

# WHO Immunisation Devices - Performance, Quality & Safety

# **E006: Temperature monitoring devices**





Product name: HEATmarker® VVM+250

IMD-PQS Code:E006-059Status:PrequalifiedDate of acceptance:28 Mar 2019

Appliance type: E006

Product description: Combined VVM250 and Threshold Indicator40

Manufacturer: Temptime Corporation, A Zebra Technologies Company

Manufacturers Reference: HEATmarker® VVM+250
Country of Manufacture: United States of America

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

United States of America

States

**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 operationChemicalFixing mechanismNoneCE markingYesTime to endpoint at 37°C250.00

(days)

Time to endpoint at 25°C

(days)

900.00 Time to endpoint at 5°C (days) 10000.00

### MECHANICAL AND ELECTRONIC DEVICES ONLY

Power source Passive device Alarm type NA

Display medium Color change Recording medium Not applicable

Comments

The VVM+ Indicator is a single-use, self-adhesive combined indicator that contains an active surface that signals by an irreversible color change from light to dark when either the defined threshold temperature profile has been exceeded or the cumulative heat exposure have been exceeded. Dots (on a clear liner) are made on film facestock. The service temperature range for the adhesive is typically -40°F to 200°F, or wider. Liner PET is designed for high speed roll-to-roll and label dispensing applications. Standard Label Size: 10.5 mm dot (circle) Indicators per Roll: 10,000 (standard)

#### PRICE AND SHIPPING

Minimum order 50000.00 Incoterms EXW

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/IN06.1 Applicable

PQS VP(s): E006/IN06-VP.1

**VERIFICATION** 

Verification Laboratory 0013X00004MI8OIQAJ Verification Report Reference LLTPL/TL/2018-02

LLTPL/TL/2018-03

PRODUCT SITES

Organization name Temptime Corporation, A Zebra Technologies Company

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.