California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

HeartSine Technologies Ltd Recalls HeartSine SAM 350P, HeartSine SAM 360P, and HeartSine SAM 450P

Recall Date	Product Description	Recalling Firm	Recall Reason
7/25/25	HeartSine SAM 350P, HeartSine SAM 360P, and HeartSine SAM 450P; The HeartSine samaritan PAD (Public Access Defibrillator)	HeartSine Technologies Ltd	Due to a component manufacturing issue, Automated External Defibrillator may not function properly (deliver shocks)

Recall Class	Product Identification	Distribution	Affected Dates
II	Product Code Information	Worldwide - U.S. Nationwide distribution including in the states of AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, and WV. The countries of Argentina, Austria, Australia, Brazil, Canada, Chile, Colombia,	June 2025 and prior.

		Costa Rica, Hong Kong, Indonesia, Ireland, Israel, Japan, Malaysia, Mexico, Netherlands, New Zealand, Philippines, Poland, Singapore, South Korea, Taiwan, Thailand, and United Kingdom.	

For additional information, please visit the FDAWebsite