

Testing and Certification of Masks

Ensure that masks are compliant with the current regulations.



The importance of certified masks in times of COVID-19

The use of masks has become a necessity in the workplace. The COVID-19 health crisis has led to a huge increase in the demand for this kind of product, sometimes making it necessary to import masks in bulk from other countries. Mask manufacturers have both the need and the responsibility to ensure that their products are compliant with the current regulations. Distributors can check the credentials provided by the export agents at the country of origin to make sure that the masks received comply with the current requirements.

The market for personal and professional masks consists of three main types: PPE masks, medical masks, and hygienic masks.

PPE Masks

Personal Protection Equipment (PPE) masks are those which should be used in the workplace. They filter the inhaled air to prevent the entry of contaminated particles in the user's organism. The FFP2 and FFP3 types, which have an exhale valve, must be used in conjunction with a medical mask to prevent the infection of other users. PPE masks are certified via CE Marking according to the EN 149 norm (*Respiratory protective devices - Filtering half masks to protect against particles - Requirements*,

testing, marking). Applus+ has ENAC's certification (nº 12/C-PR054) for CE Marking under Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment (PPE), modules B, C2 and D for masks.

Medical Masks

Medical masks are designed to prevent the user from spreading infectious agents by filtering the exhaled air. The Spanish Agency for Drugs and Medical Products (AEMPS) establishes that the evaluation of conformity must be conducted according to the EN 14683 norm (*Medical face masks - Requirements and test methods*). Applus+ has the certification of conformity according to this norm.

Hygienic Masks

Hygienic masks are those designed for people to wear when they are in stronger health. At Applus+ we have our own certification scheme for manufacturers that wish to prove the conformity of their masks in relation to the following specifications:

- UNE 0064-1 (*Non-reusable hygienic masks. Materials, design, manufacturing, marking and use requirements. Part 1: For adult use*)
- UNE 0064-2 (*Non-reusable hygienic masks. Materials, design, manufacturing, marking and use requirements. Part 2: For children use*)
- UNE 0065 (*Reusable hygienic masks for adult and children. Materials, design, manufacturing, marking and use requirements*)

Transparent hygienic masks, designed to allow correct lip-reading in aid of those with hearing impairments, must avoid significant distortion and volume reduction of the user's voice, and include this information in the labelling.

Applus+ Laboratories offers an **acoustic testing service** to determine and specify the acoustic reduction of transparent hygienic masks, allowing manufacturers to prove compliance with the relevant regulations.

See the 'Orden CSM/115/2021' requirements for the marketing and labelling of all types of hygienic masks in Spain [here](#).

Applus+ Laboratories offers a complete service of either Certification or Certification Contrast

We offer two types of service for manufacturers and distributors:

Testing and Certification: For either CE Marking or the proprietary Applus+ certification scheme. Our service includes:

- Sample collection for testing, if required.
- Testing according to current legislation.
- Check-in inspections of the factory production control system, if required.

[Certified Products Directory](#)

Certification Contrast: To corroborate the certifications issued in other countries and ensure that the products received comply with the established regulations and purchase requirements. The service includes:

- Inspection at port of origin.
- Random sample collection at port of origin.
- Testing at our own laboratories of the collected samples.
- Issuance of the Contrast Report.

Contact our experts to solve any doubts about the certification process for each type of mask.