



Concerns following the appeal by many (health) authorities to produce “artisanal” masks at home or at any possible production site.

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To : EU Commission : cabinet of Commissioner Breton, DG GROW unit C3, DG GROW unit F4 and DG SANTE unit B6

In many countries, the authorities (including health authorities) and medical services make an appeal to companies, organisations and the general public to produce masks to help the health care workers to protect themselves. This obviously with the best intentions in mind.

We would like to stress the need to urgently and clearly communicate on this topic to prevent a false feeling of protection.

The professional producers of masks, be it medical face masks or PPE masks, are working very hard to make the necessary quantities and quality of masks available to those who really need them. These masks fulfil the requirements of the EU legislation (Regulation (EU) 2016/425 for the PPE and/or Directive 93/42/EEC respectively Regulation (EU) 2017/745 for the medical devices) and therefore, offer the protection levels required and expected by the health care workers.

Masks produced ‘at home’ or ‘artisanal’ using many different materials have not gone through the conformity assessment procedures (including testing), and in many cases are made of materials that would not pass the relevant standards. Therefore, these masks should not be used by health care workers. In the current crisis, we cannot afford to put our health care workers at risk by giving them a false feeling of protection when wearing a mask that is not proven to protect them as needed.

It must be communicated clearly to all concerned that artisanal masks do not offer proven protection and should not be used by health care workers as replacement of medical or PPE masks with CE mark and proven protection levels. The artisanal masks may be used by private persons as a low level of barrier, but even the general public needs to be aware that those masks will under no circumstances offer proper protection.

Another issue related to the artisanal textile masks is the washing/disinfection of those masks. As these are made of textile material, it is to be foreseen that they will be washed and re-used. This can be the cause of further spreading of the virus

through cross contamination during the cleaning process and/or not removing the virus during the cleaning process. So even those used by citizens and washed at home can cause spreading of the virus rather than protection against the virus.

The European Safety Federation (trade organisation of PPE suppliers) makes an urgent appeal to the EU Commission to clearly communicate on this topic and urge the member states to do the same.

Henk Vanhoutte  
Secretary General

**Note as reminder of the functionality of the 2 types of masks in relation with the COVID-19 pandemic :**

MEDICAL FACE MASK (Medical Device legislation – typical compliant with harmonised standard EN 14683 type II or better type IIR)

Outward protection:

- designed only to retain the particles emitted by the wearer.
- does not have the primary function of protecting the wearer from external pathogens;
- is used to prevent the wearer from spreading the virus through sneezing and coughing;
- is more comfortable since it wears more widely on the face;
- can be worn by citizens;

PPE MASK (Personal Protective Equipment legislation – typical compliant with harmonised standard EN 149 level FFP2 or better FFP3 (American similar standard protection levels are N95 / N99)

Protection towards the wearer:

- filter the inhaled air protecting the wearer and some types also filter the exhaled air (protection towards the outside);
- levels recommended by WHO (World Health Organization). The FFP2 filters over 92% of the suspended particles, the FFP3 arrive at values equal to or greater than 98%;
- must fit tightly to the face and be worn correctly (see instructions);
- must be worn mainly by healthcare personnel as indicated by WHO