ICARE Laboratoire

Biopôle Clermont-Limagne • BP 60006 • 63360 Saint-Beauzire • **Tél. +33 (0)4 73 33 99 99**
Fax. +33 (0)4 73 33 99 77 • secretariat@laboratoireicare.com • **www.groupeicare.com**
RCS Clermont-Ferrand 402 946 917

CERTIFICATE OF PERFORMANCE QUALIFICATION

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 AURA™ FFP2 protective masks from 3M™ Ref. 1862+ "**and referenced 03851Y-13N, 03851Y-14N, 03851Y-15N, 03851Y-16N, 03851Y-17N, 03851Y-18N dated May 1, 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 (FFP2 masks).

To this end, the dose in mJ / cm2 allowing the reduction of 4 $\log_{10}$ (99.99%) 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 consecutive use tests and application of the disinfection process.

The conclusions of the performance qualification are as follows:

1. An exposure to at least 100 mJ / cm² allows a reduction in the initial inoculum greater than or equal to 4 $\log_{10}$, the minimum necessary to validate that the process has a sporicidal disinfectant effect. This value should be compared to the 10 mJ / cm2 necessary to destroy approximately 4 $\log_{10}$ (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).
2. 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.
3. A delivered dose of 1000 mJ / cm² ensures that the 2 sides of the innermost filtering layer of the mask, at the level of the central part (the most critical area in contact with the mouth and the nostrils) receive a dose of at least 100 mJ / cm².
4. No significant difference was found between the filtration efficiency of new, unworn masks and the filtration efficiency of the masks after the use test and disinfection simulation (4 successive 4 h of wearing cycles, each followed by an exposure to 2000 J / cm2 of UV-C).
5. No significant difference was found between the breathability of new, unworn masks and the breathability of the masks after use test and disinfection simulation (4 successive 4 h of wearing cycles each followed by an exposure to 2000 J / cm2 UVC).

The possible number of cycles of use and disinfection (4 hours wearing followed by exposure to 2000 mJ / cm2 of UV-C whether or not preceded by ethanol decontamination) of protective masks of the type FFP2 AURA™ from 3M™ Ref. 1862+ without alteration of filtration and breathability performance is 4 cycles.

Christian POINSOT
Directeur scientifique