

## CERTIFICATE

№ LVD- 21- 000- (2-21-458)- 004E

"CTEC" Ltd. certifies that

| Product               | HUMAN PRESENT AIR DISINFECTION DEVICE<br>model: <i>R3S UVC60-40W</i><br>230 V AC; 50 Hz; 40 W; Class I; IP 20   |
|-----------------------|---|
| Applicant             | <b>ROMMTECH-3S Ltd., Bulgaria</b><br>3 Ilinden str., Vratsa 3000<br>tel.: + 359 92 669 580, fax: + 359 92 649 370<br>e-mail: <u>info@rommtech-3s.com</u>  |
| Manufacturer          | <b>ROMMTECH-3S Ltd., Bulgaria</b><br>3 Ilinden str., Vratsa 3000<br>tel.: + 359 92 669 580, fax: + 359 92 949 370<br>e-mail: <u>info@rommtech-3s.com</u>  |
| Complies with the     | requirements applicable to the product in compliance with the standards within the scope of the <i>Low voltage</i> Directive 2014/35/EU:<br>EN 60335-1:2012<br>EN 60335-1:2012/A11:2014; EN 60335-1:2012/A13:2017<br>EN 60335-1:2012/A1:2019; EN 60335-1:2012/A14:2019<br>EN 60335-2-65:2003<br>EN 60335-2-65:2003<br>EN 60335-2-65:2003/A1:2008; EN 60335-2-65:2003/A11:2012<br>Household and similar electrical appliances - Safety<br>Part 2-65: Particular requirements for air-cleaning appliances - <i>cl.8, cl.10</i><br><i>cl.11, cl.13, t. cl.13, cl.15, 2, cl.15, 3, cl.16, 2, cl.16, 3, cl.17, cl.19, 7</i><br><i>cl.29, cl.30, 1, cl.30, 2</i><br>and standards within the scope of the <i>Electromagnetic Compatibility</i><br>Directive 2014/30/EU:<br>EN 55014-1:2017 Electromagnetic compatibility (EMC)<br>Requirements for household appliances, electric tools and similar<br>apparatus. Part 1: Emission - <i>cl.4, cl.5 - Mains terminal disturbance voltage;</i><br>EN 55014-2:2015 Electromagnetic compatibility(EMC)<br>Requirements for household appliances, electric tools and similar<br>apparatus. Part 1: Emission - <i>cl.4, cl.5 - Mains terminal disturbance voltage;</i><br>EN 55014-2:2015 Electromagnetic compatibility(EMC)<br>Requirements for household appliances, electric tools and similar apparatus.<br>Part 2: Immunity - Product family standard - <i>cl.7, cl.8:</i><br>EN 6100-4-11:2004+A1:2017 Electromagnetic compatibility(EMC)<br>Part 4-11: Testing and measurement techniques - Voltage dips, short<br>interruptions and voltage variations immunity tests |
| Certificate has bee   | n issued on the base of<br>Test reports:<br>№ 2-21-458/05.02.2021 № 2EMC-21-458/05.02.2021  |
| machinery laboratory. | e is voluntary examination of the products and testing carried out by the CTEC's ate is based on the evaluation of the above mentioned products and does not imply  |

The conformity certificate is based on the evaluation of the above mentioned products and does assessment of the production.

Date of issue: 2021-02-05 Stara Zagora Validity: 2026-02-05





Page 1 of 1



### BULGARIAN ACADEMY OF SCIENCES THE STEPHAN ANGELOFF INSTITUTE OF MICROBIOLOGY 26 Acad. Georgi Bonchev Str., 1113 Sofia, Bulgaria tel. + 359 2 979 31 57; fax. + 359 2 870 01 09; e-mail: micb@microbio.bas.bg

## REPORT

№ DI-02EN/ 12.01.2021

**From microbiological evaluation**: Determining of the index of microbial air contamination in enclosed area before and after the R3S UVC 60 - 40W "Andromeda" device operation.

Sample description: Air sample with volume 300 Liters Sampling point: lab. 207, The Stephan Angeloff Institute of Microbiology, 26 Acad. Georgi Bonchev Str., 1113 Sofia, Bulgaria Person responsible for sampling: Venelin Hubenov

Period of analysis: 01.12.2020 - 03.12.2020

Evaluation protocol: ISO 14698-1:2006 - Cleanrooms and associated controlled environments — Biocontamination control

Microorganisms in the environment are a hidden, yet a real danger when it comes to most human activities. Therefore the evaluation of the biological pollution is of extreme importance for a lot of work areas such as medicine, the industrial and the agricultural area.

ISO 14698:2003 establishes the principles and basic methodology of the official bio-pollution control system (official system) for the assessment and control of bio-pollution when clean room technology is applied for this purpose. It determines the methods necessary for the consistent monitoring of risk areas and for the application of control measures appropriate to the degree of risk involved. In areas where the risk is low, it can be used for information purposes.

This method offers only an estimate of the number of microorganisms on the surface of the nutrient medium capable of multiplying in general and of the respective nutrient medium in particular. The method does not involve obtaining information on the species affiliation and virulence of the microbial strains that have formed colonies.

Two types of nutrient media are used in the present study: Triptic-soy agar (TSA) and

Sabouraud Chloramphenicol Agar (SCA) for the evaluation of bacteria and micromycetes, respectively. The results are presented in units of  $CFU/m^3$ . The reduced quantity of microorganisms due to the action of the provided prototype was assessed by estimating the index of microbial contamination before and after its' action inside a closed area for a certain period of time.

Table 1. Technical description of device

| Power             | 53 W                    |
|-------------------|-------------------------|
| Air flow rate     | 70-80 m <sup>3</sup> /h |
| Efficiency (UV-C) | 11-12 W                 |
| UV-C range        | 254 nm                  |



Figure 1. Illustration of device.

**RESULTS**:

Desinfected room area: 46 m<sup>2</sup> Disinfected volume: 135 m<sup>3</sup> Work periods: from 1 to 4 hours

| Sample type               | Evaluated<br>characteristics,<br>dimensions            | Protocol used    | Results | Reduction of<br>number of<br>microorganisms in<br>air, % |
|---------------------------|--|------------------|---------|--|
| 1-Air<br>(control)        | Total number of<br>bacteria,<br>CFU/m <sup>3</sup>     |                  | 44±7    | -  |
| 2-Air<br>(test – 1 hour)  |  | ISO 14698-1:2006 | 11±8    | 75   |
| 3-Air<br>(test – 2 hours) |  |                  | 9±3     | 80   |
| 4-Air<br>(test – 4 hours) |  |                  | 6±5     | 86   |
| 5-Air<br>(control)        |  | ISO 14698-1:2006 | 59±13   | -  |
| 6-Air<br>(test – 1 hour)  | Total number of<br>micromycetes,<br>CFU/m <sup>3</sup> |                  | 18±5    | 69   |
| 7-Air<br>(test – 2 hours) |  |                  | 9±4     | 85   |
| 8-Air<br>(test – 4 hours) |  |                  | 5±1     | 92   |

Table 2. Summarized results from the evaluation.

Analysed by:

1. (Assist. Prof. Venelin Hubenov, PhD)

2. . . . . . . . . . . . . . .

(Assist. Prof. Jeny Miteva-Staleva, PhD)

Aprooved by:

ANGEL

neur

(Prof. Penka Petrova, DSc, Director of The Stephan Angeloff Institute of Microbiology, BAS)

## **Test Report** № 17EN/02.03.2021 *LABORATORY FOR DISINFECTION, STERILIZATION AND BIOINDICATORS*

#### 1. Test applicant:

" Security Smart Systems " Ltd. Ilinden str 3, Vratsa 3000, Bulgaria

#### 2. Test equipment :

Name : R3S UVC 60-40W

Manufacturer: "Rommtech-3S" Ltd.

**Description of the tested equipment / according to the Applicant /:** The device is designed for disinfection of air by ultraviolet radiation in the presence of people in the premises. In the body of the device is implemented ozone-free UVC tube 36 W / 12W UVC 254 nm and a fan for forced air circulation. Implemented is a replaceable washable filter. The device is designed for installation on a suspended ceiling, suspended on pendulums or wall mounting.

#### 3. Test conditions :

**Test method:** Evaluation of the microbicidal effect of sterilization and / or disinfection equipment. Code 628 / *according to Order*  $N_{2}$  452 of 26.10.2012 for the paid services performed by NCIPD /, referring to BDS EN ISO 14698-1: 2006 Clean rooms and the related controlled environment. Biological pollution control. Part 1: General principles and methods.

**Test period** : 15.02.2021 г.– 01.03.2021

**Inoculation medium** : Blood agar ( CA )

#### 4. Description of test :

The control of the air is accomplished by sedimentation method Koch (passive mode) that gives indicative, qualitative assessment of microflora air indoor.

The test was carried out in the presence of people in the room during operation of the device .

In the beginning of the day, in the test rooms are placed a number of samples (open plates CA ) for 120 minutes for the establishment of normal microbial contamination of the air.

After Sampling calibration the device is positioned in the middle of the room and switched in operating mode. After switching off the device new samples with CA are placed in the same places in the room, again for 120 minutes.

All samples are cultured in a thermostat for 48 -72 hours.

The experimental staging was performed in two repetitions.

The results are presented as the average of the total number of colonies forming units / petri dishes (kOE/petri dishes) for the experimental room before and after operation of the device .

The efficiency of the tested device in relation to the air is determined in percentages (%) after comparing the obtained values with kOE/petri dishes before and after operation of the device .

**Room area**<sup>\*</sup> and timing of operation of the device: 25 m<sup>2</sup>(75 m<sup>3</sup>)- 1 hour; 2 hours and 3 hours. \* - *The indicated values are rounded to an integer*.

NATIONAL CENTRE OF INFECTIOUS AND PARASITIC DISEASES

MINISTRY OF HEALTH

COORDINATING COMPETENT BODY OF ECDC

BULGARIA, 1504 Sofia, 26 Yanko Sakazov Blvd. DIRECTOR: +359 2 944 28 75; <u>director@ncipd.org</u> TELEPHONE EXCHANGE: +359 2 944 69 99 FAX: +359 2 943 30 75



www.ncipd.org

# Criteria for evaluating the effectiveness of *R3S UVC60-40W* in relation to air: % reduction of the normal microflora in the air.

Note: The method only offers an estimate of the number of microorganisms present on the surface of the culture medium that may form colonies on it. The method does not provide information on the species affiliation and virulence of the microbial strains.

#### 5. Test results:

| Efficiency o | fR3S | <i>UVC60-40W</i> | with respect | to air   |
|--------------|------|------------------|--------------|----------|
| Lificiency 0 | 1155 |                  | with respect | io $aii$ |

| Room # | Total number kOE/room ,<br>BEFORE work of device | Total number kOE/room ,<br>AFTER work of device | Time to work<br>of device | Efficiency<br>in percent, % |
|--------|--|---|---------------------------|-----------------------------|
| Room 1 | 306  | 140   | 1.1                       | 54.25%                      |
|        | 348  | 147   | 1 hour                    | 57.76%                      |
|        | 379  | 58  | 2 hours                   | 84.70%                      |
|        | 327  | 60  | 2 110018                  | 81.65%                      |
|        | 335  | 40  | 3 hours                   | 88.06%                      |
|        | 367  | 3 5   | 5 110018                  | 90.46%                      |

Depending on the duration of operation of the R3S UVC60-40W device in a room with the presence of people , an average reduction of the normal air microflora is reported as follows :

- when working for 1 hour 56 %.
- when working for 2 hours 83.2 %.
- when working for 3 hours 89.3 %.

#### 6. Conclusion:

The tested device R3S UVC60-40W can be applied in practice for reduction of the normal microflora in the air in rooms up to 25  $m^2$  and working regime for at least 1 hour.

To achieve the maximum effect, the appliance must be positioned in the middle of the room, so as not to impede the circulation of air through it.

The results of efficacy of R3S UVC60-40W refer only to the test conditions

## described in this protocol .

Tester: Que

ANH.

/ ch. Assistant Professor M. Nikolova, Ph.D. / / C. Yordanova/

Head. Section "ADI ": / /Nadia Ivanova-Alexandrova /