

Milan, 20 March 2020

Dear Sirs,

first of all, we would like to thank you for your kind availability at this time of emergency.

The Politecnico di Milano has been entrusted by the Lombardy Region with the preliminary assessment of the characteristics of the materials and devices proposed by the companies involved in their production, in order to verify which of them can potentially be considered suitable by the ISS and/or INAIL, and therefore exempted by the Italian Ministry of Health. The assessment will be carried out through tests covering the following three aspects: breathability, filtering capacity, bacterial load reduction.

The results of the assessment by the Politecnico di Milano will be notified to the Lombardy Region. The Lombardy Region will contact the companies directly.

In these days, many companies have made themselves available, and we are working hard to complete the tests in the shortest possible time.

Below are the provisions to which reference should be made for the production of masks and personal protective equipment, or materials intended for such productions.

CASE 1 - SURGICAL MASKS

We inform you that the SURGICAL MASKS produced by you can already be considered suitable and therefore eligible for the derogation from the CE mark according to the indications of the Italian Ministry of Health, providing they comply with the following regulations:

Standards for the production of SURGICAL MASKS	standard UNI EN ISO 14683:2019 standard UNI EN ISO 10993
QUALITY Management System	ISO 13485 or Good Manufacturing Practices (GMP)

Differently, SURGICAL MASKS may be produced by way of derogation from the provisions in force, but in any case, in compliance with the indications of ITALIAN DECREE LAW no. 18 of 17 March 2020, with particular reference to Title I, Article 15, **paragraph 2**, as outlined in the version in force:

those [...] wishing to avail themselves of the exemption [...], must send a **self-certification** to the ISS in which, under their own exclusive responsibility, they indicate **the technical characteristics of the masks and their compliance with all the safety requirements set out in the current regulations**. No later than three days from the abovementioned self-certification [...], they must also **send to the ISS any information useful for the certification of the masks covered by it**. The ISS, within three days of receipt of the above, shall rule on the compliance of the masks with the standards in force.

CASE 2 - PERSONAL PROTECTIVE EQUIPMENT (PPE)

We inform you that the PPE produced by you can already be considered suitable and therefore eligible for the exemption:

Standards for the production of Personal Protective Equipment (PPE) (FFP2 FILTER MASKS)	N95 NIOSH criteria, corresponding to technical standard EN 149:2001+A1:2009
QUALITY Management System	ISO 13485 or Good Manufacturing Practices (GMP)

Differently, Personal Protective Equipment - PPE may be produced in derogation of the provisions in force, but in any case, respecting the indications of ITALIAN DECREE LAW no. 18 of 17 March 2020, with particular reference to Title I, Article 15, **paragraph 3**, as outlined in the version in force:

those [...] wishing to avail themselves of the exemption [...], must send a **self-certification** to INAIL in which, under their own exclusive responsibility, they indicate **the technical characteristics of the abovementioned equipment and its compliance with all the safety requirements set out in the current regulations**. No later than three days from the abovementioned self-certification [...], they must also send to INAIL any information useful for the certification of the personal protective equipment covered by it. INAIL, within three days of receipt of the what indicated in this paragraph, shall rule on the compliance of the masks with the standards in force.

We therefore invite you to assess whether your products can meet the requirements that you will be asked to self-certify, in terms of:

- efficiency of the material(s) for the mask as a barrier to bacterial penetration
- air permeability, determined by the pressure difference through the mask



If you believe that your material/equipment matches the above, please send the following samples to the addresses below:

1)

Politecnico di Milano,
Via La Masa, 34
20156 Milan
To the attention of Prof. Giuseppe Sala

Samples:

- **10 mask** samples or **10 samples** of material **at least 15 x 15 cm** in size
- **10 mask** samples or **10 samples** of material **at least 20 x 20 cm** in size

2)

Politecnico di Milano
Via Mancinelli, 7
20131 Milan
To the attention of Prof. Mariapia Peddeferri

Samples:

- **10 mask** samples or **10 samples** of material **at least 15 x 15 cm** in size

In thanking you for your cooperation, I hereby send you my best regards,

Ferruccio Resta

Rector