

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 (SpO2), 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 (SpO2) 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 SpO2 Reusable Finger Clip Sensor	4325	
4	Rad-G YI SpO2 Multisite Reusable Sensor	4653	
5	RD SET Rad-G-1.5 RD SET Series Patient Cable	4772	
6	RD SET Rad-G-5 RD SET Series Patient Cable	4773	

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

