

State of California—Health and Human Services Agency

California Department of Public Health



AFL 21-37

September 22, 2021

TO: All Facilities

SUBJECT: BYD Field Action Notification

All Facilities Letter (AFL) Summary

This AFL notifies all facilities that a subset of model DE2322 N95 respirator units that were distributed do not meet the National Institute for Occupational Safety and Health (NIOSH) criteria and should be returned to the manufacturer.

The State was recently informed by BYD Precision Manufacture Co., Ltd. ("BYD") that some N95 masks within specified lot numbers do not meet NIOSH's criteria. The California Department of Public Health is advising all customers who may have received these respirators to inspect and return any nonconforming units using the enclosed instructions.

Per BYD, the particle filtration efficiency (PFE) of a small subset of model DE2322 N95 respirator units may exhibit a slight decrease in PFE below NIOSH's N95 PFE specification, and these nonconforming units do not meet the NIOSH N95 criteria. The nonconforming N95 respirators can be identified using the information in the <u>BYD Field Action Notification</u> (PDF).

BYD is confident that the affected units continue to offer the user protection in the healthcare setting when used as directed. BYD has also established a dedicated team to assist customers with replacing any affected units.

Please contact BYD's Customer Service team for questions, return and replacement at **1-800-293-2886** or **fieldaction@byd.com** (Ref #: FA-0115).

A copy of the <u>BYD Field Action Notification</u> (PDF) is available at: cdn.byd.care/D2322_Field_Action_Customer_Notification.pdf

How to Identify Affected Units:

- 1. **Step 1**: Check to see if the Lot # identified the attached table matches the Lot # on the tracking label on the bottom of your N95 respirator product box.
- 2. <u>Step 2</u>: Check to see if the Serial # identified in the attached table matches the Serial # on the tracking label on the bottom of your N95 respirator product box. In the table attached, where a Serial # digit is marked with "X", it means it does not matter what number is in that digit.
- 3. A unit is an Affected Unit **IF AND ONLY IF** the Lot # and Serial # BOTH MATCH. Otherwise, the unit is NOT an Affected Unit.

If you have any questions about this AFL, please contact the CDPH Duty Officer at DutyOfficer@cdph.ca.gov.

Sincerely,

Original signed by Cassie Dunham

Cassie Dunham

Acting Deputy Director

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