



DEVICE DETAILS

NAME OF DEVICE	MIGHTYSAT FINGERTIP PULSE OXIMETERS
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
REGISTRATION NO	GC8596221-51719
DESCRIPTION	The MightySat Fingertip Pulse Oximeter are designed for noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO ₂), Pulse Rate (PR), and Perfusion Index (PI), and Pleth Variability Index (PVI), and optional Respiratory Rate from the Pleth (RRp). The following key features are available for the MightySat Rx: • Masimo SET technology for SpO ₂ and pulse rate monitoring in motion and low perfusion environments. • Optional Bluetooth LE wireless technology for the wireless transfer of patient data to smart devices.
DEVICE GROUPING TYPE	Family
INTENDED PURPOSE	The Masimo MightySat Rx Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments, and transport. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients.
VALIDITY DATE OF REGISTRATION	06-01-2021 - 05-01-2026

LIST OF DEVICE

#	NAME OF DEVICE	IDENTIFIER
1	MightySat Rx Fingertip Pulse Oximeter, non bluetooth	9707
2	MightySat Rx Fingertip Pulse Oximeter, bluetooth	9807
3	MightySat Rx Fingertip Pulse Oximeter, bluetooth and PVI	9907
4	MightySat Fingertip Pulse Oximeter, non bluetooth	9701
5	MightySat, fingertip pulse oximeter, bluetooth	9801
6	MightySat, fingertip pulse oximeter, bluetooth and PVI	9901
7	MightySat Rx Fingertip Pulse Oximeter	9709
8	MightySat Rx Fingertip Pulse Oximeter	9909
9	MightySat Rx Fingertip Pulse Oximeter	9809

#	NAME OF DEVICE	IDENTIFIER
10	Masimo Profesion Health App IOS	24714
11	Masimo Profesion Health App (Andrioid)	24716
12	iSpO2 Rx (Android)	24717
13	iSpO2 Rx App(iOS)	24715

