California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Edan Diagnostics – Central Monitoring System (MFM-CNS, MFM-CNS Lite) Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
01/22/2026	EDAN Central Monitoring System (MFM-CNS and MFM-CNS Lite), clinical data management software used to collect, process, and store fetal monitoring, uterine activity, and maternal vital signs data from bedside monitors.	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.:** MFM-CNS, MFM-CNS Lite **UDI-DI:** **MFM-CNS:** 06944413800236 **MFM-CNS Lite:** 06944413807983 **S/N range:** Multiple serial numbers (see full list in recall data)	395 Units; Nationwide including California (**MFM-CNS**: 5 units in CA; **MFM-CNS Lite**: 58 units in CA)	October 2025 and prior.

For additional information, please visit the FDA Website.