

WHO Immunisation Devices - Performance, Quality & Safety

E006: Temperature monitoring devices



Product name: LIMITmarker ® I-K

IMD-PQS Code:E006-057Status:PrequalifiedDate of acceptance:27 Mar 2019

Appliance type: E006

Product description: Threshold Indicator40

Manufacturer: Temptime Corporation, A Zebra Technologies Company

Manufacturers Reference: LIMITmarker ® I-K

Country of Manufacture: United States of America

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

States

United States of America

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Email: rorie.doty@zebra.com

Website address: www.zebra.com/tempmonitoring

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Mode of operationChemicalFixing mechanismNone

CE marking Yes

MECHANICAL AND ELECTRONIC DEVICES ONLY

Alarm type NA Recording medium Not applicable

Comments * LIMITmarker I-K Threshold Indicator is a single-use self-adhesive indicator that contains an active

surface that signals by an irreversible color change from light to dark when the threshold temperature has been exceeded. LIMITmarker I-K Indicator dots (typically on a clear liner) are made on film facestock. The service temperature range for the adhesive is typically -40°C to 93°C. 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 order50000.00IncotermsEXWPrice 1On request to manufacturerYear of base price2019

QUALITY STANDARD

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

Specification Reference Applicable PQS specification: PQS/F006/IN04 1 Applicable

PQS/E006/IN04.1 Applicable PQS VP(s): E006/IN04-VP.1

VERIFICATION

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.