FFP3 RESPIRATORS

STANDARDS AND LEGISLATION	
Filtration Devices	**BS EN 149:2001+A1:2009.** Respiratory Protective Devices. Filtering Half Masks to protect against particles. **Medical Devices Regulation 2017/745.** **Personal Protective Equipment Directive 89/686/EEC**

- Product lines must comply with the Standards and Legislation (as amended, extended or re-enacted from time to time).

- Evidence of compliance to the Standards and Legislation (as amended, extended or re-enacted from time to time) must be provided by suppliers to NHS Supply Chain on request; in the event that sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

- The list of standards and legislation is not intended to be exhaustive and any relevant standards and legislation which (even if not stated) must be complied with by suppliers

- FFP refers to "filtering facepiece" and are designated by levels of filtration and leakage. FFP3 respirators are the highest performance class of disposable respirator, offering an Assigned Protection Factor of 20. The total leakage may amount to a maximum of 5% and they must filter 99% of all particles measuring up to 0.6 µm. FFP3 masks must comply with BS EN 149:2001+A1:2009.

- These disposable masks can be manufactured in a number of ways and can include valves or use the filtration properties of the masks material (unvalved) to attain the same level of filtration. All routes require CE marking to show conformity to the required specification and this marking must be clearly evident on the product and/or packaging.

- Products must have a minimum of 18 months shelf life from delivery into NHS Supply Chain

- Any claims to product efficacy in addition to the mandatory requirements listed in the Standards and Legislation table must be supported by an independent laboratory report for the relevant BS EN standard that must be made available to NHS Supply Chain on request

- If a product line contains phthalates this must be indicated on the packaging of that product line in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).

- All products must not contain an active or preservative of concern as identified by ECHA or Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or be within their allowable limits. Where there are allowable limits, the ingredient name, Chemicals Abstract Service (CAS) number and concentration must appear on the label.

- All product lines and packaging should be latex free where possible. If a product line or any packaging contains latex this must be labelled on the product line or packaging (as applicable) to inform the user.

- Instructions for use must be in English and include approved pictograms if the product falls within the Classification Labelling & Packaging (CLP) regulations. The instructions for use must be appropriate for the intended use of the product.

- All product labels must be in accordance with the relevant standard and/or regulation. Any shelf life limits and/or specific storage conditions required before or after opening or reconstituting the product must be stated on the product packaging. The usage period after opening must be detailed on either the product and/or product packaging and/or instructions for use made available to the end user.

- Full Technical Specifications of the product must be made available to NHS Supply Chain on request
    - Suppliers must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications
    - NHS Supply Chain reserves the right to request evidence of compliance with the Specification.

- Samples of product batch retains must be kept for a minimum of the shelf life of the products sold to NHS Supply Chain, allowing for testing to take place.

- Suppliers must provide NHS Supply Chain with Safety Data Sheets (SDS) for all products that fall under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) 2007 –more specifically, an SDS must be provided if a substance or a mixture supplied is classified as hazardous under the Classification Labelling and Packaging (CLP) Regulation (EC) No 1272/2008.

Date	Author	Reference	Version
19th March 2020	AL / JT	SCCLRPFFP3/302	1.0