State of California—Health and Human Services Agency

# California Department of Public Health

Food and Drug Branch – Device Recalls

## CALIFORNIA DEVICE RECALL INFORMATION SHEET

**Philips Respironics, Inc. Recalls Philips DreamStation Auto BiPAP and CPAP Due to Communication Errors**

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 4/12/2023 | **Philips DreamStation Auto BiPAP and CPAP**<br>1233 devices | **Philips Respironics, Inc.**<br>Murrysville, Pennsylvania | A limited number of remediated Philips DreamStation units may experience communication issues when connecting to the cloud-based care management application. Should this be the case, this may affect the ability to download prescription settings to the device or the device may have incorrect prescription settings for the patient. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| I | **Philips DreamStation Auto BiPAP and CPAP**<br>Model Numbers UCDSX500S11, UDSX500S11, UDSX500S11F, UDSX700S11, UDSX700S11F, UFRX500S14<br>Please check recall listing for Serial Numbers | Nationwide including California | February 2023 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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