

ATTESTATION DE QUALIFICATION DE PERFORMANCE

The **SterØmask** system designed by the company **INGENICA** (Immeuble Le Terminal - 2 rue Charron - 44800 SAINT HERBLAIN) was subject to a performance qualification by the **LABORATOIRE ICARE** which issued a tests report at the end of the qualification. “**Study of the effects of ultraviolet light on disinfection and physical alteration of surgical masks Vert Conformat – Réf. 2868-10**” and referenced 04712Y-1A, 04712Y-2A, 04712Y-3A, 04712Y-4A, 04712Y-5A, 04712Y-6A, 04712Y-7A, 04712Y-8A, 04712Y-9A dated May 29, 2020.

The objective of these tests was to assess the ability of the equipment to provide disinfection by an ultraviolet exposure (UV-C) process to protective masks for medical application initially intended for single use (surgical masks) and used as category 1 protective masks for professionals, in contact with the public outside the health sector.

To this end, the value D_{10} in mJ / cm² allowing the reduction of 1 log₁₀ (90%) of a population of spore-forming bacteria *Bacillus subtilis* (reference microorganism, renamed *Bacillus atrophaeus*, reputed to be the most resistant to ultraviolet treatment) has been determined.

The distribution and penetration capacity of the UV-C on the different surfaces of the mask was also determined.

Finally, the mechanical filtration and breathability properties (air permeability) were also evaluated before and after 4 and 10 consecutive use tests and application of the disinfection process.

The conclusions of the performance qualification are as follows:

1. The value D_{10} which corresponds to the dose of UVC necessary to reduce by 90% (1 log₁₀) the spore population of the *Bacillus subtilis* ATCC 9372, present on a surgical mask is **9,4 mJ/cm²**
2. The minimum dose required to obtain a disinfectant effect (sporicide) which corresponds to a reduction in the starting inoculum of 4 log₁₀ is therefore 38 mJ / cm². This value should be compared to the 10 mJ / cm² necessary to destroy approximately 4 log₁₀ (99.99%) of the SARS-CoV2 virus present on the external face of FFP2 masks (Report from DGA RP / 20-2822 / DGA MNRBC / 1801930 / version 2 in appendix 3 of our report). This confirms that the spore bacteria *Bacillus subtilis* is more resistant than the SARS-CoV2 virus to ultraviolet disinfectant treatment (UV-C).
3. A reference dose of 500 mJ / cm² delivered ensures that, at a minimum, all of the internal and external surfaces of the mask receive a dose of at least 100 mJ / cm².
4. The filtration efficiency of surgical masks after 4 and 10 cycles of use and disinfection (4-hour of wearing followed by exposure to 1000 mJ / cm² of UV-C) for the particles of 3 µm size is reduced compared to that of new, unworn masks. However, after 4 and 10 cycles of use the masks remain in accordance with category 1 of masks for non-sanitary use (filtration efficiency of 3 µm size particles is greater than 90%).
5. 4 et 10 cycles of wearing and disinfection (4 successive 4 h of wearing cycles, each followed by an exposure to 1000 J / cm² of UV-C) do not alter the breathability of the masks.

The possible number of cycles of use and disinfection (4 hours of wearing followed by exposure to 1000 mJ / cm² of UV-C) of protective masks of the type Vert Conformat – Réf. : 2868-10 without alteration of filtration and breathability performance is 4 cycles. used as protective masks of category 1 for professionals outside the Health sector, in contact with the public, **while maintaining consistent filtration performance and without altering the breathability performance is 10 cycles.**

Christian POINSOT
Directeur scientifique

