



<Customer address>

Field Safety Notice

Name of the affected product: 3M™ Aura™ Health Care Respirator, reference 1883+

FSCA-identifier: 2021-07 FSCA 3M Aura1883+

Type of action: Quarantine and disposal of affected products

Date: July 30th, 2021

Attention: 3M Customers

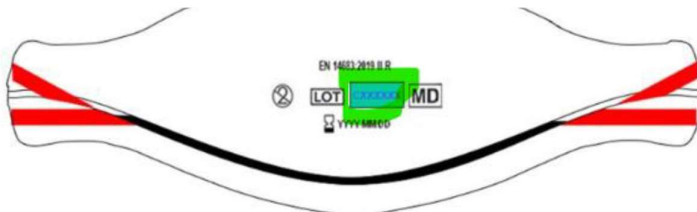
Dear Customer,

further to our previous communication dated July 23rd, 2021 with respect to a quality issue, 3M is now notifying all users of the above-mentioned **3M™ Aura™ Health Care Respirator** of a field safety corrective action.

Details on affected devices:

Please note that of the 3M™ Aura™ Health Care Respirators only **lot number C211811** of **reference number 1883+** is affected by this field action.

The lot number can be found on the product as follows:



The lot number can be found on the carton as follows:



The lot number can be found on the shipper as follows:



Description of the problem and potential hazard and risk for the patient/user:

During a recent investigation, 3M has identified an issue in lot C211811 of 3M Aura 1883+ respirators. This issue could potentially cause the lower strap to break or slip during donning or during use.

Please note that only the lot number C122811 is subject to this Field Safety Corrective Action Notification.

Action to be taken by the user:

All users of the affected 3M™ Aura™ Health Care Respirator are being asked to take the following actions:

- Ensure all your internal and external customers are informed about this corrective action.
- Please quarantine the affected product, remove from your inventory and do not use.
- Please **dispose** of any affected product per facility procedures (if not already returned to 3M as previously communicated).
- Complete and return by e-mail to meddev.de@mmm.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices you have quarantined and disposed / returned.

Transmission of this Field Safety Notice:

Please pass on this notice immediately to all departments who might use the concerned products. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

Contact reference person:

If you have questions, please contact your local 3M representative.
The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Dr. Marie Isabel Cobbers
Safety Officer
3M Deutschland GmbH, Health Care Business
Carl-Schurz-Strasse 1, 41453 Neuss, Germany
Mail: mcobbers@mmm.com

Acknowledgement Form – FSN 2021-07 FSCA 3M Aura 1883+

Email completed form to: meddev.de@mmm.com

Please examine your inventory to determine if you have any stock of the affected product lots indicated below. Note, this notification only applies to the indicated lots of 3M™ Aura™ Health Care Respirator.

We have examined our inventory, quarantined the following quantity of units and have either disposed them of or returned them to 3M.

Affected Lot	Quantity of Units in disposed	Quantity of Units in returned
C211811		

We have examined our inventory and do not have any 3M™ Aura™ Health Care Respirator of lot C211811

I acknowledge that I have read and understood this letter and will complete the actions requested.

Email completed form to: meddev.de@mmm.com

Person completing this form:

Name		Company Name	
Signature		City, State, Country	
Date		Phone	
		E-mail	