

REVISION 1

April 14, 2015

Subject: NIOSH APPROVEDMOLDEX DISPOSABLE RESPIRATORS WITH EXHALE VALVE

Re: Moldex User Voluntary Recall/Stop Use/Relabel Shelf Life Notice

Series: 2300 N95, 2700 N95, EZ23N95 and EZ23S N95

Model Numbers: 2236, 2300N95, 2300V, 2301N95, 2307N95, 2350N95, 2357N95, 2700N95, 2700V, 2701N95, 2707N95, M2700N95, M2701N95, M2707N95, EZ23, EZ23S

DEAR MOLDEX USER:

Moldex produces disposable respirators with exhale valves that contain a natural rubber diaphragm. These products are very reliable but the shelf life can be affected by storage conditions such as heat and exposure to air and light. During a recent internal audit of retained products, we found that a limited number of exhale valves used in certain respirator models showed signs of hardening of the valve diaphragm. This condition may lead to reduced life of the valve and possible reduction in performance below the NIOSH standard. This was found in few manufactured lots that were 5 years or more past their date of manufacture.

Moldex has changed its shelf life policy to 4 years for these type products even though they are almost always sold and used in a time period less than four years.

Effective 4/8/2015, all models of Moldex Disposable Respirators with exhalation valves will be standardized to carry a **4 year shelf life** (herein referred to as expiration date). Most Moldex models with Exhale Valves already carry a 4 year expiration date. Therefore, standardization of the expiration date affects only those models that have previously carried an expiration date greater than 4 years.

Pursuant to this change in policy, Users must discontinue use of product that is more than 4 years past the date of manufacture. **These products are considered “User Qualified” products and applies only to models listed above.**

Products that are less than 4 years from date of manufacture can be used for up to four years from the manufacture date and do not require recall nor removal from service.

On all product with lot numbers between 110408-000 and 150407-999, Users must cross out existing expiration/use by year , subtract 5 years from the marked year and write in the amended expiration/use by year (e.g.2024 becomes 2019) . These are not considered “User Qualified” products and do not require return nor removal from service.



Moldex will replace all returned “User Qualified” product at no charge.

Please refer to the attached Moldex User Voluntary/ Stop Use/Relabel Shelf Life Notice dated 4/14/2015 for “User Qualified” model numbers and detailed instructions to be taken on your part.

Please contact Moldex Customer Service at **800-421-0668 ext. 550** or Tech@Moldex.com if you have questions.

We apologize for any inconvenience this may cause and thank you for your immediate attention to this matter.

We appreciate your continued loyalty and support of Moldex products.

Sincerely,

Jeffrey S. Birkner, Ph.D., CIH
Vice President, Technical Services

REVISION 1

April 14, 2015

DISPOSABLE RESPIRATOR WITH EXHALE VALVE

MOLDEX USER VOLUNTARY RECALL/STOP USE/RELABEL SHELF LIFE NOTICE

For Certain Moldex Model Numbers Produced before 4/8/2015

Series: 2300 N95, 2700 N95, EZ23 N95 and EZ23SN95

Model Numbers: 2236, 2300N95, 2300V, 2301N95, 2307N95, 2350N95, 2357N95, 2700N95, 2700V, 2701N95, 2707N95, M2700N95, M2701N95, M2707N95, EZ23, EZ23S

As part of Moldex's commitment to producing safe, quality and innovative products, we constantly monitor them to ensure the health and safety of our customers. During a recent internal audit of retained products, we found that a limited number of exhale valves used in the above respirators models showed signs of hardening of the diaphragm in the valve on some manufactured lots that were 5 years or more past their date of manufacture. This condition may lead to reduced life of the valve and possible reduction in performance below the NIOSH standard.

While not all masks exhibited hardening of the valve diaphragm, in an abundance of caution, we have decided to implement a voluntary recall and stop use of the above Moldex products that are older than 4 years from the manufacture date as marked on the product packaging.

As to **USERS**, the Voluntary recall requires that you not use product that is more than 4 years past the manufacturing date and that you return for replacement any product that **will not be used before 4 years from the manufacturing date** for replacement.

PRODUCTS SUBJECT TO THIS NOTICE are those Moldex models listed above that were produced prior to April 8, 2015. These products have manufacturing lot numbers preceding 150408-000.

Any Product held by you manufactured between April 8, 2012 and prior to April 8 2015 (this means lot numbers between 120408-000 and 150407-999) should be inspected by you and the shelf life expiration marking must be corrected on the master case and the individual boxes to reduce the shelf life expiration to 4 years from the manufacturing date. **Products that will be fully used within 4 years from date of manufacture already in your possession are safe for use and do not require recall nor removal from service.** Further guidance is provided in next section.

Important note: the above models with manufacturing lot number of 150408-000 and higher will already be marked with a 4 year expiration date and are therefore not affected by this Voluntary Recall/Stop Sale Notice.

Users --Please immediately do the following:

1. Lot #'s 110408-000 through 150407-999

Date of manufacture 4/8/2011 through 4/7/2015

- A. Action-see attachment 1 and 2 for lot number location.
- B. Cross out current 9 year Expiration/Use by year, subtract 5 years from the Expiration/Use By year and mark new Expiration/Use by year. See pictures attachment 1 and 2.
- C. No product should be used if the Expiration/Use by date is **greater** than four (4) years beyond the date of manufacture. For example, if the date of manufacture is 6/17/2011 then the use by date is 6/17/2015. If the product cannot be used before the use by date, call Moldex and the product will be replaced.

2. Lot #'s 110407-999 and lower:

Date of manufacture: 4/7/2011 and prior:

- A. Action - Call your reseller to determine if they will take the product back. If not call Moldex Customer Service at 800-421-0668 ext. 550 to get an RA number

Please contact Moldex Customer Service at 800-421-0668 ext. 550 or Tech@Moldex.com if you have questions or to arrange the return of the affected Moldex models.

Note: this voluntary recall/stop sale does not apply to any other Moldex Disposable Models not listed on this recall notice

We apologize for any inconvenience this may cause and thank you for your immediate attention to this matter.

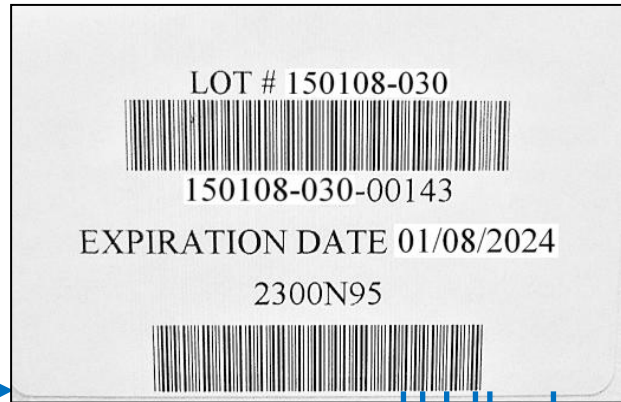
We appreciate your continued loyalty and support of Moldex products.

Sincerely,

Jeffrey S. Birkner, Ph.D., CIH
Vice President, Technical Services

Attachment 1

Outer Package Labels



Month ← Day → Year

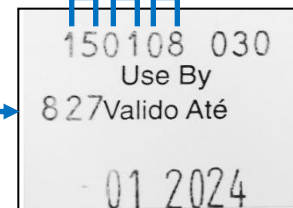
9 Year Expiration Date: (2015 + 9 years = 2024)



ManufacturingDate

Lot Number

Year Month Day

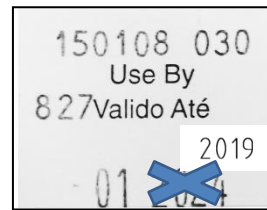


Month → Year

9 Year Expiration Date: (2015 + 9 years = 2024)

RELABELING INSTRUCTIONS – Outer Packaging Labels

4-YEAR EXPIRATION AMENDMENT:



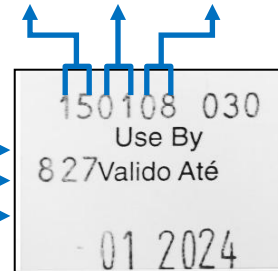
4 Year Expiration Year Amendment to be done. Using a permanent dark black ink marker, cross out existing expiration year, subtract 5 years from expiration year and write in the amended expiration year.(e.g. 2024 becomes 2019, etc.)

Attachment 2 - Inner Package labels



Manufacturing Date Lot

Year Month Day



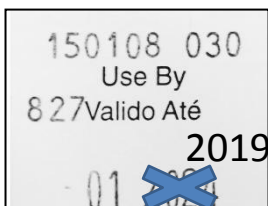
Month

Year

(2015 + 9 years = 2024)

9 Year Expiration Date

4-YEAR USE BY YEAR AMENDMENT INSTRUCTIONS:



4 Year Use By Year Amendment to be done. Using a permanent dark black ink marker, cross out existing Use By year, subtract 5 years from expiration year, subtract 5 years from expiration year and write in the amended expiration year.(e.g. 2024 becomes 2019, etc.)