

WHO Immunisation Devices - Performance, Quality & Safety

E006: Temperature monitoring devices





HEATmarker® VVM 250 Product name:

IMD-PQS Code: F006-058 Status: Prequalified 27 Mar 2019 Date of acceptance:

E006 Appliance type:

Product description: Vaccine Vial Monitor Type 250

Temptime Corporation, A Zebra Technologies Company Manufacturer:

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

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

> States United States of America

+1 973 630 6000

Telephone: Email: rorie.doty@zebra.com

Website address: www.zebra.com/tempmonitoring

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Mode of operation Chemical Fixing mechanism None 250.00 **CE** marking Time to endpoint at 37°C Yes

(days)

Time to endpoint at 25°C

(days)

900.00

MECHANICAL AND ELECTRONIC DEVICES ONLY

Passive device NA Power source Alarm type

Display medium Color change Recording medium Not applicable

Comments Title: Vaccine Vial Monitor Type 250 Dots (*on clear or brown 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. Custom solutions including a combination of approved litho/paper/film substrate and over-laminate (if applicable) are available upon request. Note: - Time to endpoint at 25°C (days): > 900 days - Time to endpoint - VVM (Arrhenius) reaction rates determined at 55°C and 45°C; the values are approximate External

dimensions (cm): 0

PRICE AND SHIPPING

EXW Minimum order 50000.00 Incoterms

Year of base price 2019

QUALITY STANDARD

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

Applicable PQS specification: **Specification Reference**

E006/IN05.3 Applicable PQS VP(s): E003/IN05-VP.3

VERIFICATION

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

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.