California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Merit Medical Systems Inc. Recalls K09/K09T (Custom Manifold Kit)

Recall Date	Product Description	Recalling Firm	Recall Reason
8/21/2024	Various Merit Medical convenience kits that contain recalled Jiangsu Shenli Medical Production Co. Ltd. syringes. To support fluid administration into the body. To support various vascular or cardiac diagnostic and interventional procedures.	Merit Medical Systems Inc. South Jordan, UT	Medical convenience kits contain plastic syringes affected by the FDA Safety Alert issued on March 19, 2024. Leaks, breakage, and/ other quality issues have been identified that may pose a risk to patient health.

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog Number/UDI-DI: K09-01467AD/00884450282441, K09-01467AF/00884450750575, K09-08493KP/00884450276860, K09-09403HP/00884450486740, K09-09499B/00884450214794, K09-10060F/00884450199817, K09-11196/00884450218082, K09-11259G/00884450750933, K09-13767/00884450603307	11777 units in California	August 2024 and prior.

For additional information, please visit the FDA Website.