



**CERTIFICATE  
AND  
EFFECTIVENESS ASSESSMENT REPORT  
OF THE VIRUCIDAL ACTIVITY OF:**

**STEAM GENERATORS EV International + detergent product EV H<sub>2</sub>O<sub>2</sub>  
SILVER BIO, 30% solution**

**STEAM GENERATORS EV International + detergent product EV H<sub>2</sub>O<sub>2</sub>  
SILVER SPRAY ready to use**

**Based on the test UNI EN ISO 16777: 2018**

CLIENT:	<b>E V International Ltd.</b> Kostur 14 A 1618 Sofia, Bulgaria
DATE OF RECEIPT:	22/06/2020
ANALYSIS LAUNCH DATE:	10/07/2020
ANALYSIS COMPLETION DATE	31/07/2020

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## **1. FOREWORD**

## **2. DESCRIPTION OF THE ACTIVITIES**

## **3. TERMS AND DEFINITIONS**

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### **1) FOREWORD**

This report was prepared and performed by the laboratory Sana srl, which is a holder of ACCREDIA certificate No. 0747 under UNI EN ISO 17025:2018, and is intended to evaluate the **VIRUCIDAL PERFORMANCE** of E V International's steam cleaners plus detergent referred to as EV H<sub>2</sub>O<sub>2</sub> Silver Bio, 30% solution and EV H<sub>2</sub>O<sub>2</sub> Silver Spray ready to use.

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## 2) DESCRIPTION OF THE ACTIVITIES

This validation protocol was made to validate the **VIRUCIDAL PERFORMANCE** of the products described above.

The tests that were performed were in compliance with the referenced norms as stated in the table below:

Action	Virus	Applicable standard	% application	Conditions		Contact time
				Dirty 3g	Clean 0.3 g	
Virucidal	Human Coronavirus Strain 229E ATCC VR-740 / VR -19	EN ISO 16777:2018	30%	yes	yes	30 sec
Virucidal	Human Coronavirus Strain 229E ATCC VR-740 / VR -19	EN ISO 16777:2018	Ready to use	yes	yes	30 sec

## 3) TERMS AND DEFINITIONS

- **Product** (chemical disinfection and/or antiseptic): chemical agent or formula used as a disinfectant or antiseptic.
- **Virucidal performance**: the capability of the product to reduce at least by **log4** the virus count “on the surface” under standard experimental conditions
- **Cleaning conditions**: conditions of the surfaces subjected to the cleaning procedure, on which there are minimal levels of organic or inorganic substances.

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- **Dirty conditions:** conditions characterized by a considerable degree of contamination, including with organic or inorganic compounds on the surfaces subject to detergent or antiseptic treatment.
- **Virus deactivation:** reducing the virulence of the virus by applying the analyzed product.
- **Interference compounds:** protein solutions and erythrocytes added to the viral suspension before adding the test product to demonstrate the effect of the proteins and erythrocytes on the **virucidal** performance of the tested product.
- **Plaque-forming units (PFU):** the number of virus particles capable of forming plaque per unit of volume (ml).
- **ID50:** infecting dosage 50 % of the viral suspension or diluting the viral suspension which induces in the cellular cultures a 50 % cytopathic effect (CPE).
- **Virus count:** equivalent of the infection virus per unit of volume present in the cellular structure after lysis

#### 4) VIRUCIDAL PERFORMANCE (PHASE 2, STEP 2)

**The study is intended to demonstrate and evaluate the effectiveness of a particular product on the human coronavirus, strain 229E ATCC VR-740 / VR -19 virus.**

Procedural phases include:

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- Preparation of the sample viral suspension and the cellular line
- Testing procedure
- End-result assessment

## **MATERIALS AND REAGENTS**

- Basis for the culture: EMEM for cellular structures
- Cellular structures: human fibroblasts ATCC CCL-171
- Organisms to test: **Human coronavirus, strain 229E ATCC®VR-740 / VR -19**
- Neutral red (solution 1: 1000)
- Foetal calf serum (FCS)
- Trichloroacetic acid (10% solution)
- Hard water
- Interfering compound (bovine serum albumin and sheep's blood)

## **Preparing the test virus suspension in accordance with EN ISO 16777: 2018**

The viral suspension is multiplied in a suitable cellular line to produce a large viral count. Cellular waste is separated by centrifugal force. The preparation process results in the so called „**viral treatment suspension**“. The count of the testing suspension must be at least 10 by the power of 8 TCID<sub>50</sub> / ml. In any case, the count must be high enough to allow a **log<sub>4</sub> count reduction to take place**.

**Testing procedure based on customers indicators.**

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**1) Test with EV International's steam generator + EV H<sub>2</sub>O<sub>2</sub> Silver Bio at 30%**

- Plug the unit into the power grid and switch it on.
- Wait until it heats up.
- Attach the SANIX tool/accessory to the flexible steam hose.
- Fill up the SANIX bottle with the EV H<sub>2</sub>O<sub>2</sub> Silver Bio (30% solution) and water. Shake well before use.
- Spray the steam + the EV H<sub>2</sub>O<sub>2</sub> Silver Bio from a distance of 20 to 30 cm for 4 to 5 seconds on the sample surface 10 x 10 cm, then wait for 30 seconds.

**2) Test with EV International's steam generator + EV H<sub>2</sub>O<sub>2</sub> Silver Spray ready to use**

- Plug the unit into the power grid and switch it on.
- Wait until it heats up.
- Attach the SANIX tool/accessory to the flexible steam hose.
- Fill up the SANIX bottle with the ready to use EV H<sub>2</sub>O<sub>2</sub> Silver Spray. Shake well before use.
- Spray the steam + the EV H<sub>2</sub>O<sub>2</sub> Silver Spray from a distance of 20 to 30 cm for 4 to 5 seconds on the sample surface 10 x 10 cm, then wait for 30 seconds.

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## Evaluation of the results

**STEAM GENERATORS of EV International + detergent EV H<sub>2</sub>O<sub>2</sub> SILVER BIO at 30% solution in clean and dirty conditions**

Contact time	Virus count (clean)	Virus count (dirty)
30 seconds	n.d Not detected	n.d Not detected

**n.d = virus count not detected**

**STEAM GENERATORS of E V International + detergent EV H<sub>2</sub>O<sub>2</sub> SILVER SPRAY ready to use in clean and dirty conditions**

Contact time	Virus count (clean)	Virus count (dirty)
30 seconds	n.d Not detected	n.d Not detected

**n.d = virus count not detected**

## TEST REPORT

**UNI EN ISO 16777: 2018 - QUANTITATIVE TESTING OF NON-POROUS SURFACES TO ASSESS - USING NO MECHANICAL INFLUENCE - THE ANTIVIRAL PERFORMANCE OF CHEMICAL DISINFECTANTS USED IN MEDICINE**

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## Test method and requisites

Phase 2 Step 2

## Laboratory

The Microbiology and Chemistry Laboratory of SANA srl, 17 Lecce St., 03100 Frosinone, holder of ACCREDIA certificate No. 0747

<b>Formulation</b>	Steam generated by EV International's steam cleaners + EV H <sub>2</sub> O <sub>2</sub> Silver Bio at 30% solution
<b>Disinfectant batch</b>	EV H <sub>2</sub> O <sub>2</sub> Silver Bio - 20-01184
<b>Best before</b>	05/2022
<b>Composition:</b>	Hydrogen peroxide H <sub>2</sub> O <sub>2</sub> with silver ions + dry steam

## Manufacturer

**E V International Ltd.**

Kostur 14A

1618 Sofia, Bulgaria

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## Testing conditions

Test date: 10/07/2020- 31/07/2020

Test surface: 10 x 10 cm

Ambient temperature: 20°C

Interference compounds: Clean conditions: Bovine serum albumin 0.3 %  
Dirty conditions: Bovine serum albumin and sheep's blood 3 %

Concentration: 30% solution

Usage conditions: Spraying steam from EV International's steam generators + the EV H<sub>2</sub>O<sub>2</sub> Silver Bio from a distance of 20 to 30 cm for 4 to 5 seconds on the sample surface 10 x 10 cm, then waiting for 30 seconds sec

## Conclusions

Based on the test data and the criteria of UNI EN ISO 16777: 2018, the application of EV H<sub>2</sub>O<sub>2</sub> Silver Bio (at 30%) with steam from EV International's steam generators under both clean and dirty conditions, triggered a reduction by more than 4 *log* of the viability of the tested organisms after 30 seconds contact time, i.e. virus count was not detected on the test surface.

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## TEST REPORT

### UNI EN ISO 16777: 2018 - QUANTITATIVE TESTING OF NON-POROUS SURFACES TO ASSESS - USING NO MECHANICAL INFLUENCE - THE ANTIVIRAL PERFORMANCE OF CHEMICAL DISINFECTANTS USED IN MEDICINE

#### Testing method and requisites

Phase 2, Step 2

#### Laboratory

The Microbiology and Chemistry Laboratory of SANA srl, 17 Lecce St., 03100 Frosinone, holder of ACCREDIA certificate No. 0747

Formulation	Steam generated by EV International's steam cleaners + EV H <sub>2</sub> O <sub>2</sub> Silver Spray ready to use
Disinfectant batch	EV H <sub>2</sub> O <sub>2</sub> Silver Spray 20-01249
Best before	05/2022
Composition	Hydrogen peroxide H <sub>2</sub> O <sub>2</sub> with silver ions + dry steam

#### Manufacturer

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## Testing conditions

Test date:	10/07/2020- 31/07/2020
Test surface:	10 x 10 cm
Ambient temperature:	20°C
Interference compounds	Clean conditions: Bovine serum albumin 0.3 % Dirty conditions: Bovine serum albumin and sheep's blood 3 %
Concentration:	ready-to-use product
Usage conditions:	Spraying steam from EV International's steam generators + the EV H <sub>2</sub> O <sub>2</sub> Silver Spray from a distance of 20 to 30 cm for 4 to 5 seconds on the sample surface 10 x 10 cm, then waiting for 30 seconds

## Conclusions

Based on the test data and the criteria of UNI EN ISO 16777: 2018, the application of EV H<sub>2</sub>O<sub>2</sub> Silver Spray with steam from EV International's steam generators under both clean and dirty conditions, triggered a reduction by more than 4 log of the viability of the tested organisms after 30 seconds contact time, i.e. virus count was not detected on the test surface.

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