



Regione Lombardia

Annex 1

MEASURES AND REGULATORY FRAMEWORK FOR THE PRODUCTION AND SUPPLY OF PERSONAL PROTECTIVE EQUIPMENT AND SURGICAL MASKS.

In these days, the regulatory framework establishing measures to be implemented during the emergency by way of derogation from the current regulations for the production and marketing of surgical masks and PPE (Personal Protective Equipment) is progressively being amended and clarified.

The Law-Decree 18 of 17 March 2020, in art. 15 and 16, sets out new provisions for the production and marketing of both surgical masks and PPE.

Specifically, art. 15 introduces exceptions and specifies the technical characteristics and safety requirements of masks and PPE produced and marketed during the current emergency, as well as the related authorisation procedure to be followed.

Art. 16 specifies the protective measures that workers and the community are required to adopt.

The subsequent interpretative note of the Ministry of Health (prot. 3572 of 18 March 2020), specifies, above all, the scope of application of art. 16 and, in particular, the distinction between the measures provided for workers and those provided for the community; as for workers, they are required to use specific protective equipment, whereas, for the community, filter masks without the CE marking and produced in derogation from the current regulations are sufficient, provided that they cause no additional harm or risks. Please note that for the production and marketing of the masks used by the community, the authorization procedure provided for by art. 15 of Law Decree 18/2020 shall not apply.

Therefore, it is possible to produce and market surgical masks intended for social/health-care workers or PPE intended for all other workers still authorised to carry out their activity and not in the condition to keep social distancing of at least one metre only if such equipment has the same protection characteristics as the certified one.

Other types of masks, not suitable for health workers or active workers due to technical characteristics and protection capacities, can only be used by other citizens wishing to use them as a precaution, provided that they comply with the provisions regulating social distancing and other precautionary rules, in light of their limited protection capacity against contagion from Covid19.

To deal with the current emergency, the Lombardy Region, prior to the publication of Law Decree no. 18_2020, has started a collaboration with the Politecnico di Milano which, by carrying out adequate laboratory tests, is checking materials, types and products that can be considered scientifically suitable and with the same characteristics as the certified equipment.

Therefore, in order to ensure effective protection for our citizens, we invite those who intend to produce and market surgical masks or PPE by resorting to the derogations provided for in art. 15 of Law Decree 18/2020, to comply with the technical indications provided by the Politecnico or in any case to self-certify equipment with similar or better performances.

Clearly, the Lombardy Region will only acquire masks and PPE with these characteristics which, for health workers and active workers, will be assessed by the bodies indicated in the aforementioned art. 15; all citizens are also strongly advised to opt for this specific type considered its proven protective capacity.