



DEVICE DETAILS

NAME OF DEVICE	MASIMO O3 REGIONAL OXIMETER SYSTEM
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC8312426-231596
BRAND NAME	MASIMO
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
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 tissue under the sensors in patients in healthcare environments. The O3 Regional Oximeter is only to be used with Masimo O3 sensors. The use of any other sensor is not supported or recommended by Masimo and could give erroneous results. 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 ≥ 40kg. 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) on cerebral sites and trending rSO ₂ on non-cerebral sites 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) on cerebral sites and trending rSO ₂ on non-cerebral sites in neonates < 10kg. The ΔcHb, ΔO ₂ Hb, ΔHHb provided as part of the Masimo O3 are indicated for the monitoring of the relative hemoglobin changes of oxygenated hemoglobin (ΔO ₂ Hb), deoxygenated hemoglobin (ΔHHb), and total hemoglobin (ΔcHb) as measured from the Masimo O3 sensor when applied to the cerebral tissue in adults.
VALIDITY DATE OF REGISTRATION	29/04/2026 - 28/04/2031

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		