
Urgent Field Safety Notice

Keep/KeepSafe Mask

FSCA-1

Information regarding Instructions for Use supplied with Keep masks

Date: 3.3.2021

Attention: Distributors and Users

Affected products:

Keep/Keep Safe surgical mask: sizes: S/M, M/L, Kids, grey or black

LOT: AZ001/07/2020

Description of the problem:

The mask is functioning as intended, but a need for additional testing and more clear labelling was identified during inspection.

The label instruction shall be reinforced with the following: Keep surgical mask has been laboratory tested to be washed up to 15 times, when following the care instructions. Stop using the mask if there are visible signs of wear.

Advise on action to be taken by the user and distributor:

Users are advised to take note of the reinforcement of Instructions for Use.

Distributors shall add a new sticker or attach notice with the reinforced IFU to existing packaging in storage.

Action taken by manufacturer:

4N Health Oy Ltd will contact distributors and ask them to add stickers or attach notice to existing packaging. 4N Health will recall packaging sent to pharmacies and add new stickers to packaging. Future production will follow the revised labelling.

Potential risks to users:

If used incorrectly, the mask may lose its effectiveness as a TYPE II surgical mask. The mask does not pose any direct hazard to users.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected products have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.


Contact reference person:

In case of any questions please contact Magdalena Pawlowicz, Technical manager, 4N Health Oy Ltd, Ruosilantie 7, 00390 Helsinki, Finland.

magdalena@4nature.fi, +358 407 403 525

The undersign confirms that this notice has been notified to the following:

- Fimea (Finland)
- Laegemiddelstyrelsen (Denmark)

A handwritten signature in black ink, appearing to be 'M. Pawlowicz', written over a horizontal dashed line. The signature is contained within a rectangular box.

Magdalena Pawlowicz
Technical manager