State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Smiths Medical Recalls Endotracheal Tubes for Inadequate Pouch Seal

Recall Date	Product Description	Recalling Firm	Recall Reason
11/3/2021	**Bivona Aire-Cuf Endotracheal Tube**	**Smiths Medical ASD Inc.,** Minneapolis, Minnesota	Inadequate pouch seal leading to a compromised sterile barrier on products with a shaft length of 325mm

Recall Class	Product Identification	Distribution	Affected Dates
II	**Bivona Aire-Cuf Endotracheal Tube** SKU 25W090 Lots #'s 322657 and 3342023	7 units in California	August 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov