

Declaration of effectiveness for



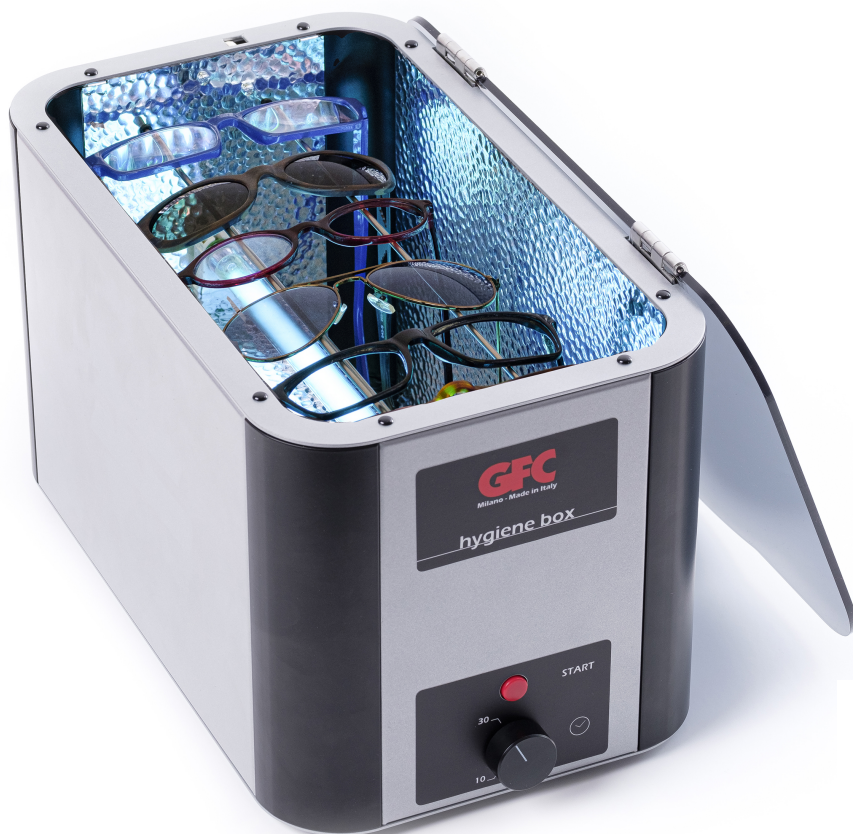
Vismederi Life Sciences Srl

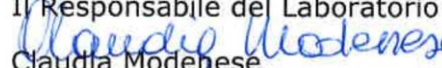
Strada del Petriccio e Belriguardo, 35
53100 - Siena Italy

following the tests carried out in its own laboratories

Declares

*that the device **Hygiene Box** manufactured by the company **GFC srl** seated in Viale Lombardia, 18 - 20021 Bollate (Milan) - Italy, demonstrates an average of reduction of 99.9% after 30 seconds of exposure against the virus SARS-CoV-2_COV2019, an average of reduction of 99.9% after 60 seconds of exposure against the bacterium Escherichia Coli ATCC 8739 and an average of reduction of 99.9% after 90 seconds of exposure against the bacterium Staphylococcus Aureus ATCC 6538P.*



Il Responsabile del Laboratorio

Claudia Modenese



Evaluation of virucidal activity of the device GFC Hygiene Box for glasses sterilisation.

Aim of the Study

The aim of this study is to determine the virucidal activity of the device **Hygiene Box** against SARS-CoV2.

The aforementioned device consists of a base that emits UV rays.

Glasses are positioned on two supports.

*The device was created by **GFC srl** seated in Viale Lombardia, 18 - 20021 Bollate (Milan) – Italy.*

Method

Glasses are inoculated with 50µL of a viral suspension on two positions, on glass near temples (1) and near nose pad (2).

Inoculum was left to dry for 30 minutes.

After a contact time we tested the residual virus activity by evaluating by Tissue Culture Infective Dose 50% (TCID₅₀).

Name of product	Hygiene Box for glasses sterilisation
Date of delivery	03/11/20
Period of analysis	03/11/20 – 06/11/20
Temperature of incubation	37°C
Identification of Viral strain	SARS-CoV-2_COV2019 ITALY/INMI1
Contact time	See protocol



Contact Time Protocol

Box	30 sec	Position 1 and 2 3 repetitions
	60 sec	Position 1 and 2 3 repetitions

All repetitions were tested for SARS-CoV-2 concentration by TCDI₅₀ using VERO E6 C1008 (ATCC CRL-1586) cell line.

Results

Suspension virus used 10^{6.5} TCID₅₀/mL (6.5 expressed by Log)

Value of Log TCDI₅₀ = 1.50 (Note that this value means total viral inactivation)

	Results
Cytotoxicity	No Cytotoxicity observed

	Time	Media Log TCDI ₅₀
Control	60 sec	4.50
Temples	30 sec	1.50
	60 sec	1.50
Nose pad	30 sec	1.50
	60 sec	1.50



Conclusion

*The purpose of the study was to determine the virucidal efficacy of the device manufactured by GFC srl against **SARS-CoV-2_COV2019 ITALY/INMI1** at a contact time of 30 and 60 seconds at an exposure of room temperature.*

The evaluated test device demonstrated an average of 3 Log10 reduction in viral titer (99.89% reduction) after 30 seconds.

The Plate Recovery Control demonstrated a viral titer of 4.50 log10 TCID50 per 1 ml.

No test substance cytotoxicity was detected.

Il Responsabile del Laboratorio


Claudia Modenese



Evaluation of bactericidal activity of the device GFC Hygiene Box for glasses sterilisation.

Aim of the Study

The aim of this study is to determine the bactericidal activity of the device **Hygien Box** against *Staphylococcus aureus* and *Escherichia coli*.

The aforementioned device consists of a base that emits UV rays.

Glasses are positioned on two supports.

*The device was created by **GFC srl** seated in Viale Lombardia, 18 - 20021 Bollate (Milan) – Italy.*

Method

Glasses are inoculated with 100µL of a bacterial suspension on two positions, on glass near temples (1) and near nose pad (2), then left to dry for 15 minutes.

After an exposure for various time described in contact time table we tested the residual number of bacteria by spread on a specific medium.

Name of product	Hygiene Box for glasses sterilisation	
Date of delivery	03/11/20	
Period of analysis	03/11/20 – 06/11/20	
Temperature of incubation	37°C	
Identification of bacterial strain	E. coli ATCC 8739	Staphylococcus aureus ATCC 6538P
N° bacteria inoculated	6.34 Log cell/ml	6.00 Log cell/ml
Exposition time	See protocol	



Contact Time Protocol

Box	30 sec	Position 1 and 2 3 repetitions
	60 sec	Position 1 and 2 3 repetitions
	90 sec	Position 1 and 2 3 repetitions

Results

Identification of bacterial strain	E. coli ATCC 8739
N° bacteria inoculated	6.34 Log cell/ml

	Time	Media Log Log cell/area	% reduction
Control not exposed	60 sec	4.12	/
Temples	30 sec	2.75	95.7
	60 sec	<1	99.9
Nose pad	30 sec	2.38	98.1
	60 sec	<1	99.9

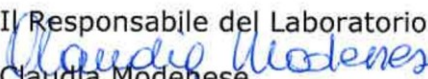


Identification of bacterial strain	Staphylococcus aureus ATCC 6538P
N° bacteria inoculated	6.00 Log cell/ml

	Time	Media Log Log cell/area	% reduction
Control not exposed	60 sec	4.39	/
Temples	30 sec	3.78	76.4
	60 sec	2.96	96.4
	90 sec	<1	99.9
Nose pad	30 sec	3.84	72.9
	60 sec	3.05	95.6
	90 sec	1.12	99.9

Conclusion

*The purpose of the study was to determine the antibacterial efficacy of the device manufactured by GFC srl against **two bacterial strain (Gram+ and Gram-)** at a contact time of 30, 60 and 90 seconds at an exposure of room temperature. The evaluated test device demonstrated an average of reduction of 99.9% after 60 seconds of exposure against E.coli ATCC 8739 and an average of reduction of 99.9% after 90 seconds of exposure against Staphylococcus aureus ATCC 6538P.*

Il Responsabile del Laboratorio

 Claudia Modenese

