California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Edan Diagnostics – Vital Signs Monitor (Model M3) Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
01/22/2026	The EDAN Vital Signs Monitor (Model M3) is a portable device used by healthcare professionals to monitor physiological parameters including non-invasive blood pressure (NIBP), oxygen saturation (SpO2), and body temperature.	Edan Diagnostics San Diego, CA, USA	Potential cybersecurity vulnerabilities related to improper IP address configuration identified following an FDA It Has Come to Our Attention (IHCTOA) letter.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Lot Code:** N/A **Model No.:** M3 **UDI-DI:** 06944413800618 **S/N range:** Multiple serial numbers (see full list in recall data).	13,934 Units; Nationwide including California (4,416 units in CA)	October 2025 and prior.

For additional information, please visit the FDA Website.