

To the Company

NEW WAVE PROJECT SA  
Corso San Gottardo 9/A  
6830 CHIASSO (TI) - CH

Arzignano, November 23, 2020

**OBJECT : MICROBIOLOGICAL SAFETY EVALUATION OF THE DEVICE NAMED**

## **ReSPR SELF**

The agent company:

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(hereinafter "client") requested a study on the

### **"ASSESSMENT OF MICROBIOLOGICAL SAFETY"**

of the production item called "ReSPR SELF"

## PROCEDURE USED

## § 1.0 PURPOSE

The purpose of the following preliminary study is to define the degree of abatement of the bacterial flora that is found in the vicinity of the respiratory tract of people, considering that it is usually applied under the chin and emits a constant and intense flow of ionized air for which the client requires to verify the actual degree of bacterial abatement.

### ReSPR "SELF"



The study is therefore aimed at verifying firstly whether under normal conditions of use the device can effectively suppress the overall microbiological load present in the inhaled air and then evaluate, with appropriate methods, its ability to suppress the "viral" load.

## § 2.0 DEVICE DESCRIPTION

The device of small dimensions (8.7cm L x 7.5cm W x 2.5cm D) is equipped with a USB rechargeable battery and contains an internal system capable of generating an ionic flow such as to reduce airborne dust and bacterial load present in the air inhaled by the person who wears it around their neck.

### § 3.0 Methods of verifying the abatement of the bacterial load

For the purpose of verifying the effectiveness of the device under the microbiological profile of the environmental air breathed by the subjects who wear it, it is decided to carry out a series of environmental sampling in certain conditions to test the degree of reduction of the bacterial load.

For this purpose, aeriform samples are carried out by passing air on agar plates applied to a SAS Mod. Super90 sampler of PBI (s / n. 97D / 25480) calibrated at a charge flow equal to 100 ml/minute.

Double tests were carried out:

- A) In the warehouse of the materials to be eliminated in the Dedalo laboratory by sucking the ambient air as it is under known conditions;
- B) In the same place where the blank sample was taken, the device was subsequently activated which is placed frontally in the lower part with respect to the mouth of the sampling plate to carry out new samplings in the presence of ionic flow.
- C) The efficacy of the test was calculated by means of the results reported in the "analytical results" section after the development and count of the total bacterial load at 37°C seven days after the sampling carried out as described above.

### §3.1 TECHNICAL STANDARDS USED FOR TESTING

Environmental sampling was performed in accordance with the following technical standard:

- UNI EN 13098 : 2019 -;

The sampling volume was set at 500 liters for each test.

The environmental conditions are as follows :

- Ambient temperature  $20 \pm 2$  °C
- rH :  $50 \pm 3$  %

*Some photos of the development of agar plates*



## ANALYTICAL OUTCOMES

### § 1.0 PLATES EVALUATION

analysis start date: November 11, 2020

analysis end date: November 16, 2020

the values obtained are reported in the table below

<b>Mod.</b>	<b>Sampling time minutes</b>	<b>Liters taken</b>	<b>CBT at 37°C UFC/m<sup>3</sup></b>	<b>Molds</b>	<b>Sampling Code</b>
<b>BLANK</b>	10.0	1000	<b>&gt; 300</b>	<b>&gt; 300</b>	B
<b>ReSPR SELF</b>	10.0	1000	<b>28</b>	<b>0</b>	SELF

## **§ 2.0 CONCLUSIONS**

Following the data acquired from the microbiological tests carried out to simulate normal conditions of use, it was found that the DEVICE analyzed (ReSPR SELF) significantly reduces bacterial loads and almost completely eliminates mold.

The results achieved in this first phase of evaluation encourage the development of a more articulated process of technical tests useful to obtain a broader framework of evaluation that can also embrace more critical species such as pathogenic microorganisms and even viruses.

Yours truly,

dr. Renzo Padovan EurChem

