

WHO Immunisation Devices - Performance, Quality & Safety

E006: Temperature monitoring devices



IMD-PQS Code:E006-001Status:PrequalifiedDate of acceptance:30 Sep 2007

Appliance type: E006

Product description: Vaccine Vial Monitor Type 2

Manufacturer: Temptime Corporation, A Zebra Technologies Company

Manufacturers Reference: HEATmarker® VVM 2
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 operationChemicalSensor type(s)--Maximum sensor lead length0.00Maximum number of sensor0.00

(metres) channels

Chaine

Activation mechanism Temperature >-12°C Fixing mechanism Adhesive

CE marking No Time to endpoint at 37°C 2.00

(days)

Time to endpoint at 5°C (days) 225.00

MECHANICAL AND ELECTRONIC DEVICES ONLY

 Power source
 Passive device
 Battery type
 -

 Battery shelf life (year)
 - Activated battery life
 -

 Alarm type
 NA
 User interface
 -

Display medium Color change Recording medium Not applicable

Ingress protection rating IP --

Comments Full labels (typically white of clear liner) and dots (typically brown or clear liner) are made on

lightweight litho/paper/film facestock offering exceptional printability and flexibility. The service temperature range for the adhesive is typically -40°F to 160°F, or wider. Liner (can either be PET or coated paper) is designed for high-speed roll-to-roll and label dispensing applications. A clear film-based over-laminate is used for dots (brown liner) for added stability and protection. This laminate is not intended to print on. Custom solutions, including a combination of approved litho/paper/film substrate and overlaminate (if applicable) are available upon request. Verification laboratory: Intertek UK (formerly WHO-accredited) Accuracy: -- External dimensions (cm): 1 cm dot or 1.6 x 1.0

cm rectangle Memory size: -- External dimensions (cm): 1 cm dot or 1.6 x 1.0 cm rectangle

PRICE AND SHIPPING

Minimum order500000.00IncotermsEXWPrice 1On request to manufacturerYear of base price2017

QUALITY STANDARD

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

Specification Reference Applicable PQS specification: E006/IN.05.1 Applicable PQS

VP(s): E006/IN.05 VP.1

Verification Report Reference

A65155

PRODUCT SITES

Address

Organization name

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.