



DEVICE DETAILS

NAME OF DEVICE	FINGERTIP PULSE OXIMETER
ESTABLISHMENT NAME	REANNEQ SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC2559524-183885
BRAND NAME	OUSON
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The Fingertip Pulse Oximeter is a non-invasive device intended for measure oxygen saturation (SpO2) and pulse rate of adults and children. This oximeter is intended for use in home, hospital, clinical institution, healthcare community. The oximeter is NOT design for newborn and infant. The product is suitable for adults or children (Weight should be between 25kg to 110kg). The safety and performance of this device comply with standard IEC/EN 60601-1, ISO 80601-2-61.
DEVICE INTENDED PURPOSE	The Fingertip Pulse Oximeter is a non-invasive device intended for measure oxygen saturation (SpO2) and pulse rate of adults and children. This oximeter is intended for use in home, hospital, clinical institution, healthcare community. The oximeter is NOT design for newborn and infant. The product is suitable for adults or children (Weight should be between 25kg to 110kg). The safety and performance of this device comply with standard IEC/EN 60601-1, ISO 80601-2-61.
VALIDITY DATE OF REGISTRATION	17/09/2024 - 16/09/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fingertip Pulse Oximeter	BSX 231
2	Fingertip Pulse Oximeter	BSX 233