California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Ambu Inc. Ambu aScope 5 Broncho HD 5.6/2.8 Sampler Set

Recall Date	Product Description	Recalling Firm	Recall Reason
05/06/2025	Ambu aScope 5 Broncho HD 5.6/2.8 Sampler Set Model Number: 622002000US	Ambu Inc.	Incorrect labeling in which the front red pouch label did not match the actual size of the medical device. The label on the front of the scope incorrectly states 5.0/2.2 while the back label, shipping box and product inside correctly states 5.6/2.8.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model Number: 622002000US UDI-DI: 05707480156542 Lot Number: 1001080963	20 units in California	April and prior

For additional information, please visit the FDA Website.