**One year of surgical mask testing at the University of Bologna labs**

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The outbreak of SARS-CoV-2 pandemic highlighted the worldwide lack of surgical masks and personal protective equipment, which represent the main defense available against respiratory diseases as COVID-19. At the time, masks shortage was dramatic in Italy, the first European country seriously hit by the pandemic: aiming to address the emergency and to support the Italian industrial reconversion to the production of surgical masks, a multidisciplinary team of the University of Bologna organized a laboratory to test surgical masks according to European regulations. The group, driven by the expertise of chemical engineers, microbiologists, and occupational physicians, set-up the test lines to perform all the functional tests required. In Europe, surgical masks must be labeled with the CE mark and must meet the requirements defined in EN 14683:2019 and in EN ISO 10993-1. Four test lines were assembled to perform the required tests, namely breathability, bacterial filtration efficiency (BFE), microbial cleanliness (bioburden), and splash test (for IIR type masks). According to the standard, the experimental workflow included first a breathability test that was used to exclude non-suitable materials on the basis of the air permeability. Suitable masks were then tested for BFE, which provides the indication on the filtration capabilities towards droplets with size within the range of the breathing aerosol. Eventually, the microbial cleanliness of the masks was also assayed as an additional parameter of user safety. For masks of Type IIR, the resistance to blood penetration was determined by means of the splash test using synthetic blood. The laboratory started its activity on late March 2020, and as of the end of December of the same year, more than 600 surgical mask prototypes were tested, with nearly 1200 tests performed in total. Here, a critical analysis of the results is presented, with correlations between results for breathability and BFE on surgical mask prototypes. Finally, the protocols for mask testing and validation indicated in the EN standard are discussed, revealing some critical aspects and possible room for improvement. Such analysis aims to optimize the characterization methods for what concern the reliability and the accuracy, as well as the duration, of the surgical masks’ standard tests.

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