



## DEVICE DETAILS

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| NAME OF DEVICE                | FINGERTIP PULSE OXIMETER  |
| ESTABLISHMENT NAME            | SMARTOPTZ PLT   |
| REGISTRATION NO               | GC10537221-68594  |
| BRAND NAME                    | MBH   |
| DEVICE GROUPING TYPE          | SINGLE  |
| DEVICE DESCRIPTION            | The Fingertip Pulse Oximeter determines functional oxygen saturation of arterial hemoglobin (SpO <sub>2</sub> ) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate. |
| DEVICE INTENDED PURPOSE       | The Fingertip Pulse Oximeter is indicated for use in measuring oxygen saturation of arterial hemoglobin (SpO <sub>2</sub> ) and pulse rate. It is intended for patients during no-motion condition. The patients are limited to adults and children (weight above 40kg or 88lb). The device is indicated for non-invasive spot checking.  |
| VALIDITY DATE OF REGISTRATION | 07/08/2021 - 06/08/2026   |

## LIST OF DEVICE

| NO | NAME OF DEVICE           | IDENTIFIER |
|----|--------------------------|------------|
| 1  | FINGERTIP PULSE OXIMETER | TD-8255    |