Public Search

Malaysia Medical Device Register (MMDR)

DEVICE DETAILS

NAME OF DEVICE	FINGER PULSE OXIMETER
ESTABLISHMENT NAME	PENMED MARKETING SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB6942221-72898
BRAND NAME	SHENZHEN FITFAITH TECHNOLOGY CO., LTD.
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Finger Pulse Oximeter Model: M100, M110, M120, M130, M150, M160, M170. Classification: Class IIa, Rule 10 ACCORDING TO ANNEX IX OF THE MDD 93/42/EEC. Parameters measured by the oximeter include: arterial oxygen (SpO2), pulse rate (PR), bargraph and plenthysmogram. The security classification of the M100 system software is class B, that is it won't cause serious damage. Before measuring those parameters, select a suitable site for the oximeter, for example the users index finger. Alternative sites recommended are the thumb, large toe or little finger. The material which contact with the body parts is silicone without any medical substance, tissue or blood products, and it is non sterile and latex free. Users contact materials have undergone extensive biocompatibility testing. The M100 series oximeter is operated and controlled by the buttons on the top. It adopts a 0.96 inch color OLED screen in displaying measurements and in supplementary status indication.
DEVICE INTENDED PURPOSE	This product is suitable for the hospital (including surgery, paediatrics, and clinical use), and community health care, etc. The product is not suitable for monitoring patient in ICU.
VALIDITY DATE OF REGISTRATION	20/09/2021 - 19/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Finger Pulse Oximeter	M170
2	Finger Pulse Oximeter	M120