



## DEVICE DETAILS

|                                      |   |
|--------------------------------------|---|
| <b>NAME OF DEVICE</b>                | MASIMO O3 REGIONAL OXIMETER SYSTEM  |
| <b>ESTABLISHMENT NAME</b>            | NYPRAX BUSINESS SOLUTIONS   |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE   |
| <b>REGISTRATION NO</b>               | GC5363421-59812   |
| <b>BRAND NAME</b>                    | MASIMO  |
| <b>MEDICAL DEVICE CATEGORY</b>       | MD 1302 - Monitoring devices of vital physiological parameters  |
| <b>DEVICE GROUPING TYPE</b>          | SYSTEM  |
| <b>DEVICE DESCRIPTION</b>            | 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 <sub>2</sub> ). It can be used in any hospital and hospital-type facility where rSO <sub>2</sub> measurements might improve patient outcomes.  |
| <b>DEVICE INTENDED PURPOSE</b>       | 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 <sub>2</sub> ) 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 <sub>2</sub> ) 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 <sub>2</sub> ) 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 <sub>2</sub> ) in neonates < 10 kg. |
| <b>VALIDITY DATE OF REGISTRATION</b> | 20/04/2021 - 19/04/2026   |

## LIST OF DEVICE

| NO                | NAME OF DEVICE | IDENTIFIER |
|-------------------|----------------|------------|
| No results found. |                |            |