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Brussels, 23 May 2023

Commission interpretation on placing Personal Protective Equipment (PPE) category III products on the market burdens SMEs

Brussels, 23 May 2023 – Small Business Standards (SBS) today published a [position paper](#) highlighting the obstacles that emerge from the European Commission's interpretation disclosed on 2 May 2022 regarding conformity assessment procedures for new PPE category III products. According to SBS, the new reading hinders European SMEs from placing this type of equipment onto the market.

The market introduction of new personal protective equipment has become considerably more difficult in the EU following a new legal assessment made by DG GROW on 2 May 2022 and shared with the Commission Expert Group on PPE. The assessment relates to Regulation (EU) 2016/425 on PPE and the conformity assessment procedures for PPE category III products. The new interpretation imposes a complete product test and a type-examination before the product can be placed on the market.

One year later, market realities show that SMEs are negatively impacted by this interpretation as the process has resulted in delays and complexity, placing unnecessary burdens, especially on SME manufacturers. SMEs' inability to place products on the market within a reasonable time leads to losing important market segments, which are not based on competitive factors (superior technologies/processes, better quality) but on complex regulatory procedures.

SBS Secretary-General Maitane Olabarria commented: "The Commission's 2022 interpretation is creating unnecessary burdens on the predominantly SME PPE industry. We urge the Commission to review its latest interpretation with an appropriate legal assessment and call for more resources for market surveillance authorities to do checks in a timely manner and avoid unfair situations in the market".

The SBS position paper can be found on the [SBS website](#).

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EDITORS' NOTES: Small Business Standards (SBS) is the association representing European SMEs in standardisation. SBS is co-financed by the European Union and EFTA, its 22 members are national and European sectoral and inter-professional associations representing SMEs in 32 European countries.

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