**Type IIR Face Masks**

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| **STANDARDS AND LEGISLATION** | |
| Filtration Devices | **BS EN 14683:2019.** Medical Face Masks and test methods  **Medical Devices Directive (MDD/93/42/EEC).**  **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
  + Fluid Resistant Type IIR Surgical Facemasks - the ‘R’ designation defines that the masks must be fluid-resistant, compliant with Medical Device Directive (MDD/93/42/EEC) and be ‘CE’ marked. These Surgical masks are tested against the safety standard BS EN14683:2019; this series of tests measures the performance of a surgical mask in bacterial filtration efficiency, breathing resistance and splash resistance. Type IIR surgical masks are both tested against this standard; however only Type IIR masks must pass the splash resistance test with a resistance of at least 120mmHg.
  + These disposable masks are typically manufactured from soft polypropylene or cellulose materials and require CE marking to show conformity to the required specification. This marking must be clearly evident on the product and/or packaging.
  + Lightly fragranced or fragrance free.
  + 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.

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