

U.S. Biological Indicators Market Size, Share & Trends Analysis Report By Product (Self-Contained, Strips, Cards / Rapid Readout BIs), By Method (Steam Sterilization, Ethylene Oxide Sterilization), By End Use, And Segment Forecasts, 2026 - 2033

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Abstracts

The U.S. biological indicators market size was estimated at USD 214.15 million in 2025 and is projected to reach USD 334.96 million by 2033, growing at a CAGR of 5.87% from 2026 to 2033. The market is primarily driven by the growing emphasis on sterilization validation and infection control across the healthcare and life sciences industries.

Increasing volumes of surgical procedures and hospital-acquired infection (HAI) prevention initiatives are pushing hospitals, pharmaceutical manufacturers, and medical device companies to adopt reliable sterilization monitoring solutions. Strict regulatory requirements from organizations such as the U.S. Food and Drug Administration and the Centers for Disease Control and Prevention mandate routine monitoring of sterilization processes using biological indicators to ensure their effectiveness in hospitals, laboratories, and pharmaceutical manufacturing facilities.

The U.S. biological indicators industry is driven by rising surgical procedure volumes and the growing emphasis on effective sterilization monitoring across healthcare facilities. As surgical procedures continue to grow in hospitals, ambulatory surgical centers, and specialty clinics, the need to ensure proper sterilization of surgical instruments becomes critical to prevent healthcare-associated infections (HAIs) and maintain patient safety. Biological indicators play a key role in validating sterilization processes such as steam, ethylene oxide, and hydrogen peroxide, ensuring that sterilization cycles effectively eliminate microbial contaminants.

In addition, the growth in elective cosmetic surgeries is further increasing the frequency of sterilization cycles. According to the 2024 Plastic Surgery Statistics Report published by the American Society of Plastic Surgeons, breast augmentation procedures increased from 304,181 in 2023 to 306,196 in 2024, reflecting a 1% year-on-year rise. This increasing surgical throughput is expected to drive the routine adoption of biological indicators as part of standard sterilization monitoring practices in the U.S. healthcare system.

The growth of the U.S. biological indicators industry is supported by rising investments in pharmaceutical and medical device manufacturing nationwide. Several companies are expanding their production capabilities to meet rising domestic demand and comply with stringent regulatory standards for sterile manufacturing. For instance, in April 2025, BDR Pharmaceuticals announced plans to expand its U.S. operations through the acquisition of manufacturing facilities, supported by an investment of USD 100 million.

Similarly, in June 2025, UCB revealed plans to establish a new biologics manufacturing facility in the U.S., with an estimated economic impact of approximately USD 5 billion. Such investments are increasing the need for validated sterilization processes within pharmaceutical and medical device production. Biological indicators play a critical role in confirming the effectiveness of sterilization for products such as injectable drugs, vials, and syringes in pharmaceutical manufacturing, as well as for implantable medical devices, including pacemakers, stents, and orthopedic implants. As a result, the expansion of sterile manufacturing infrastructure in the U.S. is expected to drive consistent demand for biological indicators used in sterilization monitoring.

The increasing availability of advanced automated sterilization monitoring technologies is expected to support the growth of the U.S. biological indicators industry. Healthcare facilities, particularly sterile processing departments (SPDs), are under growing pressure to improve operational efficiency while maintaining strict compliance with regulatory sterilization standards. As a result, many hospitals and healthcare systems are adopting automated solutions that reduce manual, time-consuming monitoring procedures and enhance workflow efficiency. Industry players are introducing innovative systems that enable faster and more reliable sterilization verification.

For instance, the STERRAD VELOCITY BI/PCD System developed by Advanced Sterilization Products offers one of the fastest biological indicator readout times of approximately 15 minutes. The system integrates automated features that streamline several stages of the monitoring process, including guided biological indicator

processing, automatic generation of audit-ready documentation, storage of up to 22,000 BI results, and correlation of sterilizer loads with monitoring data. Such rapid and automated processing can reduce instrument quarantine times by up to 38%, enabling faster turnaround of sterilized instruments and supporting improved sterilization workflow management in U.S. healthcare facilities.

U.S. Biological Indicators Market Report Segmentation

This report forecasts revenue growth at the country levels and provides an analysis of the latest industry trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the U.S. biological indicators market report based on the product, method, and end use:

Product Outlook (Revenue, USD Million, 2021 - 2033)

Self-Contained (Vials/Ampoules)

Strips

Cards / Rapid Readout BIs

Others

Method Outlook (Revenue, USD Million, 2021 - 2033)

Steam Sterilization

Ethylene Oxide Sterilization

Hydrogen Peroxide Sterilization

Irradiation Sterilization (Gamma, E-beam)

Dry Heat Sterilization

End Use Outlook (Revenue, USD Million, 2021 - 2033)

Hospitals & Clinics (CSSD / Infection Control Units)

Ambulatory Surgery Centers (ASCs) & Dental Clinics

Biopharma & Biotech Companies

Medical Device Manufacturers

Contract Sterilization Service Providers

Research & Academic Institutes

Other End Uses

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