California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Maquet Critical Care AB Recalls Servo-u Ventilator System

Recall Date	Product Description	Recalling Firm	Recall Reason
05/30/25	Servo-u Ventilator System. Model Number: 6688600. Model Number: 6694800.	Maquet Critical Care AB Rontgenvagen 2 Solna Sweden	Potential for inaccurate measurement of the patient circuit compliance during the patient circuit test due to combination of incorrect pre-use leakage test and use of an incorrect active humidifier.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model Number: 6688600. UDI-DI: 07325710001042. All software versions. Model Number: 6694800. UDI-DI: 07325710001110. All software versions.	US Nationwide distribution and Puerto Rico. No international distribution.	May 2025 and prior

For additional information, please visit the FDA Website.