

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

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Abstracts

The global biological indicators market size was estimated at USD 572.28 million in 2025 and is projected to reach USD 1,106.24 million by 2033, growing at a CAGR of 8.78% from 2026 to 2033. This growth is attributed to the growing emphasis on sterilization and infection control across healthcare, pharmaceutical, and food industries.

Increasing concerns over hospital-acquired infections (HAIs) and stringent regulatory requirements for validating sterilization processes are boosting demand for reliable and rapid BI solutions. In addition, advancements in rapid-readout and automation technologies, coupled with the rising adoption of sterilization methods in emerging markets, are further accelerating the growth of the market. Stringent regulatory requirements play a pivotal role in driving the biological indicators industry, as global health authorities mandate the validation of sterilization processes across industries such as medical devices, pharmaceuticals, and biotechnology. Biological indicators are the gold standard for confirming sterilization efficacy, making them a necessity for compliance. For instance, the U.S. Food and Drug Administration (FDA) requires medical device manufacturers to demonstrate sterilization validation under 21 CFR Part 820 (Quality System Regulation), while the European Medicines Agency (EMA) and the ISO 11138 standard outline specific criteria for biological indicator use in sterilization assurance. Similarly, compliance with Good Manufacturing Practices (GMP) in pharmaceuticals necessitates biological indicator-based validation for sterilized drug products and equipment. These strict regulatory frameworks ensure patient safety and

product reliability, fueling consistent demand for biological indicators across critical healthcare and life sciences sectors.

The rising burden of hospital-acquired infections (HAIs) is a key factor driving the growth of the biological indicators industry, as healthcare facilities are increasingly focusing on strengthening infection control and sterilization practices. According to the WHO's Global Report on Infection Prevention and Control 2024, a large-scale systematic review of nearly 400 studies estimated the global prevalence of HAIs at around 14% in 2023. Furthermore, a European point prevalence survey conducted in 2022/2023 across 28 EU/EEA countries and three Western Balkan nations/territories reported an adjusted prevalence of 8% for patients with at least one HAI. This growing incidence of HAIs underscores the critical need for reliable sterilization validation, fueling the demand for biological indicators to ensure the effectiveness of sterilization processes over the forecast period.

Global Biological Indicators Market Report Segmentation

This report forecasts revenue growth at global, regional, and 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 global biological indicators market report based on product, method, end use, and region:

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

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

North America

U.S.

Canada

Mexico

Europe

UK

Germany

France

Italy

Spain

Denmark

Sweden

Norway

Asia Pacific

Japan

China

India

Australia

Thailand

South Korea

Latin America

Brazil

Argentina

Middle East & Africa

South Africa

Saudi Arabia

UAE

Kuwait

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