



# CHARACTERIZATION OF DELUX: ULTRAVIOLET LIGHT STERILIZATION DEVICE FOR PFF2 / N95 MASKS AGAINST COVID-19

## CARACTERIZACIÓN DO DELUX: DISPOSITIVO DE ESTERILIZACIÓN POR LUZ ULTRAVIOLETA PARA MÁSCARAS PFF2/N95 CONTRA COVID-19

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Received: 15-11-2021, Received after review: 20-12-2021, Accepted: 26-12-2021, Published: 01-01-2022

### Abstract

The World Health Organization (WHO) has declared a public health pandemic state due to the transmission of the new coronavirus on March 11th, 2020. COVID-19, that is caused by SARS-CoV-2, has a very broad clinical spectrum, with predominantly respiratory symptoms developments. The role of the health professionals in fighting the pandemic requires the use of Personal Protective Equipment (PPE). PFF2 / N95 masks are suitable PPEs for this purpose. Due to the high demand for PFF2 / N95 masks to fight the pandemic, there was a shortage of this PPE worldwide. This work aims to present a characterization of the device called DELUX, utilized for UVC (ultraviolet C light spectra) sterilization of PFF2 / N95 masks, and allowing to extend the time of safe use of this PPE in emergency conditions. The photometric validation of the device resulted in the verification of the emission spectrum of the lamps used in the device, and the measurement of the optical power, demonstrating the adequacy of irradiation with UVC light, with a 15-minute cycle, and safely. Biological validation showed that DELUX is capable of inactivating SARS-CoV-2 present on the surface of PFF2 / N95 masks, thus being efficient for their sterilization. The safety offered by the sterilization cycle allows to extend the safe use of those masks.

**Keywords:** COVID-19, equipment, protective, radiation, sterilization, ultraviolet

### Resumen

La Organización Mundial de la Salud (OMS) declaró un estado pandémico de salud pública debido a transmisión del nuevo coronavirus el 11 de marzo de 2020. La COVID-19, causada por el SARS-CoV-2, tiene un espectro clínico muy amplio, con predominio de desarrollos sintomáticos respiratorios. El papel de los profesionales de salud en la lucha contra pandemia requiere el uso de Equipo de Protección Personal (EPP). Las máscaras PFF2 / N95 son EPP adecuados para este propósito. Debido a gran demanda de máscaras PFF2 / N95 para combatir la pandemia, hubo escasez en el mercado. Este trabajo tiene como objetivo caracterizar un dispositivo denominado DELUX para la esterilización por UVC (espectros de luz ultravioleta C) de mascarillas PFF2 / N95, ampliando el tiempo de uso seguro de este EPP en condiciones de emergencia. La validación fotométrica del dispositivo permitió la verificación del espectro de emisión de las lámparas utilizadas en el dispositivo y la medición de la potencia óptica, demostrando la idoneidad de la irradiación con luz UVC, en ciclos de 15 minutos, de forma segura. La validación biológica mostró que DELUX es capaz de inactivar el SARS-CoV-2 presente en la superficie de las mascarillas PFF2 / N95, siendo así eficiente para su esterilización. La seguridad que ofrece el ciclo de esterilización permite extender el tiempo de uso seguro de estas mascarillas.

**Palabras clave:** COVID-19, equipo, esterilización, protección, radiación, ultravioleta

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Suggested citation: Lombello, C. B.; Ali Daghanli, N.; Windisch Neto, H.; Affonso Fonseca, F. L.; Nogueira Ambrosio, F.; Arbex, R.; Kobb Fernando, I.; da Silva, V. A.; Pataquini dos Santos, L. and Aparecida da Ana, P. "Characterization of DELUX: Ultraviolet light sterilization device for PFF2 / N95 masks against COVID-19," *Ingenius, Revista de Ciencia y Tecnología*, N.º 27, pp. 23-31, 2022, DOI: <https://doi.org/10.17163/ings.n27.2022.03>.

## 1. Introduction

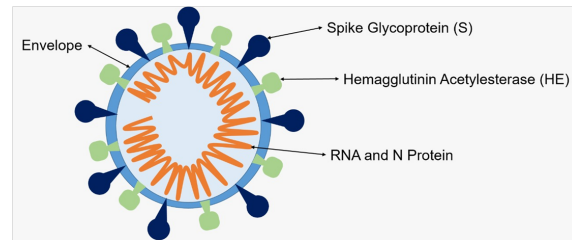
Viruses known as coronaviruses belong to the order Nidovirales, family Coronaviridae, subfamily Coronavirinae, genus Coronavirus (CoVs) [1]. They were first identified in poultry in the 1930s and many of them have been associated with respiratory, gastrointestinal, liver and neurological diseases in animals. Some coronaviruses are known to cause disease in humans [2]. Of these, four species (229E, OC43, NL63 and HUK1) usually cause symptoms of a common cold in humans, and only rarely can result on a severe lower respiratory tract infection, such as pneumonia. These cases are particularly important in children, the elderly and immunodepressed patients [3–5].

However, three other species considered zoonoses (SARS-CoV, MERS-CoV and SARS-CoV-2) are associated with more severe respiratory infections in humans, and can be fatal [3,4]. SARS-CoV was identified in 2002 as the cause of Severe Acute Respiratory Syndrome (SARS), while MERS-CoV was identified in 2012 as the cause of Middle Eastern Respiratory Syndrome (MERS) [4]. More recently, SARS-CoV-2 (Figure 1), known as the new coronavirus, was first detected on December 2019 in the city of Wuhan (China), and identified as the etiologic agent of the disease capable of aggravating the respiratory system [3], [6] with an important impact on global public health due to consequent morbidity and mortality worldwide [7,8]. According to the World Health Organization (WHO), the official nomenclature for the disease caused by this virus was defined as Coronavirus Disease-2019 (COVID-19) and, on March 11, 2020, WHO declared a state of pandemic in public health, due to the transmission of the new coronavirus [9,10].

COVID-19 disease, caused by SARS-CoV-2, has a very broad clinical spectrum. There are asymptomatic variations or diverse clinical symptoms, such as sore throat, diarrhea, anosmia or hyposmia, myalgia, tiredness, fatigue, and skin manifestations, like dermatoses and urticaria were also recorded [8], [11,12]. However, mainly respiratory symptoms such as dry cough and shortness of breath, associated with fever, and other symptoms mentioned above are directly related to the high rates of hospitalization and death resulting from the disease [8], [12].

The health professionals work is fundamental during the infection combat, in prevention, detection, patient treatment and recovery, and these professional efforts are recognized worldwide [13]. During the professional activities the use of Personal Protective Equipment (PPE) can provide safety, preventing accidents or occupational diseases. The Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária*, Anvisa) determines that the PPE required during the activities performed by health professionals with possible exposition to SARS-CoV-2 include: cap, protection

glasses or face shield, mask (surgical or respiratory protection mask), long-sleeved coat and gloves [14].



**Figure 1.** Structure of the coronavirus. The envelope, capsid proteins (S and HE), N protein and viral RNA are represented

As this is a disease with preferential transmission through the air, masks are essential PPE in controlling the spread of the disease. These devices are also called Respiratory Protection Equipment (RPE). Surgical masks are indicated to prevent the contamination of the professionals' airways by respiratory droplets (particles larger than 5  $\mu\text{m}$ ) when acting less than 1 meter from the patient. However, not all the masks provide protection against aerosols [14,15]. Although these masks, as well as fabric masks, are not considered PPE by Anvisa, their use by the population was mandatory in several countries, like Brazilian one, in order to contain the transmission of COVID-19. In health services, masks must be used by asymptomatic patients, visitors, companions and professionals in administrative areas who do not have contact with patients at distances of less than 1 meter [14], [16].

The masks called semi-facial filtering piece (PFF) are PPEs with a minimum efficiency of 95% in the filtration of particles up to 0.3  $\mu\text{m}$ . The classification of masks occurs according to the level of penetration and breathing resistance, which can be PFF1, PFF2 and PFF3 in Brazil. For the protection of aerosols (that is, particles smaller than droplets) containing biological agents, PFF2 must be used, equivalent to the N95 mask adopted in the United States [14], [16–18].

These RPEs should be used by healthcare professionals who work in procedures with risk of generating aerosols, such as collection of nasotracheal secretions, bronchoscopy, non-invasive ventilation, manual ventilation before intubation, intubation or tracheal aspiration, and cardiopulmonary resuscitation. In addition, they are also recommended to support professionals who develop their activities in areas of carrying out procedures that generate aerosols [14], [16]. However, in cases of prolonged use, it is important that this equipment remains adjusted in the face, and functional. In this context, the Brazilian Institute for Patient Safety (IBSP) warns that these masks remain effective when used for up to 8 consecutive hours [19]. PFF2/N95 masks are formed by superimposed layers of fabric-non-woven (TNT) polypropylene, which filter the air

and trap particles in the order of 0.3  $\mu\text{m}$ , including microorganisms such as the SARS-CoV-2 virus [20].

The impact of the COVID-19 pandemic on health-care services included the high demand for PPE used by healthcare professionals in the combat of the coronavirus, resulting in a shortage of supply of this equipment. Although not ideal, the lack of availability of PFF2/N95 masks on the market makes the reuse of these PPEs necessary. The Anvisa agency states that respiratory protection masks may, exceptionally, be used for a longer period or for several times greater than that foreseen by the manufacturer. However, the reuse of these PPE for a time beyond what is considered safe exposes health professionals to contamination by the virus, due to the conditions of prolonged use, handling and storage. Some Anvisa recommendations described in the Technical Note GVIMS/GGTES/AN-VISA N. 04/2020 [16] indicates the proper use of this PPE that must be followed. The reprocessing of a PPE regularized at Anvisa as disposable must ensure that it is as safe as a new PPE, in addition to not affecting the performance characteristics. Possible reprocessing protocols must be validated in order to guarantee the sterilization of the product as well as its integrity and functionality [16].

Among the alternatives developed to ensure safety in the extension of the useful life and reuse of these masks, the sterilization of these equipments with UVC radiation has shown to be promising. This technique, in addition to enabling the reuse of masks quickly, does not require large infrastructure and elaborate spaces, as well as the frequent replacement of supplies. Thus, the use of a sterilization device with such a function guarantees a versatile possibility so that, at first, healthcare workers can sterilize their PPE safely and quickly [21].

This paper aims to characterize a low-cost and fast production equipment, developed in the ABC region of São Paulo, for the sterilization of PFF2/N95 masks, with the proposal to extend the time of use of this PPE in emergency conditions of shortages in the market due to the current COVID-19 pandemic.

## 2. Materials and methods

### 2.1. Emission of UVC lamps

The characterizations of the emission spectrum of the UVC lamps (PURITEC 15W, Osram, Brasil) used in the DELUX device was carried out using three different devices.

#### 2.1.1. Ultraviolet-visible photodiode spectrophotometer (Cary 50, Varian)

Measurements were taken to obtain the emission spectrum of UVC lamps (PURITEC 15W, Osram, Brasil).

#### 2.1.2. OCEAN OPTICS spectrometer (UV-VIS-NIR spectrometer)

This spectrometer is coupled to an optical fiber ( $\varphi=400\text{ nm}$ ) to measure the emission of the UVC lamp in loco, that is, inside the sterilization and measurement equipment of the internal environment of the irradiation chamber.

#### 2.1.3. FieldMaxII-TO optical powermeter (Coherent-USA)

Powermeter was coupled to the PM10 sensor (Coherent-USA) to measure the power values per area ( $\text{mW}/\text{cm}^2$ ) through the PM10 semiconductor sensor in the desired spectral region.

## 2.2. Biological Tests

Validation of efficacy was carried out together with the ABC Medical School (FMABC). To ensure the correct PFF2/N95 mask sterilization through the DELUX system, a methodology was proposed to assess the effectiveness against the presence of viruses after the sterilization cycle. For this study the virus were detected using RT-PCR (polymerase chain reaction) [22,23].

Three N95 masks of the same type used by health professionals during their daily activities were used (in particular the respiratory mask 8801H 9 PFF-2 Respirators for biological risks (Brand: 3M®, Brasil). A control sample with the SARS-CoV-2 virus was used to mimic the contamination on the front of the mask, following the experimental procedures. Initially a swab containing a viral sample was used to spread the contents from bottom to top and left to right. The swab was used for 6 times for spreading in the anterior direction of each of the masks, and rested at room temperature for 3 minutes, in biosafety cabinet. The masks were then positioned in the DELUX device in order to maximize their complete illumination with UVC light. Irradiation of the masks with UVC light was carried out in a single 15-minute cycle.

After irradiation, samples were collected from the masks. For this purpose, the masks were kept for 1 minute in a biosafety cabinet, and using a sterile swab was rubbed on the surface of the mask in the anterior region from the bottom to the top and from the left to the right, repeated 6 times. The swab was placed in an extraction solution in order to obtain the viral RNA. RNA extraction and amplification followed the Centers for Disease Control and Prevention (CDC) protocol.

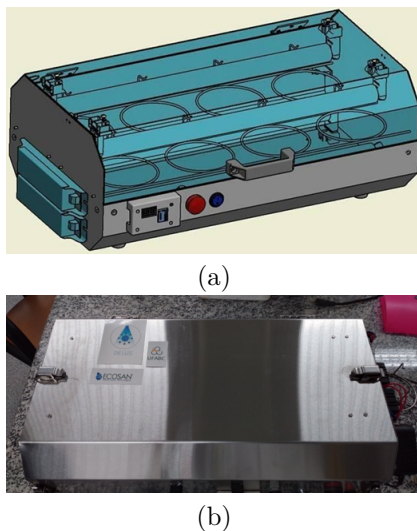
## 3. Results and discussion

For the sterilization of PFF2/N95 masks, one of the possible measures adopted worldwide is sterilization

with UVC radiation, a physical agent. Ultraviolet light is in the electromagnetic spectrum, and UVC radiation comprises wavelengths between 190 and 280 nm, located within the spectrum of UV light (electromagnetic spectrum between 100 and 390 nm). However, wavelengths below 200 nm have no biological significance, as they are intensely absorbed by air [24].

UVC radiation lamps used for germicidal action usually have peak emission at a wavelength of 254 nm. This parameter is suitable for the inactivation of several microorganisms, including coronaviruses, as stated in previous studies with SARS-CoV and MERS-CoV [25, 26]. The photolytic effect of UVC radiation is capable of destroying or inactivating the microorganism, preventing it from multiplying. It is intensely absorbed by nucleic acids and proteins, causing the disruption of nucleic acid bases and the inactivation of enzymes. Unlike other techniques, its photolytic action rarely produces potentially dangerous by products [27–29].

The device called DELUX (Figure 2) was developed in partnerships with the ABC School of Medicine, FMABC, and with the company based in the ABC region of São Paulo (named Ecosan). The device was made with materials compatible with the purpose and use, mainly using 304 stainless steel sheets, carrying handle, electrical system to drive 4 ultraviolet light lamps (PURITEC 15W, Osram, Brasil), automated timer system, lamp activation indicator LED and safety system to prevent the activation of the lamps with the equipment open.



**Figure 2.** DELUX. (a) prototype, (b) device

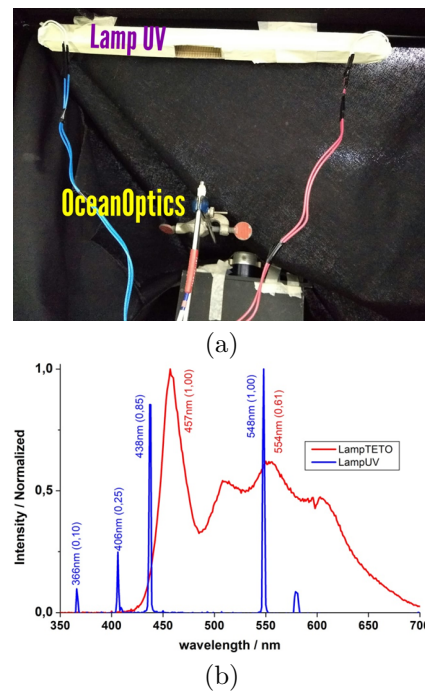
The device allows the simultaneous accommodation of up to 16 masks, in niches that allow the identification of each mask. It was carried out with the validation of the photometric efficacy of the device and the verification of the biological efficacy against the coronavirus.

### 3.1. Photometric Measures

Ultraviolet light (UV) is part of the electromagnetic spectrum characterized by wavelengths ( $\lambda$ ) smaller than those of the visible light (VIS) spectrum, which varies between 400nm - 800nm. The spectral range of UV light is between 100 - 400 nm, and it is divided into 3 different regions: UVA (long-wave) between 315 - 400 nm; UVB (medium-wave) between 280-315 nm, and UVC (short-wave) between 100 - 280 nm [24]. UVC light has a germicidal effect compared to visible light [24], [28, 29].

Regarding safety, exposure to UVC can cause several adverse biological effects, such as acute inflammation of human tissues, conjunctivitis, erythema, in addition to being associated with chromosomal alterations that can even cause some types of cancer [24]. Thus, the use of UV light must be carried out carefully to prevent possible adverse effects. The biological effects of the action of UV light can be evaluated as a function of damage through the parameter of Relative Spectral Effectiveness,  $S(\lambda)$ , thus when exposure to UV light occurs, care must be taken [24], [26], [28, 29].

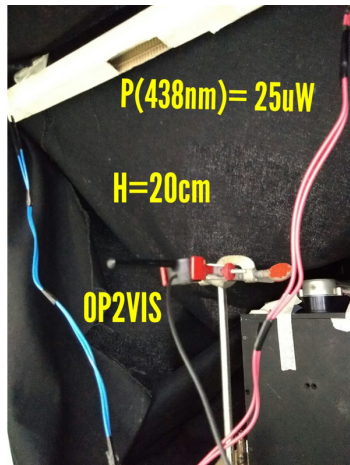
The measurements of the optical power of the lamps used in the DELUX prototype were started with the photometric characterization of the PURITEC 15W, (Osram, Brasil), by measuring the emission spectrum in the UV-VIS region (Varian spectrophotometer), as shown in Figure 3. Typical emission peaks at specific wavelengths were observed.



**Figure 3.** (a) Experimental setup with the light probe (Ocean Optics). (b) Emission spectra of a white light lamp (LampTETO) and UVC light (LampUV). Emission peaks in the region of interest, below 400 nm.



The measurements of the power emission intensities were complemented with the optical powermeter. Measurements of the power emitted by the UVC lamp were performed using peak emission at  $\lambda = 256 \text{ nm}$ , and  $\lambda = 438 \text{ nm}$ , shown in Figure 4. These data allowed us to evaluate the emission of the UVC lamps used in DELUX at the relevant wavelengths ( $\lambda$ ) (Figure 4).

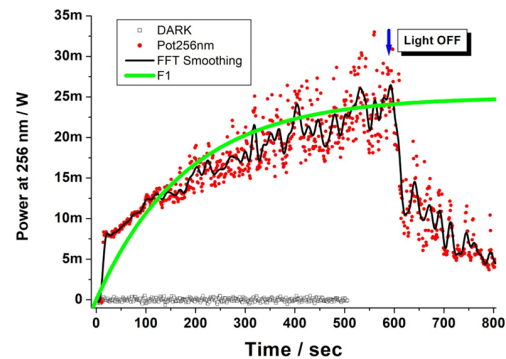


**Figure 4.** Assembly for measuring the power of UV light emitted by UV lamps. Measurements were performed with two different power probes (Coherent), OP2-VIS and PM10 (for UVC). Height (H), optical power (P)

Temporal measurements of UVC light emission (at 256 nm) were performed from the moment the lamps were turned on at an interval of 800 s. Figure 4 shows the kinetic curve of the UV lamp emission. We observe that the power emission efficiency of the lamp increases from exponential-like transient to constant emission (Figure 5).

Measurements were performed using the UV lamps in the interior of the device, and possible leak of light to the exterior of the device was verified. The equipment has the installation of rubber blankets that were effective for the complete blocking of light. Measurements of light power were not obtained on the outside of the device, closed and turned on, with activation of the lamps, which is an important result to guarantee safety for users.

For sterilization to be effective, some factors must be taken into account. The dose (or intensity) of light delivered ( $\text{J}/\text{cm}^2$ ) is determined by the product between the irradiance of the light source ( $\text{mW}/\text{cm}^2$ ) and the irradiation time. The dose of light must be sufficient and adequate to penetrate the material to be sterilized. The penetration of light radiation is controlled by the material's absorption coefficient: the lower the coefficient, the greater the success of the application [28,29].



**Figure 5.** Kinetic curve of UV lamp emission. Temporal measurements. Red dots are the monoexponential fit of light emission at 256 nm (10Hz). Black line is dot smoothing (FFT - Origin). Solid green line is the monoexponential fit of the experimental data, UVC lamp emission reaches maximum value of 25mW after 400s. Minimum power emitted  $\sim 8 \text{ mW}$

The sterilization efficiency also depends on the regularity and exposed area on the material surface, as there is a minimum dose of UVC radiation to inactivate the microorganisms [20,21], [28,29]. Thus, a successful sterilization will only occur if the entire surface of the material is exposed to UVC radiation, as any shadows produced by the fabric layers of the masks can reduce the effectiveness of the sterilization. As the surface requires high intensity UV light, the lamps must be close to the material to be sterilized [30].

Different mask models may have different sterilization results [21]. Models with extra layers of outer protection can make it difficult or even prevent UVC light from penetrating the innermost layers. There are more studies that allow the standardization of this procedure, and individual tests are recommended for each type of mask that is used in a particular location [21], [31].

The recommended dose of UVC radiation to ensure effective sterilization is  $1 \text{ J}/\text{cm}^2$ . The dose between  $0.5$ - $1.8 \text{ J}/\text{cm}^2$  was able to inactivate 99.9% of pathogens, such as some types of Influenza A, MERS-CoV, SARS-CoV and the MS2 bacteriophage. The mask's filtering capacity was maintained even with high doses of UVC radiation [20,21], [28–31].

The use of UVC light is a possible solution for the sterilization of N95 masks in their reuse, as they have antimicrobial and antiviral effects and do not generate toxic residues that may remain in the masks. UVC radiation can promote the degradation of the polypropylene that makes up the filtering layers, but this is a slow process, in which doses lower than  $950 \text{ J}/\text{cm}^2$  do not present any significant loss of filtration efficiency [32,33].

### 3.2. Biological Tests

Upon analyzing the results, all samples were classified as «Not Detected». It was possible to conclude that the samples tested after the SARS-CoV-2 scattering procedure and submitted to DELUX presented a «Not Detected» result, showing that the 15 minute UVC light cycle with the DELUX device was sufficient to sterilize the masks.

Due to high demand associated with production and logistical difficulties, the quantity of N95 masks was shown to be limited and insufficient to attend healthcare professionals during a pandemic situation [34, 35]. The Anvisa determines that, due to the public health emergency situations, exceptionally, these masks can be used for longer periods of time and for a several times greater than the specifications provided by the manufacturer, which must be followed by some precautions. These must include PPE protection, proper handling and inspection before each period of usage [36, 37]. The reuse limit is not stipulated by Anvisa, which must be recommended by each healthcare facility, and proper protocols related to the reuse of these PPE are encouraged, as well as, health professionals care with the PPE.

A review study demonstrated that an irradiation dose of 4 J/cm<sup>2</sup> resulted in a 3-log (99.9%) reduction in viral presence, which represents a total decontamination in models using Influenza virus [31]. In addition to the irradiation dose, the time elapsed after contamination also results in a decrease in the presence of microorganisms, with a reduction of 1 log (90%) occurring after 24 hours [31]. Studies consider a period of 60 seconds of irradiation for sterilization [38]. For the MERS-CoV virus, the appropriate time was 5 minutes [26]. Meanwhile for the H1N1 virus, the appropriate time was 15 minutes, and the distance between the UVC lamp and the masks was 25 centimeters [39]. The DELUX device was based on 15 minute cycle sterilization, proposing a unique cycle per day per mask.

In Brazil, due to lack of funds, many centers do not have space or equipment to implement or develop protocols regarding sterilization by ultraviolet radiation (UVC), and the lack of this PPE has been a persistent problem since the beginning of the pandemic. This study allowed the characterization of the DELUX device that can be used to sterilize PFF2/N95 masks using UVC radiation, in a standardized way, ensuring the extension of the time of use of these PPEs safely for health professionals, as shown by photometric and biological characterizations.

Another advantage of this UVC PFF2/N95 masks sterilization includes the reduction of potentially infectious waste generated by the disposal of the large amount of masks used in the COVID-19 pandemic [40].

### 4. Conclusions

The DELUX device is based on the UVC sterilization strategy for irradiating PFF2/N95 masks with a 15 minute cycle. It is a low-cost, fast and effective device to sterilize PFF2/N95 masks, allowing for its proper and safe reuse in order to alleviate the shortage of PPE during the COVID-19 pandemic. The photometric measurements show that the DELUX can make an adequate UVC-light irradiation, resulting in an efficient sterilization on masks. Additionally, photometric measurements allowed, guarantying a safe device to handle with. The biologic characterization resulted in inactivation of SARS-CoV-2 on the masks surface.

### Acknowledgments

The UFABC for financial support, UFABC Multiuser Center (CEM UFABC) for the equipment support, the ABC Medical School (FMABC) for the partnership and biological validation, and Ecosan for the development of the DELUX device.

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