

# Report to the Tyne and Wear Trading Standards Joint Committee

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## Personal Protective Equipment: Face Masks and Coverings. June 2020

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Purpose of the report

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1. To update the Committee on the publication by the Office for Product Safety & Standards (OPSS) of guidance to enforcement authorities on the implications of the Personal Protective Equipment (PPE) legislation on Face Masks and Coverings, during the Covid19 Pandemic.

### Summary

2. During the pandemic and lockdown from March 2020, it became very clear that the demand for PPE, significantly increased and Trading Standards services working in partnership with OPSS, dealt with a number of complaints that certain businesses were not following the legislative provisions in respect of the safety of certain PPE including face masks.
3. Guidance relevant to face masks that are regulated under PPE, and Medical Devices (MD) legislation and face coverings regulated under the General Product Safety Regulations 2005.
4. There are three different categories of products, as follows:
  - Face masks that are designed to protect the wearer, and are subject to the requirements of the PPE regulations;
  - Surgical face masks, that are intended to protect others (the patient) from the wearer and are subject to the requirements set out in the Medical Devices regulations; and
  - General purpose face coverings, that are not PPE or Medical Devices, these are regulated by the General Product Safety Regulations.

### Regulations: Definition and Categories of PPE

5. The relevant legislation is EU Regulation 2016/425 on Personal Protective Equipment (the PPE Regulation). PPE must meet the essential health and safety requirements that are set out in Annex II of the PPE Regulation.
6. PPE is defined by the regulations as *“equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person’s health or safety; interchangeable components for this equipment, or connection systems that are not held or worn but are designed to connect that equipment to an external device or to a reliable anchorage point, that are not*

*designed to be permanently fixed and that do not require fastening works before use.”*

7. The regulations establish three categories of PPE, based on the severity of hazard that the equipment offers protection from, rather than the complexity of the PPE itself. These categories are:
  - Category 1: PPE that protects from simple or minimal risks, these are listed in Annex 1 of the Regulations. Manufacturers are able to self-declare conformity. Examples of this category include items such as sunglasses and washing up gloves.
  - Category 2: PPE that does not fall into categories 1 or 3. These products requires ‘type approval’ by a notified body, and manufacturers are able to self-declare on production control. The notified body number is not required on the product. Examples of this category include high visibility jackets, bicycle helmets, hardhats and oven gloves.
  - Category 3: PPE where the hazard may cause serious harm to the health and safety of the user and includes hazards such as biological agents as listed in Annex 1 of the PPE Regulation. Products must normally be ‘type approved’ and the production control system must be reviewed by a notified body, either through audit or sample testing. Examples of this category include items such as respirator masks and life jackets. All PPE for specific use to protect against the risk of COVID-19 including respiratory face masks, is category 3 PPE.
8. The enforcement authority for the legislation which applies to PPE intended for consumer use are LA Trading Standards services.

### **PPE in the context of COVID-19: easements**

9. The Government has put in place two regulatory easements in relation to COVID-19 PPE from the requirements set out in Regulation EU 2016/425 and issued revised guidance on PPE within the context of COVID-19.
10. For a limited time, to speed up supply of essential equipment, COVID-19 related PPE can be placed on the market before it has completed conformity assessment procedures, provided it meets essential health and safety requirements in line with Regulation EU 2016/425. However, manufacturers must have contacted a notified body and have begun conformity assessment. The notified body must be in a position to support the claim that the product meets the essential health and safety requirements.
11. The second easement, also for a limited time, is that any COVID-19 related PPE that is being procured by the Government/NHS for use by healthcare workers does not need to be conformity assessed, providing it has been manufactured either in line with a relevant European Standard, in accordance with a standard referenced in the WHO guidelines or to an alternative technical solution that delivers adequate safety. Equipment procured in this way will be assessed by the MSA, the Health and Safety Executive, against the essential health and safety requirements to ensure it is safe and effective. PPE procured in this way must be offered through the official channels, with contact made through the GOV.UK webform. This route is best suited to large-scale manufacturers.

## **Application of regulations to small businesses and donated PPE**

12. Within the context of COVID-19, small businesses, individuals, and organisations such as charities and schools are offering PPE for donation or sale. This includes 'home made' sewn or 3D printed PPE for both workplace and personal use. If such equipment is intended to provide protection and is PPE, OPSS made it clear that such equipment is subject to the same regulations and market surveillance activities as PPE imported and manufactured in any other way.
13. Officers dealt with a number of enquiries from businesses which had switched to manufacturing PPE and also responded to intelligence received from the OPSS which expressed concerns where suspected illegal PPE had been imported into the UK.

### **Recommendation**

14. The Committee is asked to note the information as contained within the report.  
Appendix  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/892749/Guidance-for-local-authorities-on-face-masks-and-coverings-version-2.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/892749/Guidance-for-local-authorities-on-face-masks-and-coverings-version-2.pdf)

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