



New EU CEN guidelines for Community masks | Quality & Compliance

As the use of community masks –also referred to as hygienic masks- becomes part of our daily lives, the European Committee for Standardization (CEN) has published, by request of the European Union, the Workshop Agreement (CWA) guidelines CWA 17553.

This freely available document includes a guide to minimum requirements, methods of testing and use for reusable or disposable face coverings intended for the general public exempting those for children under the age of 3.

Eurofins service offering

Testing against minimum requirements as per CWA 17553

- Visual inspection - Tears, harness detachment, ill-fit, deformation, etc.
- Size - Adapted to the morphology of the average user.
- Materials – should withstand handling and wear throughout the claimed lifetime.
- Cleaning – if reusable, shall withstand at least 5 cleaning cycles according to EN ISO 6330.
- Surface condition of the parts - No sharp edges or burrs.
- Filtration efficiency of the material – Checked against the two determined levels (90% and 70%), based on the efficacy to filtrate particles ($3 \pm 0.5 \mu\text{m}$).

- Head harness – Self-adjusting, elastic or with laces, over the head or ears and designed to fit the average user, the harness should be robust enough while avoiding discomfort. It shall withstand 5 donning and doffing cycles by at least three subjects with different morphologies.
- Breathing resistance and air permeability – The material shall not exceed a differential pressure $\leq 70 \text{ Pa/cm}^2$ (correlates to 80 l/s/m^2) for a vacuum pressure of 100 Pa.

Marking checks

Marking on the product packaging is mandatory, in the concerned official domestic language(s).

Eurofins' label and marking check service includes:

- Completion of name, trademark, address and contact details of the responsible actor (producer or importer).

- Product batch ID.
- If tested against the CWA document, designation “Community face coverings CWA” followed by the version of the concerned CWA document.
- The filtration efficiency level, method used and standard.
- Durability - “reusable” or “disposable”.
- Targeted user age, “child” or “adult”.
- Restriction warning: “Not suitable for children under 3 years of age”.

Instructions for use and artwork check

Either displayed on the packaging or on a separate sheet inside, the usage instruction information should be duly checked for accuracy. It should include, among other, the following:

- Warning statements, with the word “WARNING” preceding them, such as (non-exhaustively):
 - If you are ill, this community face covering is unsuitable. Seek advice from your doctor.
 - This community face covering is not classified as a medical device as per Directive 93/42/CEE or Regulation EU/2017/745 (surgical masks) nor is it personal protective equipment as per Regulation EU/2016/425 (respiratory protective devices).
 - If applicable: Community face coverings are not suitable for children under 3 years of age.
 - This community face covering does not replace protective measures (regular hand-washing, physical separation, reduced contact with other people).
 - ... for the comprehensive list, check the EU-CEN-CWA link displayed on the footer.
- Instructions as to how to fit, use, put on and remove.
- Recommended storage conditions.
- Cleaning instructions (both washing and drying), including indication of the maximum recommended washing cycles.

On-site inspections and audits

Assessing manufacturing sites before initiating mass production and checking product quality prior to shipment are key parts of the quality control process, and vital to ensure that production is carried out according to the quality standards and expectations of destination markets.

Quality Assurance and Control throughout the Supply Chain

Whichever your role in the supply chain, you need to safeguard the reputation of your brand and/ or that of your client.

From suppliers’ assessment and R&D support to regulatory guidance and supply chain mapping, all the way through compliance and bespoke testing, QC inspections, failure analysis and market surveillance, we cover every stage of your product’s quality journey.

