State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

LumiraDx SteriPack Sterile Polyester Spun Swab for Failed Post-Sterilization Sterile Swabs Cantilever Testing

Recall Date	Product Description	Recalling Firm	Recall Reason
6/21/2023	**SteriPack Sterile Polyester Spun Swabs** (25 units/Pack)- Intended for sample collection in the intended nasal area. Catalog Number: 60566RevB	**LumiraDx** Waltham, MA	Fails Post-Sterilization Sterile Swabs Cantilever (Bend) Testing and may be more susceptible to breakage. If the swab breaks in the nasal cavity of a patient may cause injury or medical intervention to remove part of the swab

Recall Class	Product Identification	Distribution	Affected Dates
II	**SteriPack Sterile Polyester Spun Swabs** GTIN-DI: 00850027193205 Pack Lot Number : 85438; Individual Swab Lot Number: 86445 Exp Date: 28-Oct-2023	284 Units in California	April 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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