

PPE Dedicated Supply Channel

Important Customer Alert

Type IIR masks – Cardinal Health
Product Notice – all lots

ICA: 003

Date: 26 June 2020

Alert:

- Our email on 28 May 2020 informed you that NHS Supply Chain had received some complaints about Cardinal Type IIR face masks from health and care staff. At that time, the request was to check the affected lots prior to use, given a limited number of lots affected.
- Although these masks meet the breathability, filtration and splash resistance requirements of BS EN 14683, in light of ongoing monitoring, further complaints reported and testing from the manufacturer on the masks, the MHRA recommends that **all lots of this product are disposed of locally**. There is a risk to staff wearing the mask if the foam strip on the mask flakes and enters their airway or mouth.
- There have also been complaints of the ties and/or stitching coming away from the mask.

Product Affected:

There is one product impacted

- Mask, Type IIR
- Supplier: Cardinal Health
- NPC: BWM028
- MPC: AT74535UK

Applies to all lots of AT74535UK. (See lot numbers at Annex 1 below.)

Safety details

- You will see that boxes have been labelled with a new expiry date. This is because they were subject to shelf life extension testing by the manufacturer in 2013/2014 and passed a number of relevant tests to support a new expiry date.
- When potential issues were identified in May, a sample size of 7 lots was put through additional testing by the manufacturer in June 2020. 6 lots did not pass a material inspection of the foam strip.
- However, these masks meet the breathability, filtration and splash resistance requirements of BS EN 14683.
- MHRA has recommended that **all lots of this product are disposed of locally**.

Action:

- Identify, stop using and immediately quarantine all lots relating to BWM028 of the Cardinal Type IIR masks.
- All stock should be disposed of locally.
- If you have a shortage of Type IIR masks, please notify NSDR on 0800 915 9964 who will arrange an emergency delivery if required.
- For all general enquiries for the PPE Dedicated Channel, call Customer Services on 0800 876 6802.

Annex 1 – Lot numbers of BWM028 Cardinal Type IIR masks

| | |
|-----------|-----------|
| 0120GLP09 | 0517CLP10 |
| 0302FLP09 | 0517JLP09 |
| 0305HLP09 | 0518CLP10 |
| 0310GLP09 | 0518LLP09 |
| 0321FLP09 | 0518LLP09 |
| 0321FLP09 | 0519ALP10 |
| 0327FLP09 | 0519KLP09 |
| 0402HLP09 | 0519MLP09 |
| 0408HLP09 | 0520CLP10 |
| 0411FLP09 | 0520JLP09 |
| 0411HLP09 | 0520LLP09 |
| 0413HLP09 | 0521KLP09 |
| 0416HLP09 | 0521MLP09 |
| 0419HLP09 | 0522ALP10 |
| 0422HLP09 | 0522LLP09 |
| 0425HLP09 | 0523CLP10 |
| 0428HLP09 | 0523JLP09 |
| 0431HLP09 | 0523MLP09 |
| 0501ALP10 | 0524KLP09 |
| 0502BLP10 | 0524LLP09 |
| 0502CLP10 | 0525ALP10 |
| 0502LLP09 | 0525JLP09 |
| 0503DLP10 | 0526CLP10 |
| 0503JLP09 | 0526LLP09 |
| 0503KLP09 | 0526MLP09 |
| 0504ALP10 | 0527KLP09 |
| 0504LLP09 | 0528JLP09 |
| 0505BLP10 | 0528LLP09 |
| 0506ALP10 | 0529CLP10 |
| 0506JLP09 | 0529KLP09 |
| 0506KLP09 | 0529MLP09 |
| 0506LLP09 | 0530JLP09 |
| 0508DLP10 | 0531CLP10 |
| 0508KLP09 | 0531KLP09 |
| 0508MLP09 | |
| 0509JLP09 | |
| 0510KLP09 | |
| 0511ALP10 | |
| 0511JLP09 | |
| 0511MLP09 | |
| 0513ALP10 | |
| 0513KLP09 | |
| 0513MLP09 | |
| 0514JLP09 | |
| 0516ALP10 | |
| 0516KLP09 | |
| 0516MLP09 | |