INFORMATION ON SPECIFIC PRODUCTS AND QUALITY ASSURANCE

This communication provides information on several products, along with clarification of the central assurance undertaken to approve the release of these items into the supply chain.

It has been agreed by the Department of Health and Social Care with input from Health Safety Executive, MHRA, and NHSE/I.

Prior to releasing PPE stock into the supply chain a number of checks are undertaken to ensure it meets the relevant technical and regulatory health and safety requirements. This includes an upfront assurance process which includes checking of certifications and testing information to ensure the product meets relevant technical and regulatory health and safety requirements to be released.

In addition, currently when stock arrives into the national warehouse in Daventry (push stock) checking of documentation is undertaken by the relevant regulators; Health and Safety Executive (HSE) and the Medicines and Healthcare products Regulatory Agency (MHRA).

The regulators will only release products into the UK supply chain if the product is fit for its intended use.

This note covers the following products, all of which are safe to use:

- Type IIR masks and latex labelling
- Weian face masks
- Blue sail nitrile gloves
- INTCO nitrile gloves
- Cardinal FFP3 respirator masks
- 3M 9330+ FFP3 respirators
- Reminder about registering product or PPE safety queries

1. Type IIR Masks - latex content and clarification of labelling requirements

Given the prevalence of latex allergies in the community, we receive requests for confirmation of whether masks contain natural rubber latex and for clarification on labelling requirements.

Any Type IIR mask which is CE marked and where natural rubber latex has been used in the manufacture of that mask (or the packaging) will be labelled with the following symbol and/or appropriate warning on its packaging.

If an organisation has a CE marked product which does not contain this symbol and/or warnings on the packaging, it is not made with natural rubber latex.

Any non-CE marked product sent out nationally (with derogation approval by the MHRA) has been checked to ensure the requirements for natural rubber latex labelling are consistent with that outlined above.

Organisations should refer to their own organisation's policies with regards to staff allergies which will detail mitigations and management of staff or patients presenting with an allergy and through Occupational Health Departments.

Specific checks for Type IIR masks recently released
MHRA has sought confirmation of latex status of the Type IIR masks released via national stocks.

This confirmation is not always provided in the form of a 'datasheet' which is not a mandatory requirement in regulation. However, in all cases, MHRA has sought and provided evidence, in addition to the checks that were carried out prior to release of stock from Daventry, that these masks are not made with latex.

The full list of products that have been reviewed to date, including those which have been included under a derogation from the MHRA, are set out below.

Manufacturer or Brand name and Daventry SKU (not exhaustive)	**Latex status**
GUANGXI 3NOD INTELLIGENT HEALTH TECHNOLOGY BWM9928	Not made with latex
Touren BWM9999	Not made with latex
Weian BWM9927	Not made with latex
DSBJ BWM9943	Not made with latex
Evereast	Not made with latex
Sichuan Xinglin Medical Device BWM9915	Not made with latex
Gemtier	Not made with latex
Genmed BWM533	Not made with latex
Molnlycke Barrier Multiple SKUs	Not made with latex
Medicare BWM9958	Not made with latex

Guardian BWM9967	Not made with latex
GB healthcare UK BWM9950	Not made with latex
Ecoma mask	Not made with latex
Tiger	Not made with latex
Cardinal	Not made with latex
Universal Hospital Supplies/Bunzl	Not made with latex
Pennine	Not made with latex
Yeso-Med BWM9918	Not made with latex

Derogation – medical face mask approved by MHRA

Manufacturer and Derogation number	**Product name**	**Latex status**
Optimum Medical rcx/016/003/019/78	OptiPro 3ply Disposable Protective Face Mask – Type IIR	Not made with latex
Naton Biotechnology (Beijing) Co DEU/004/2020/020	Type IIR masks	Not made with latex
365 Healthcare DEU/004/2020/028 DEU/004/2020/029	UNIPROTECT FLUIDPROTECT MASKS UN49205, UN49210, UN49245, UN49250 Type IIR) UNIVERSAL FLUIDPROTECT MASKS, Fluid Resistant Face Masks with Earloops (Ref UN49212) and Fluid Resistant Face Masks with Ties (Ref UN49207	Not made with Latex
Meller Designs DEU/005/2020/031	3-ply earloop medical face mask type IIR EN 14683:2019	Not made with Latex
Danameco DEU/005/2020/060	Medical Face Mask 3 ply Model: KTY3PLY	Not made with latex

Weian Type IIR surgical masks

Given the prevalence of latex allergies in the general population, there have been a small number of queries relating to Weian Type IIR surgical masks and whether this product contains latex.

MHRA has confirmed with the manufacturer that the Weian IIR mask is not made from natural rubber latex.

The Weian IIR masks have passed the technical assurance processes to confirm they meet the relevant technical and regulatory health and safety requirements.

As part of the assurance process, MHRA approved the release of this stock following a review of available documentation and other checks to support the CE mark.

2. Blue Sail nitrile gloves

Blue Sail nitrile examination gloves (National Product Codes (NPC) below) released from the national inventory have passed the technical assurance processes to confirm they meet the relevant technical and regulatory health and safety requirements.

As part of the assurance process, MHRA approved the release of this stock following a review of available documentation and other checks to support the CE mark including test certification to confirm compliance with relevant parts of BS EN 455.

Stock Keeping Units (SKUs) / NPC codes for Blue Sail that underwent review by MHRA are:

- FTE9965
- FTE9966
- FTE9967
- FTE9968
- FTE9969

3. INTCO nitrile gloves

These gloves have also been assessed, passed technical assurance and were cleared for supply from Daventry stock. Although the expiry date is in Chinese, the production date is April 2020, Nitrile gloves usually have a shelf life of three years, therefore they are deemed acceptable for use.

SKUs FTE9973, FTE9974 & FTE9975 and URN0001 are the Daventry SKUs cleared for the INTCO gloves.

4. Cardinal FFP3 respirator masks

Cardinal FFP3 respirator masks have been gradually rolled out to NHS trusts following successful piloting with a small number of trusts earlier in the pandemic to improve fit-testing rates. As of 9 July they have now been rolled out to around 90 Trusts in England.

Some recent media coverage suggested their delivery has been halted due to fit testing problems – this is inaccurate.

Further information about regulatory checks on Cardinal FFP3s
Cardinal FFP3s are from the Government's pandemic stockpile and were tested by an independent test house using a pre-testing protocol agreed with the Health and Safety Executive (HSE).

Providing the respirators pass these tests, have been stored in original packaging and conditions as recommended by the manufacturer and undergo a visual inspection by the wearer before use, HSE are satisfied they can enter the NHS Supply Chain.

Those delivered to the NHS had a 100% pass rate. Any lots that did not pass this testing were not distributed to the NHS. A continuous cycle of quality assurance testing every three months has been commissioned to confirm these respirators remain fit for purpose while stocks endure.

The specific tests that HSE have requested be undertaken to ensure that these respirators are fit for use are:

1. Simulated Wearing
2. Material – Mechanical Failure
3. Paraffin Oil 3-minute penetration ('as received' condition)
4. Breathing resistance ('as received' condition)
5. Strap Assessment
6. Total Inward Leakage (TIL)

5. 3M 9330+ FFP3 respirators

Manufacturer 3M has confirmed that the 3M 9330+ FFP3 respirator model (advertised as a Worker Health and Safety Respirator FFP3) is the industrial equivalent of the 3M 1863+ FFP3 respirator model (advertised as a Disposable Healthcare Respirator FFP3), which is used commonly across the NHS.

Therefore no additional fit-testing is required for users already successfully fit-tested with the 1863+ model.

This is consistent with the Health Safety Executive's published guidance on face fit testing and is permitted where the manufacturer confirms equivalence. Both respirators meet all the required standards for a FFP3 respirator (BS EN 149).

FFP3 respirators are suitable for use in settings and situations as set out in the guidance on infection prevention and control for COVID-19.

Product image

Reminder about PPE quality or safety queries

All personal protective equipment (PPE) has to meet UK and European technical and safety standards, and more than 2 billion items of PPE have been issued to health and care services since the start of the pandemic.

Any concerns with a PPE product should be reported through the MHRA yellow card scheme for medical devices and for other types of PPE where the issues are not resolved locally they should be reported to the HSE through their Concerns and Advice Team.

https://coronavirus-yellowcard.mhra.gov.uk/
https://www.hse.gov.uk/contact/concerns.htm

If the product has come from national stock, please also log any issues using the form available on the PPE Dedicated Supply Channel website - https://www.ppe-dedicated-supply-channel.co.uk/product-issues/

We would advise all organisations to follow the national and regional guidance in incident management aligned to your local policies and procedures when raising concerns about products.

We would discourage organisations from informing other trusts of their immediate concerns as this can lead to products being removed/quarantined unnecessarily, and for trusts to allow due process to take place. Should it be necessary to withdraw a product, trusts will be informed through the correct channels.