximeter is small in size, low power consumption, convenient to use and easy to carry. You just need to put a finger into the sensor of the device, the SpO2 value will appear in the screen immediately.
VALIDITY DATE OF REGISTRATION	20/06/2022 - 19/06/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	FINGERTIP PULSE OXIMETER	PC060B1