

MINISTRY OF HEALTH
**NATIONAL CENTRE OF INFECTIOUS AND
PARASITIC DISEASES**

COORDINATING COMPETENT BODY FOR ECDC

TEST REPORT

No. 66/25.11.2021

DISINFECTION, STERILIZATION AND BIOINDICATORS LABORATORY

1. Applicants:

STARIMPEX-Bulgaria LTD
25 Dragoman Street
Varna
and
MEDICAL IMPEX LTD
6 Panagyurishte Street
Varna

2. Apparatus to be tested:

Name: *BACTOSPHERA ORBB 30/BACTERICIDAL RECIRCULATOR medical and household apparatus for ozone-free air disinfection.*

Description of the apparatus to be tested /according to applicant's information/:

The apparatus is intended for ozone-free UVC air disinfection in continuous operation in rooms with the presence of humans and animals. It is equipped with HEPA filter and enables programming of different operating modes.

3. Test conditions:

Test method: Assessment of the microbicidal effect of a sterilization and/or disinfection apparatus. Code 628 /in accordance with Order No. 452 of 26.10.2021 on paid services provided by the National Centre of Infectious and Parasitic Diseases/ referring to BDS EN ISO 14698-1:2006 Cleanrooms and associated controlled environments – Biocontamination control – Part 1: General principles and methods.

Test period: 01.11.2021 – 12.11.2021

Test temperature: 20-22°C

Culture medium: Blood agar (BA)

4. Test description:

Air control has been carried out by an active sampling method with air suction speed of 100 L/min. An automatic sampler for microbiological air controls, model SPIN AJR (IUL S.A., Spain), has been used for this purpose.

BACTOSPHERA ORBB 30 air disinfection apparatus with UV-C rays was positioned horizontally in the centre of the test room at 1 m above the ground. The test has been carried out in the presence of people during operation of the apparatus.

Air sampling was undertaken in two stages: immediately **before** apparatus operation and **at intervals of 1 hour during operation**.

5/7 samplings have been made at each stage of the test in different points of the test room. The amount of air set to go through the apparatus for each sample was 200 L.



All samples were cultured in a thermostat for 48 hours.

Results are presented as an average number of colony forming units (CFU)/m³ air for the test room before and after operating the apparatus. The efficiency of *BACTOSPHERA ORBB 30* disinfection apparatus with regard to air was determined as a percentage (%) after comparing the obtained values of CFU/m³ in the room before and after apparatus operation. Tests have been carried out in duplicate for each test room.

Test room*:

1. 25 m² (75 m³)
2. 16 m² (48 m³)

* - The values are rounded up to a whole number.

Hours of apparatus operation during which samplings were carried out: 3rd hour, 4th hour and 5th hour.

Criteria for assessing the efficiency of *BACTOSPHERA ORBB 30* with regard to air:

% reduction of the normal microflora in the air.

Note: This method only enables an estimate of the number of colony forming microorganisms hit the surface of the nutrient medium.

5. Test results:

Efficiency of *BACTOSPHERA ORBB 30* air disinfection apparatus:

| Type of room | Average number of CFU/m ³ air before operating the apparatus | Average number of CFU/m ³ air after operating the apparatus | | | Efficiency in percentage (%) after operating the apparatus | | |
|--|---|--|-----|-----|--|---------|---------|
| | | 3 h | 4 h | 5 h | 3 h | 4 h | 5 h |
| Room of 25 m ² (75 m ³) | 374 | 195 | 185 | 155 | 47.85 % | 50.53 % | 58.56 % |
| | 302 | 144 | 153 | 138 | 52.32 % | 49.34 % | 54.30 % |
| Average efficiency in percentage for 75 m ³ (%) | | | | | 50.09 % | 49.94 % | 56.43 % |
| Room of 16 m ² (48 m ³) | 324 | 108 | 123 | 73 | 65.67 % | 62.01 % | 77.47 % |
| | 468 | 265 | 128 | 85 | 43.38 % | 72.65 % | 81.84 % |
| Average efficiency in percentage for 48 m ³ (%) | | | | | 55.03 % | 67.35 % | 79.66 % |

The results obtained show that the reported efficiency of *BACTOSPHERA ORBB 30* air disinfection apparatus with UV-C rays varies according to the room volume and duration of operation.

For a period of 5 hours of operation the reported efficiency for a room of 48 m³ is 79.7%, while under the same operating mode in a room of 75 m³ a reduction of the normal air microflora is 56.4%.

6. Conclusion:

The tested *BACTOSPHERA ORBB 30* closed-type apparatus for ozone-free air disinfection with UV-C rays can be effectively applied in practice to reduce the normal air microflora in continuous operation for rooms of up to 25 m² (75 m³).



In order to achieve maximum effect in rooms, it is recommended to place 1 apparatus/50 m³ air in a way as not to prevent the circulation of air through it.

Note: Microbial contamination of air in the rooms is the result of multiple factors such as the number of people present, their activity, opening/closing of doors and windows, air temperature and humidity, etc., which cannot be controlled. In this context, the results obtained for the efficiency of *BACTOSPHERA ORBB 30* apparatus for ozone-free air disinfection with UV-C rays only refer to the test conditions as described in this report.

Test performed by:

Chief Asst. M. Nikolova – signed
S. Yordanova – signed

Head of Disinfection, Sterilization and Bioindicators Laboratory:

Chief Asst. M. Nikolova – signed

I, the undersigned Boryana Krasteva, certify the authenticity of the translation of the document attached /Test Report/ from Bulgarian into English. The translation comprises four pages.

Translator: *Boryana Krasteva*

