MEDICOM SAS
Boulevard de la Chanterie,
49124 Saint-Barthélemy-d'Anjou
France

Date : 06/08/2025
FSN n° : FSN-2025-0001

Object : Safety notification – Recall of medical device

Dear Madam, Sir,

We would like to inform you that an FSN is currently underway concerning a medical device marketed by our company.

Information on the related device :

- **Type of Product :** TIIR medical face masks with visor
- **Trade name :** Op-Air One / FEELDRY – TIIR
- **Intended use :** single-use, non-sterile, medical face masks Type IIR with visor, intended to cover the nose and the mouth of the healthcare professional during surgical procedures, medical cares or examinations, in order to prevent risk of cross-contamination and to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be worn by patients or other persons to reduce the risk of spreading of infections, particularly in epidemic or pandemic situations.
- **Product reference :** M34101V-30
- **Related batches n°:**
  - 23221125
  - 23291446
  - 24271757
  - 24311958
  - 24412398
  - 25201227
  - 25161261
  - 25181350
  - 25221423

- **Manufacturer :** Medicom SAS

Description of the issue :

Over the past two months, Medicom has received several reports of incidents involving medical masks with visors, in which the visor detached during surgical procedure. In all reported cases, the visor fell onto the surgical field, without ever coming into direct contact with the patient or falling into the surgical area. Therefore, these events do not present a safety risk and do not meet the definition of a serious incident under EU MDR (Regulation 2017/745).

Internal investigation indicates the potential for isolated instances of inadequate adhesion of the visor face mask material during the manufacturing process. Although no damage has been observed to date, this is a product defect that compromises its proper functioning.

Mesures to be taken :

We kindly ask you to :

- Stop distributing/using all affected products.
- Destroy any opened boxes and products currently available in operating rooms and departments.
  Complete the attached acknowledgment receipt form for any remaining stock in your possession and return it within three (3) business days.
  NOTE: Even if you no longer have any stock of the affected batches, please complete and return the form
- For distributors: contact your affected customers, inform them of the voluntary recall, and provide them with a copy of this letter. Include your contact details on the acknowledgment form and ask them to return any remaining unused stock.
- Contact Medicom customer service at tenders.eu@medicom.com to obtain a shipping label for the return of your stock and a credit note.
- Return all stock in your possession to the following address:
  Medicom SAS
  Boulevard de la Chanterie
  49124 Saint-Barthélemy-d'Anjou
  France

Contact :

If you have any questions or require assistance, please contact us at the following address:

Name : Brenda GUILLET – Yannick CHEVALIER
Phone number: 02 41 96 34 10
Email : materiovigilance.pro.eu@medicom.com

This action is being taken in accordance with the requirements of Regulation (EU) 2017/745 on medical devices and the recommendations of the ANSM.

We thank you for your cooperation and vigilance in implementing this safety measure.

Yours sincerely,

Regulatory Affairs Department - Medicom SAS

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