

## WHO Immunisation Devices - Performance, Quality & Safety

# **E006: Temperature monitoring devices**

Product name: FREEZEmarker® L

IMD-PQS Code:E006-067Status:PrequalifiedDate of acceptance:08 May 2020

Appliance type: E006

Product description: Chemical Freeze Indicator

Manufacturer: Temptime Corporation, A Zebra Technologies Company

Manufacturers Reference: FREEZEmarker® L
Country of Manufacture: United States of America

Address: 116 American Road, Morris Plains, NJ, 07950, United

States United States of America

**Telephone:** +1 973 630 6000

Email: rorie.doty@zebra.com

Website address: www.zebra.com/tempmonitoring

Valid until: 31 May 2026

## **Specifications**

#### **PRODUCT SPECIFICATIONS - MAIN**

Mode of operationChemicalExternal dimensions height20.00

(mm)

External dimensions width

(mm) CE marking

Yes

29.00 Fixing mechanism

Adhesive

#### MECHANICAL AND ELECTRONIC DEVICES ONLY

Power source Passive device Alarm type NA

Display medium Color Change Indicator Recording medium Not applicable

#### Comments

The FREEZEmarker® Indicator is designed as a single-use self-adhesive indicator that provides an easy-to-read visual signal when there has been exposure to a freeze event. They can be ordered on rolls for label dispensing applications, or on a backing card. The TransTracker® backing card is an example of a single-use unit for monitoring temperature during transportation or short-term storage. The visible surface of the freeze indicator contains an area of color-changing liquid encapsulated in a blister. The FREEZEmarker varies in appearance: Before a Freeze Event, it is a clear liquid covering a green circle with a white checkmark inside the circle; at the Endpoint after a Freeze Event, the liquid will partially or completely change to appear white opaque/cloudy inside the blister. If uncertain whether the Endpoint has been reached, press the Active Zone with your fingertips to evenly distribute the white particles. The surface to which the FREEZEmarker will be applied (carton, card, glass, etc.) must be above 2°C (35.6°F). Standard backing cards with an indicator applied are 86 mm x 54 mm and provided in boxes of 200. Specification: -0.5°C ± 1°C, 60 minutes (maximum) Minimum order: 1 roll Indicators per Roll: 1,000 (standard)

### PRICE AND SHIPPING

Minimum order 1.00 Price 1 On request to manufacturer

**QUALITY STANDARD** 

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001:2015

**Specification Reference** Applicable PQS specification:

PQS/E006/IN07.1 Applicable

PQS VP(s):

**VERIFICATION** 

Verification Laboratory 0013X00004MI8OIQAJ Verification Report Reference LLTPL/TL/2019-02

**PRODUCT SITES** 

Organization name Address

Temptime Corporation, A Zebra Technologies Company 116 American Road, Morris Plains, NJ, 07950, United States

United States of America

Current PQS status: Prequalified Valid until: 31 May 2026

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.