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Global FDA-cleared Wearable Pulse Oximeter Market Growth 2026-2032

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Abstracts

The global FDA-cleared Wearable Pulse Oximeter market size is predicted to grow from US$ 1148 million in 2025 to US$ 1748 million in 2032; it is expected to grow at a CAGR of 6.2% from 2026 to 2032.

In 2025, global FDA-cleared Wearable Pulse Oximeter production reached approximately 3925 k units with an average global market price of around US$299 per unit. Single-line annual production capacity averages 125 k units with a gross margin of approximately 38%. The upstream of the FDA-cleared Wearable Pulse Oximeter industry primarily consists of electronic components such as microprocessors, sensors, and batteries, as well as precision molds and packaging materials, which are concentrated in the field of electronic information manufacturing. In terms of downstream applications, medical decision-making accounts for approximately 40%, daily monitoring for about 50%, and other applications for around 10%. The market demand for these devices continues to grow, particularly with the increasing global health awareness and the aging population trend. The business opportunities are primarily reflected in technological innovation, market expansion, and service upgrades, with the industry expected to enter a period of rapid development.

A FDA-cleared wearable pulse oximeter represents a specific regulatory and technical designation. Unlike general wellness devices or those with only CE marking, it has undergone the U.S. Food and Drug Administration's 510(k) premarket notification process or De Novo classification. This clearance is contingent upon the device demonstrating substantial equivalence to a legally marketed predicate device in terms of its intended use and technological characteristics, or establishing safety and effectiveness for a new type of device. The core substantiation involves rigorous validation of its measurement accuracy (SpO2 and pulse rate) under both controlled

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laboratory conditions and anticipated real-world use scenarios, including motion artifacts and low perfusion states. It must meet predefined performance standards (e.g., ISO 80601-2-61) and provide sufficient clinical data to support its claims. The clearance mandates adherence to Quality System Regulation (QSR), ensuring design controls, manufacturing consistency, and post-market surveillance. The outcome is a device whose functional reliability and safety profile are formally recognized by the FDA for use in measuring physiological oxygen saturation and heart rate. This establishes a higher threshold of verifiable performance and risk management compared to non-cleared wearables, translating to outputs that clinicians and users can rely upon for observational, spot-check, or ongoing monitoring outside clinical settings, with the understanding that it is not typically intended for diagnosis or life-critical alarms without further validation.

United States market for FDA-cleared Wearable Pulse Oximeter is estimated to increase from US$ million in 2025 to US$ million by 2032, at a CAGR of % from 2026 through 2032.

China market for FDA-cleared Wearable Pulse Oximeter is estimated to increase from US$ million in 2025 to US$ million by 2032, at a CAGR of % from 2026 through 2032.

Europe market for FDA-cleared Wearable Pulse Oximeter is estimated to increase from US$ million in 2025 to US$ million by 2032, at a CAGR of % from 2026 through 2032.

Global key FDA-cleared Wearable Pulse Oximeter players cover Nonin Medical, Zacurate, Viatom Technology, OxiWear, Masimo, etc. In terms of revenue, the global two largest companies occupied for a share nearly % in 2025.

LP Information, Inc. (LPI) ' newest research report, the “FDA-cleared Wearable Pulse Oximeter Industry Forecast” looks at past sales and reviews total world FDA-cleared Wearable Pulse Oximeter sales in 2025, providing a comprehensive analysis by region and market sector of projected FDA-cleared Wearable Pulse Oximeter sales for 2026 through 2032. With FDA-cleared Wearable Pulse Oximeter sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US$ millions of the world FDA-cleared Wearable Pulse Oximeter industry.

This Insight Report provides a comprehensive analysis of the global FDA-cleared Wearable Pulse Oximeter landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyzes the strategies of leading global companies with

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a focus on FDA-cleared Wearable Pulse Oximeter portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global FDA-cleared Wearable Pulse Oximeter market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for FDA-cleared Wearable Pulse Oximeter and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global FDA-cleared Wearable Pulse Oximeter.

This report presents a comprehensive overview, market shares, and growth opportunities of FDA-cleared Wearable Pulse Oximeter market by product type, application, key manufacturers and key regions and countries.

Segmentation by Type:

Over-the-counter Pulse Oximeter

Prescription Pulse Oximeter

Segmentation by Monitoring Frequency:

Continuous Monitoring

Spot-check Monitoring

Segmentation by Application:

Medical Decision Making

Daily Monitoring

Others

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This report also splits the market by region:

- Americas
  - United States
  - Canada
  - Mexico
  - Brazil
- APAC
  - China
  - Japan
  - Korea
  - Southeast Asia
  - India
  - Australia
- Europe
  - Germany
  - France
  - UK
  - Italy
  - Russia
- Middle East & Africa

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Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analysing the company's coverage, product portfolio, its market penetration.

Nonin Medical

Zacurate

Viatom Technology

OxiWear

Masimo

Movano Health

BodiMetrics

Medtronic

MightySat Medical

Guangdong Transtek Medical Electronics

Jiangsu Yuyue Medical Equipment and Supply

Contec Medical Systems

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Beijing Lepu Medical

Hunan Cofoe Medical Technology

Key Questions Addressed in this Report

What is the 10-year outlook for the global FDA-cleared Wearable Pulse Oximeter market?

What factors are driving FDA-cleared Wearable Pulse Oximeter market growth, globally and by region?

Which technologies are poised for the fastest growth by market and region?

How do FDA-cleared Wearable Pulse Oximeter market opportunities vary by end market size?

How does FDA-cleared Wearable Pulse Oximeter break out by Type, by Application?

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Figure 86. Global FDA-cleared Wearable Pulse Oximeter Revenue Market Share Forecast by Application (2027-2032)

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