

WHO Immunisation Devices - Performance, Quality & Safety

E006: Temperature monitoring devices

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HEATmarker@ VVM 14 Product name:

IMD-PQS Code: F006-054 Prequalified Status: 15 Jun 2018 Date of acceptance:

E006 Appliance type:

Product description: Vaccine Vial Monitor Type 14

Manufacturer: Temptime Corporation, A Zebra Technologies Company

Manufacturers Reference: HEATmarker@ VVM 14 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

channels

(days)

PRODUCT SPECIFICATIONS - MAIN

Mode of operation Chemical Maximum sensor lead length 0.00

(metres)

Maximum number of sensor

0.00

Activation mechanism

Always active

Fixing mechanism

Time to endpoint at 37°C

Time to endpoint at 5°C (days) 1095.00

Adhesive

CE marking Time to endpoint at 25°C Yes 90.00

(days)

MECHANICAL AND ELECTRONIC DEVICES ONLY

N/A Power source Passive device **Battery type** Alarm type NA User interface device itself

Recording medium Display medium Color change Not applicable

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 filmbased 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.

PRICE AND SHIPPING

Minimum order **EXW** 500000.00 Incoterms Price 1 On request to manufacturer Year of base price 2007

QUALITY STANDARD

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

Applicable PQS specification: **Specification Reference**

PQS/E006/IN05.3 Applicable

PQS VP(s):

VERIFICATION

Verification Report Reference A65115

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.