**Safety Glasses/Visors**

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| **STANDARDS AND LEGISLATION** | |
| Filtration Devices | **BS EN 166:2002** Personal Eye Protection  **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
  + Safety Glasses and/or visors must be designed to provide eye protection with a wrap around design to also provide sideways protection. They must be comfortable enough to be worn for extended periods or even all day. Nose supports (universal) across bridge to provide adequate support and comfort. Lenses should provide general impact and splash protection (fluids) and be fog-free. Polycarbonate is commonly used for the shield which should be scratch resistant.
  + Manufacture and testing must conform to BS EN 166:2002 Personal eye protection. Specifications. For visors this would include requirements for an adjustable head band arrangement.  Safety visors need to be fog free.
  + All products must have their CE marking clearly evident on the product and/or packaging and must conform to the relevant directive: Medical Devices Regulation 2017/745 Any product that contains phthalates must be indicated on the packaging in accordance with: Medical Devices Regulation 2017/745.  Personal Protective Equipment Directive 89/686/EEC
  + 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 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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