

URGENT: MEDICAL DEVICE FIELD ACTION



BYD PRECISION MANUFACTURE CO., LTD.

Date: *July 27, 2021*

RE: FIELD ACTION CUSTOMER NOTIFICATION
FOR CERTAIN UNITS OF MODEL DE2322 N95 RESPIRATOR

Ref #: _____

Dear Customer:

The purpose of this letter is to advise you that BYD Precision Manufacture Co., Ltd. (“BYD”) has become aware of an issue whereby the particle filtration efficiency (the “PFE”) of a small subset of model DE2322 N95 respirators 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. We have already completed and implemented all corrective actions to prevent recurrence of this issue. The nonconforming N95 respirators are identified in Attachment A-1 (the “Affected Units”).

BYD is confident that the Affected Units continue to offer the user protection in the healthcare setting when used as directed.

BYD’s highest priority is customer satisfaction and industry compliance, and to this end, we have a dedicated team to assist our customers with replacing any Affected Units that are currently in their inventory. Please contact our dedicated Customer Service team for replacement activities at 1-800-293-2886 (telephone) or fieldaction@byd.com (e-mail).

BYD apologizes for any inconvenience this issue may have caused you, and we thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

/s/

Dr. Yubo Guan
Product Manager

Customer Notification

July 27, 2021

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Attachment A-1: List of Affected Units

LOT #	SERIAL #																						
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
6200609	B	1	3	0	2	9	2	2	0	2	0	0	6	0	9	A	X	X	X	X	X	X	X
6200609	B	1	3	0	2	9	2	2	0	2	0	0	6	0	9	S	X	X	X	X	X	X	X
6200610	B	1	3	0	2	9	2	2	0	2	0	0	6	1	0	S	X	X	X	X	X	X	X
6200611	B	1	3	0	2	9	2	2	0	2	0	0	6	1	1	A	X	X	X	X	X	X	X
6200612	B	1	3	0	2	9	2	2	0	2	0	0	6	1	2	S	X	X	X	X	X	X	X
6200613	B	1	3	0	2	9	2	2	0	2	0	0	6	1	3	S	X	X	X	X	X	X	X
6200614	B	1	3	0	2	9	2	2	0	2	0	0	6	1	4	A	X	X	X	X	X	X	X
6200617	B	A	3	0	2	9	2	2	0	2	0	0	6	1	7	X	X	X	X	X	X	X	X
6200619	B	A	3	0	2	9	2	2	0	2	0	0	6	1	9	X	X	X	X	X	X	X	X
6200619	B	6	3	0	2	9	2	2	0	2	0	0	6	1	9	X	X	X	X	X	X	X	X
6200619	B	8	3	0	2	9	2	2	0	2	0	0	6	1	9	X	X	X	X	X	X	X	X
6200620	B	S	3	0	2	9	2	2	0	2	0	0	6	2	0	X	X	X	X	X	X	X	X
6200621	B	A	3	0	2	9	2	2	0	2	0	0	6	2	1	X	X	X	X	X	X	X	X
6200622	B	6	3	0	2	9	2	2	0	2	0	0	6	2	2	X	X	X	X	X	X	X	X
6200623	B	A	3	0	2	9	2	2	0	2	0	0	6	2	3	X	X	X	X	X	X	X	X
6200623	B	6	3	0	2	9	2	2	0	2	0	0	6	2	3	X	X	X	X	X	X	X	X
6200623	B	Z	3	0	2	9	2	2	0	2	0	0	6	2	3	X	X	X	X	X	X	X	X
6200624	B	A	3	0	2	9	2	2	0	2	0	0	6	2	4	X	X	X	X	X	X	X	X
6200624	B	6	3	0	2	9	2	2	0	2	0	0	6	2	4	X	X	X	X	X	X	X	X
6200625	B	A	3	0	2	9	2	2	0	2	0	0	6	2	5	X	X	X	X	X	X	X	X
6200627	B	6	3	0	2	9	2	2	0	2	0	0	6	2	7	X	X	X	X	X	X	X	X
6200627	B	Z	3	0	2	9	2	2	0	2	0	0	6	2	7	X	X	X	X	X	X	X	X
6200628	B	A	3	0	2	9	2	2	0	2	0	0	6	2	8	X	X	X	X	X	X	X	X
6200628	B	S	3	0	2	9	2	2	0	2	0	0	6	2	8	X	X	X	X	X	X	X	X
6200630	B	S	3	0	2	9	2	2	0	2	0	0	6	3	0	X	X	X	X	X	X	X	X
6200701	B	S	3	0	2	9	2	2	0	2	0	0	7	0	1	X	X	X	X	X	X	X	X
6200702	B	6	3	0	2	9	2	2	0	2	0	0	7	0	2	X	X	X	X	X	X	X	X
6200702	B	S	3	0	2	9	2	2	0	2	0	0	7	0	2	X	X	X	X	X	X	X	X
6200703	B	Z	3	0	2	9	2	2	0	2	0	0	7	0	3	X	X	X	X	X	X	X	X
6200703	B	8	3	0	2	9	2	2	0	2	0	0	7	0	3	X	X	X	X	X	X	X	X
6200704	B	6	3	0	2	9	2	2	0	2	0	0	7	0	4	X	X	X	X	X	X	X	X
6200709	B	6	3	0	2	9	2	2	0	2	0	0	7	0	9	X	X	X	X	X	X	X	X
6200710	B	S	3	0	2	9	2	2	0	2	0	0	7	1	0	X	X	X	X	X	X	X	X
6200711	B	Z	3	0	2	9	2	2	0	2	0	0	7	1	1	X	X	X	X	X	X	X	X
6200712	B	8	3	0	2	9	2	2	0	2	0	0	7	1	2	X	X	X	X	X	X	X	X
6200713	B	3	3	0	2	9	2	2	0	2	0	0	7	1	3	X	X	X	X	X	X	X	X
6200714	B	8	3	0	2	9	2	2	0	2	0	0	7	1	4	X	X	X	X	X	X	X	X

N95 Particulate Respirator
 LOT: 6200904
 Production Date: 2020/09/04
 Expiration Date: 2022/09/03
BS3029220200904S17001UN

STEP 1

STEP 2

Instructions on How to Identify Affected Units:

1. Step 1: Check to see if the Lot # identified the chart above matches the Lot # on the tracking label on the bottom of your N95 respirator product box.
2. Step 2: Check to see if the Serial # identified the chart above matches the Serial # on the tracking label on the bottom of your N95 respirator product box. In the chart above, 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.