California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

SunMed Holdings, LLC Adult Manual Resuscitator with Medium Adult Mask

Recall Date	Product Description	Recalling Firm	Recall Reason
05/30/2025	Adult Manual Resuscitator with Medium Adult Mask, Bag Reservoir, Filter, Manometer and 7 ft Oxygen Tubing REF: CPRM1116F	SunMed Holdings, LLC	Affected lots were manufactured with B/V Filter incorrectly attached to the wrong port (patient port instead of the exhalation port). If not noticed prior to patient use, there would be interruption or delay in patient resuscitation, which may lead to life threatening consequences, including hypoxia, hypercapnia, organ failure, and death.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI: 10884389164822 (ea), 40884389164823 (case) Lots: 526782 - 526818	11,358 units nationwide	May and prior

For additional information, please visit the FDA Website.