



DEVICE DETAILS

NAME OF DEVICE	MASIMO RAD-97 PULSE CO-OXIMETER
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
REGISTRATION NO	GC7505721-58612
BRAND NAME	MASIMO
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The Rad-97 Pulse CO-Oximeter is a non-invasive device intended to monitor functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), perfusion index (Pi), and Pleth Variability Index (PVi) along with optional non-invasive measurements of total hemoglobin (SpHb), carboxyhemoglobin (SpCO), total oxygen content (SpOC), methemoglobin (SpMet), Acoustic Respiration Rate (RRa), Oxygen Reserve Index (ORi) and Pleth Respiration Rate (RRp).
DEVICE INTENDED PURPOSE	The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RR). The Masimo Rad-97 and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. In addition, the Masimo Rad-97 and Accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Rad-97 and Accessories for functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR) to multi-parameter devices for the display on those devices.
VALIDITY DATE OF REGISTRATION	31/03/2021 - 30/03/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		