

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 TH MDD 93/42/EEC. Parameters measured by the oximeter include: arterial oxygen (SpO2), pulse rate (PR), bargraph and plenthysmogram. The secur 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		
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	20/09/2021 - 19/09/2026		

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

REGISTRATION