



DEVICE DETAILS

NAME OF DEVICE	RAD-G PULSE OXIMETER
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC1159221-57852
BRAND NAME	MASIMO
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The Rad-G Pulse Oximeter is a rugged, portable, handheld device with a rechargeable battery and LCD display. Leveraging clinically proven Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry technology, Rad-G delivers a high-quality and reliable monitoring solution that empowers clinicians to quickly assess patients and make informed care decisions even in low-resource settings.
DEVICE INTENDED PURPOSE	The Rad-GTM Pulse Oximeter and Accessories are intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), Pulse Rate (PR), and Pleth Respiration Rate (RRp). The Rad-GTM Pulse Oximeter and Accessories are indicated for noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and Pulse Rate (PR) of adult, pediatric, infant, and neonate patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, transport, and home environments. The Rad-GTM Pulse Oximeter and Accessories are indicated for the noninvasive spot-checking or continuous monitoring of Respiration Rate from the photoplethysmogram (RRp) of adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, transport, and home environments.
VALIDITY DATE OF REGISTRATION	22/03/2021 - 21/03/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Rad-G Pulse Oximeter	9847
2	Rad-G Pulse Oximeter	9849
3	Rad-G SpO ₂ Reusable Finger Clip Sensor	4325
4	Rad-G YI SpO ₂ Multisite Reusable Sensor	4653
5	RD SET Rad-G-1.5 RD SET Series Patient Cable	4772

NO	NAME OF DEVICE	IDENTIFIER
6	RD SET Rad-G-5 RD SET Series Patient Cable	4773
7	RD SET Rad-G-12 RD SET Series Patient Cable	4774

