Placing PPE on the EU market – New Conformity Procedures in Response to Covid-19

In the context of the current COVID-19 global outbreak as well as the rapid spread of the virus across various regions of the EU, the demand for PPE such as face masks, gloves, protective coveralls or eyewear protection, as well as for medical devices such as surgical masks, has seen an exponential growth. In response to this need, the Commission have published Recommendation (EU) 2020/403 to facilitate the rapid uptake of new products on the EU market while also urging all notified bodies (third party testing bodies) to prioritise any new requests submitted by manufacturers for COVID-19 related products.

The Recommendation provides for two scenarios in which PPE products, may be placed on the market before the conformity assessment procedures have been concluded or, in exceptional cases, initiated.

To assist the interpretation of the process the HSA as the Competent National Authority for workplace PPE (EU (PPE) Regulations 2018) has produced the following two flow diagrams:.

- Diagram 1 - Procedure for Implementation of Paragraph 7 of the Commission Recommendation in relation to placing PPE products (non-CE marked), where the conformity assessment has been initiated, on the market.

- Diagram 2 - Procedure for Implementation of Paragraph 8 of the Commission Recommendation related to PPE products specifically for use by healthcare staff only and which are purchased by the relevant Member State Authority.

Applications from importers or manufacturers of PPE who wish to avail of the procedures above should be sent to the Health &Safety Authority at PPEnewtomarket@hsa.ie.

Further Information are provided at the links below:

- Commission **FAQ** on Commission Recommendation 2020/403
- Information regarding Medical Devices should be directed to the Health Products Regulatory Authority www.hpra.ie