



Australian Government
Department of Health
Therapeutic Goods Administration

URGENT PRODUCT DEFECT ALERT*

LEVEL: Retail

CLASS: Class II

REFERENCE: RC-2020-RN-01167-1

DATE AGREED: 13/11/2020

PRODUCT: **Softmed surgical face masks**

ARTG Number: 333133 - M House Pty Ltd - Mask, surgical, single use

SPONSOR: M House Pty Ltd

PHONE: Email M House via: sergio@softmed.com.au

REASON: TGA testing and post-market review indicate an absence of batch numbers and inconsistent testing results requiring further investigation/review.

Certain batches tested for fluid resistance demonstrated inconsistencies:

1. A number of batches have been supplied under ARTG 333133, the majority of which do not have batch numbers to enable easy identification;
2. Supply of various batches has been direct to customers or via a number of third party distributors; and
3. The claim of "Level 3" fluid resistance when tested by TGA Laboratories indicate some batches failed at Level 3, but passed at Level 2. Others failed at Level 3 and Level 2, but passed at Level 1.

Due to the variability in fluid resistance performance, users should take a precautionary approach where masks supplied under ARTG 333133 are being used in a medical / healthcare/ surgical / aged care setting where the wearer could be exposed to splashes of potentially contaminated liquids or droplets.

PROPOSED CUSTOMER ACTIONS: These masks are not being removed from the market. Regarding batches supplied under ARTG 333133, consideration should be given to the setting in which these are used, as the masks have variability in fluid resistance. Due to the inability to trace certain batch numbers, users should take a precautionary approach if masks without batch numbers are being used in a medical / healthcare/ surgical / aged care setting to reliably protect the wearer against splashes of potentially contaminated liquids or droplets.

Users should consider:

1. quarantining the product;
2. using them in another setting; and/or
3. if they do not have alternatives, ensuring that a face shield is used in high risk settings.

It is at the user's discretion to determine if these products should or could be re-deployed depending on where they are currently being used.

If you have supplied potentially affected goods to another facility or organisation, please let that facility know of this Product Defect Alert by providing a copy of this letter.

The sponsor has already dispatched letters to their primary distributors. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product export status: Unknown

This issue was first identified by the TGA

*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>