



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	FINGERTIP PULSE OXIMETER
<b>ESTABLISHMENT NAME</b>	REANNEQ SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GC2559524-183885
<b>BRAND NAME</b>	OUSON
<b>MEDICAL DEVICE CATEGORY</b>	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	The Fingertip Pulse Oximeter is a non-invasive device intended for measure oxygen saturation (SpO <sub>2</sub> ) 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.
<b>DEVICE INTENDED PURPOSE</b>	The Fingertip Pulse Oximeter is a non-invasive device intended for measure oxygen saturation (SpO <sub>2</sub> ) 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.
<b>VALIDITY DATE OF REGISTRATION</b>	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