



DEVICE DETAILS

NAME OF DEVICE	MASIMO O3 REGIONAL OXIMETER SYSTEM
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC5363421-59812
BRAND NAME	MASIMO
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	The O3 Regional Oximeter System (O3 System), which consists of the O3 Module and O3 Sensor, is a patient-connected, noninvasive oximeter designed to continuously measure and monitor regional hemoglobin oxygen saturation in the tissue (rSO ₂). It can be used in any hospital and hospital-type facility where rSO ₂ measurements might improve patient outcomes.
DEVICE INTENDED PURPOSE	The non-invasive Masimo O3® Regional Oximeter System and accessories are indicated for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood (rSO ₂) in the cerebral region under the sensors in patients in healthcare environments. The O3 Regional Oximeter is only to be used with Masimo O3 sensors. When used with the O3 Adult Sensor, the O3 Regional Oximeter is indicated for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO ₂) in adults ≥ 40 kg. When used with the O3 Pediatric Sensor, the O3 Regional Oximeter is indicated for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO ₂) in pediatrics ≥ 5 kg and < 40 kg. When used with the O3 Neonatal Sensor, the O3 Regional Oximeter is indicated for measuring only trending regional hemoglobin oxygen saturation of blood (rSO ₂) in neonates < 10 kg.
VALIDITY DATE OF REGISTRATION	20/04/2021 - 19/04/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	O3 Regional Oximeter	9637
2	O3 Sensor	3756
3	O3 Pediatric Sensor	4235
4	O3 Infant and Neonatal Sensor	4384
5	O3 Regional Oximeter (D8)	4496
6	O3 Regional Oximeter	4431

