California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Fresenius Kabi USA, LLC Recalls LVP Primary Administration Set

Recall Date	Product Description	Recalling Firm	Recall Reason
8/1/25	LVP Primary Administration Set, Dual-Inlet, Low-Sorbing, Needle-Free Port, Dual Y-Site (Qty 25). Product Code: SET-0032-25.	Fresenius Kabi USA, LLC	Potential for external cassette leaks
8/1/25	LVP Primary Administration Set, Dual-Inlet, Low-Sorbing, Needle-Free Port, Y-Site (Qty 25). Product Code: SET-0013-25.	Fresenius Kabi USA, LLC	Potential for external cassette leaks
8/1/25	LVP Primary Administration Set, Single Outlet Low Sorbing (Qty 25). Product Code: SET-0021-25.	Fresenius Kabi USA, LLC	Potential for external cassette leaks

Recall Class	Product Identification	Distribution	Affected Dates
II	Product Code: SET-0032-25. UDI-DI: 00811505030214. Lot Codes: FA24J03137, FA24J03145, FA24J07013, FA24J07021, FA24J14019, FA24J14027, FA24J21246, FA24J21253, FA24J24141, FA24J24166, FA24J28027, FA24J28035, FA24K01154, FA24K01162, FA24K11039, FA24K11047, FA24K11161, FA24K18034, FA24K18042, FA24K18059, FA24K25229, FA24L03133, FA24L09221, FA24L10203, FA24L11201, FA24L11219, FA24L16010, FA24L16028, FA24L16036, FA24L18180, FA24L19139, FA24L19147.	US Nationwide distribution in the states of CA, CO, DE, FL, GA, ID, IL, MA, MD, MI, MN, MS, NJ, NV, OK, OR, SC, TX, VA, WA, WI. 348,150 units nationwide	June 2025 and prior.
II	Product Code: SET-0013-25. UDI-DI: 00811505030054. Lot Codes: FA24I26149, FA24I30133, FA24I30141, FA24J01131, FA24J01149.	US Nationwide distribution in the states of CA, CO, DE, FL, GA, ID, IL, MA, MD, MI, MN, MS, NJ, NV, OK, OR, SC, TX, VA, WA, WI. 19,225 units nationwide **7,720 units in California**	June 2025 and prior.
II	Product Code: SET-0021-25. UDI-DI: 00811505030108. Lot Codes: FA24K25146, FA24K25153.	US Nationwide distribution in the states of CA, CO, DE, FL, GA, ID, IL, MA, MD, MI, MN, MS, NJ, NV, OK, OR, SC, TX, VA, WA, WI. 35,925 units nationwide	June 2025 and prior.

For additional information, please visit the Z-2235-2025, Z-2232-2025, Z-2234-2025