



DEVICE DETAILS

NAME OF DEVICE	MASIMO PULSE OXIMETER SENSORS
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC484561060118
BRAND NAME	MASIMO
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>MASIMO SET SENSORS: THE SERIES OF SENSORS ARE MULTI-WAVELENGTH SENSORS USED TO DISTINGUISH BETWEEN OXYGENATED BLOOD, DEOXYGENATED BLOOD, BLOOD WITH CARBON MONOXIDE, AND BLOOD WITH OXIDIZED HEMOGLOBIN. SIGNAL DATA IS OBTAINED BY PASSING VARIOUS VISIBLE AND INFRARED LIGHTS (7+ LIGHT-EMITTING DIODES (LED%U2019S)) THROUGH A CAPILLARY BED (FOR EXAMPLE, A FINGERTIP, A HAND, A FOOT) AND MEASURING CHANGES IN LIGHT ABSORPTION DURING THE BLOOD PULSATILE CYCLE. THE PHOTODETECTOR RECEIVES THE LIGHT, CONVERTS IT INTO AN ELECTRONIC SIGNAL AND SENDS IT TO THE INSTRUMENT FOR CALCULATION AND DISPLAY OF FUNCTIONAL OXYGEN SATURATION (SPO2), PULSE RATE, FRACTIONAL CONCENTRATIONS OF CARBOXYHEMOGLOBIN (SPCO), METHEMOGLOBIN (SPMET), AND/OR TOTAL HEMOGLOBIN (SPHB), AND/OR FRACTIONAL OXYGEN SATURATION* (SPFO2). THE RAINBOW SERIES OF SENSORS (AND CABLES) ARE INDICATED FOR SPOT-CHECKING AND/OR CONTINUOUS NONINVASIVE MONITORING OF FUNCTIONAL/ARTERIAL OXYGEN SATURATION (SPO2), CARBOXYHEMOGLOBIN SATURATION (SPCO), METHEMOGLOBIN SATURATION OF ARTERIAL HEMOGLOBIN (SPMET), AND/ OR TOTAL HEMOGLOBIN CONCENTRATION (SPHB), AND/OR FRACTIONAL OXYGEN SATURATION (SPFO2), AND OXYGEN CONTENT, AND PULSE RATE, FOR ADULT, PEDIATRIC, INFANT, AND/ OR NEONATAL PATIENTS IN HOSPITALS, HOSPITAL-TYPE FACILITIES, MOBILE, AND HOME ENVIRONMENTS. MASIMO SET SENSORS: THE M-LNCS SERIES OF SPO2 PULSE OXIMETRY SENSORS MEASURE THE LIGHT ABSORPTION OF BLOOD FROM TWO LIGHT EMITTING DIODES (LED%U2019S). OXYGEN SATURATED BLOOD ABSORBS LIGHT DIFFERENTLY AS COMPARED TO UNSATURATED BLOOD. THE AMOUNT OF LIGHT ABSORBED BY THE BLOOD IS USED TO CALCULATE THE RATIO OF OXYGENATED HEMOGLOBIN TO TOTAL HEMOGLOBIN IN ARTERIAL BLOOD.</p>
DEVICE INTENDED PURPOSE	<p>THE SENSORS ARE INDICATED FOR THE CONTINUOUS NON-INVASIVE MONITORING OF ARTERIAL SATURATION (SPO2), ARTERIAL CARBOXYHEMOGLOBIN SATURATION (SPCO&reg;), ARTERIAL METHEMOGLOBIN SATURATION (SPMET&reg;) AND PULSE RATE. THE SENSORS ARE FOR USE WITH INSTRUMENTS CONTAINING MASIMO TECHNOLOGY OR LICENSED TO USE COMPATIBLE SENSORS.</p>
VALIDITY DATE OF REGISTRATION	16/07/2023 - 15/07/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		

