



# FREEZEmarker®

## Freeze Event Indicator

- Identifies when a potentially damaging freeze event has been experienced for a short period of time.
- Easy-to-read, irreversible visual color change.
- Used to identify and prevent the administration or use of products that can be damaged or lose strength after a freeze event.

FREEZEmarker, manufactured by Temptime, is a single-use indicator that provides an easy-to-read, irreversible visual signal when there has been exposure to a freezing temperature for a short period of time. When the indicator temperature remains above the specified temperature, the green circle with a white checkmark inside the circle is visible. When exposed to temperatures at or below the specified temperature, the green circle with a white checkmark inside the circle will partially or completely change to white opaque/cloudy, showing that a temperature excursion has occurred, and the endpoint has been reached.

FREEZEmarker can be affixed to an individual unit to monitor the product from manufacture to use, or later in the cold chain to monitor the product for a portion of its distribution. Many medical products can be damaged and lose strength if they are frozen. Such excursions can go unnoticed during shipping and storage. Leading medical product manufacturers and distributors use FREEZEmarker.



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## Features

- Irreversible
- Easy to understand
- Single-use
- Multiple Temperature Ranges
- No device activation required
- Nontoxic materials

## Benefits

- Identify and avoid administration of freeze exposed products
- Extend quality management system from manufacturing to ultimate use
- Strengthen conformance to International Code on Harmonization (ICH) Q9 and Q10
- Reduce unnecessary waste by limiting the destruction of products incorrectly suspected of freeze abuse
- Environmentally friendly

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## Performance and Use

### Sensor Specifications

**Response Temperatures:** 0°C / -1°C / -6°C (±2°C)

**Accuracy:** ±1°C

**Response Time:** Within 30 minutes

**Storage Temperature:** Refrigerated temperature (2°C to 8°C)

**Shelf Life:** 2 to 4 years, determined by category

**Usage:** Single use

**Temperature Monitoring:** Continual

**Device Size:** 20mm x 29mm

**Additional Features:** Adhesive backing

### Quality System

- Temptime's quality management system is consistent with FDA Quality System Requirement (QSR) 21 CFR 820 (GMP for medical devices)
- ISO 9001
- ISO 13485



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