

| FILE NO:DQA/DEL/MEC/GeM/TP/143(12)(Patient exam & monitoring product-UNSPSC:4218 | | | | | | | |
|---|---|----|---|--------------|----------|------|-------------|
| Sub Product Category - Pulse oximeter UNSPSC CODE 421818 | | | | | | | |
| Product category - Pulse oximeter units, line powered UNSPSC CODE 42181801 ITC-HS Code : 90189019 | | | | | | | |
| (*Demand aggregation to be done on UNSPSC code) | | | | | | | |
| S No. | Parameters | | Value 1 | Remarks | Priority | unit | Validation |
| 1 | GMDN name and Code | CH | Pulse oximeter CT 1446 | | | | |
| 2 | Pulse Oxymeter, line Powered:A mains electricity (AC-powered) photoelectric device intended for the continuous transcutaneous measurement and display of haemoglobin oxygen saturation (SpO2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO2 values and may calculate / display other parameters, e.g., pulse rate, electrocardiogram (ECG). The device is typically used at the bedside. | CH | 0 | | | | |
| 3 | SpO2 measurement range at least 40-70 and 70 to 99 %, minimum gradation 1% | CH | yes | | | | |
| 4 | Accuracy of SpO2 better than $\pm 1\%$ for range 40-70 and better than $\pm 3\%$ for range 70-99. | Ch | yes | | | | |
| 5 | Pulse rate range at least 30 to 240 bpm, minimum gradation 1 bpm | CH | yes | | | | |
| 6 | Accuracy of pulse rate better than ± 5 bpm | CH | yes | | | | |
| 7 | Signal strength or quality to be visually displayed | ch | yes | | | | |
| 8 | Audiovisual alarms required: high and low SpO2 and pulse rate (operator variable settings), sensor disconnected,sensor failure, low battery | Ch | yes | | | | |
| 9 | Display type | | TFT Screen | | | | |
| 10 | Memory | | Minimum 24 hrs trend memory for SpO2 & PR | | | | |
| 11 | User's interface | | Easily accessible touch button to operate the machine | | | | |
| 12 | Inbuilt Software and/or standard of communication | | yes | | | | |
| 13 | weight | N | | must declare | | gram | 5000 \leq |

| | | | | | | | |
|----|---|----|--|-----------------------|--|-------|-----|
| 14 | Mobility, portability | CH | Protective splashproof case for clean storage and safe transport | | | | |
| 15 | Display must allow easy viewing in all ambient light levels | Ch | yes | | | | |
| 16 | Noise Level | N | | must declare | | dba | 50≤ |
| 17 | Heat Dissipation: Should maintain nominal Temp and the heat should be dispersed through a exhaust cooling fan | Ch | yes | | | | |
| 18 | power input and frequency | CH | 220 to 240V, 50 Hz | | | | |
| 19 | Power consumption | N | | must declare | | watt | |
| 20 | Power cable length | N | 3 | | | meter | |
| 21 | Electrical protection provided by fuses in both live and neutral supply lines. | CH | yes | | | | |
| 22 | Operating condition: Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. | CH | yes | | | | |
| 23 | STANDARDS AND SAFETY: Should be FDA / CE approved product ISO 80601-2-61-2011: Medical Electrical equipment- part 2-61: Particular requirements for the basic safety and essential performance of pulse oxymeter. Electrical safety conforms to standards for electrical safety IEC-60601-1, EMC safety confirms to IEC 60601-1-2 standard requirement; | CH | yes | | | | |
| 24 | Warranty | CH | 3 years warranty & one year with min. 3 free servicing. | | | | |
| 25 | Others: List of important spare parts and accessories with their part number and costing. Certificate of Calibration and Inspection to be provided | CH | YES | | | | |
| | Approved By | | Moderated By | Prepared By | | | |
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