

# Global Biological Indicators Supply, Demand and Key Producers, 2026-2032

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## Abstracts

The global Biological Indicators market size is expected to reach \$ 656 million by 2032, rising at a market growth of 5.8% CAGR during the forecast period (2026-2032).

Biological indicators (BIs), as defined by ANSI/AAMI and ISO, are test systems containing viable microorganisms providing a defined resistance to a specific sterilization process. A biological indicator provides information on whether necessary conditions were met to kill a specified number of microorganisms for a given sterilization process, providing a level of confidence in the process.

Biological Indicators (BIs) play a critical role in sterilization validation and infection control, widely used in medical devices, pharmaceuticals, food processing, and life sciences laboratories. They assess the effectiveness of steam, dry heat, ethylene oxide (EO), hydrogen peroxide, and other sterilization methods, ensuring compliance with ISO 11138, USP, and FDA regulations.

Based on form factor, BIs can be categorized into Self-Contained Biological Indicators (SCBIs), BI Strips, and BI Suspensions. Among them, SCBIs are widely used due to their convenience, reduced contamination risk, and enhanced validation efficiency.

In terms of application, the medical sector dominates the market, as hospitals and medical device manufacturers must routinely validate sterilization equipment like autoclaves and plasma sterilizers. The pharmaceutical industry also has stringent requirements for sterilization, especially in injectable drugs, vaccines, and sterile drug production. Additionally, the food and beverage sector is increasingly adopting BIs to monitor sterilization efficiency in processing equipment, ensuring food safety and regulatory compliance.

Regionally, North America is the largest market, with a share nearly 55%. North America and Europe lead the market due to stringent medical regulations and high industry standards. The Asia-Pacific region (especially China and India) is experiencing rapid growth in the BI market, driven by expanding healthcare and pharmaceutical industries and evolving regulatory frameworks. Latin America and the Middle East are also emerging markets, benefiting from improvements in healthcare infrastructure.

Looking ahead, the BI industry is shifting toward more efficient, intelligent, and automated solutions. Rapid-read BIs, electronic BIs (E-BIs), and smart monitoring systems are gradually replacing traditional methods, reducing manual intervention, accelerating sterilization validation, and improving quality control. As pharmaceutical regulations tighten and medical device standards advance, the demand for BIs is expected to rise, ensuring a more reliable approach to sterilization validation and infection control worldwide.

This report studies the global Biological Indicators demand, key companies, and key regions.

This report is a detailed and comprehensive analysis of the world market for Biological Indicators, and provides market size (US\$ million) and Year-over-Year (YoY) growth, considering 2025 as the base year. This report explores demand trends and competition, as well as details the characteristics of Biological Indicators that contribute to its increasing demand across many markets.

### **Highlights and key features of the study**

Global Biological Indicators total market, 2021-2032, (USD Million)

Global Biological Indicators total market by region & country, CAGR, 2021-2032, (USD Million)

U.S. VS China: Biological Indicators total market, key domestic companies, and share, (USD Million)

Global Biological Indicators revenue by player, revenue and market share 2021-2026, (USD Million)

Global Biological Indicators total market by Type, CAGR, 2021-2032, (USD Million)

Global Biological Indicators total market by Application, CAGR, 2021-2032, (USD Million)

This report profiles major players in the global Biological Indicators market based on the following parameters - company overview, revenue, gross margin, product portfolio, geographical presence, and key developments. Key companies covered as a part of

this study include 3M, Getinge Group, Cantel Medical, Mesa Laboratories, Steris, Fuze Medical, Matachana, Hu-Friedy, Advanced Sterilization, Bag Health Care, etc.

This report also provides key insights about market drivers, restraints, opportunities, new product launches or approvals.

Stakeholders would have ease in decision-making through various strategy matrices used in analyzing the world Biological Indicators market

### **Detailed Segmentation:**

Each section contains quantitative market data including market by value (US\$ Millions), by player, by regions, by Type, and by Application. Data is given for the years 2021-2032 by year with 2025 as the base year, 2026 as the estimate year, and 2027-2032 as the forecast year.

Global Biological Indicators Market, By Region:

United States

China

Europe

Japan

South Korea

ASEAN

India

Rest of World

Global Biological Indicators Market, Segmentation by Type:

Self-Contained Biological Indicator

Biological Indicator Strip

Others

#### Global Biological Indicators Market, Segmentation by Application:

Hospital

Pharma Companies

Others

#### Companies Profiled:

3M

Getinge Group

Cantel Medical

Mesa Laboratories

Steris

Fuze Medical

Matachana

Hu-Friedy

Advanced Sterilization

Bag Health Care

Terragene

Andersen

GKE

### **Key Questions Answered**

1. How big is the global Biological Indicators market?
2. What is the demand of the global Biological Indicators market?
3. What is the year over year growth of the global Biological Indicators market?
4. What is the total value of the global Biological Indicators market?
5. Who are the Major Players in the global Biological Indicators market?
6. What are the growth factors driving the market demand?

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