Translated from Serbian

УНИВЕРЗИТЕТ У КРАГУЈЕВЦУ ФАКУЛТЕТ МЕДИЦИНСКИХ НАУКА



UNIVERSITY OF KRAGUJEVAC FACULTY OF MEDICAL SCIENCES

No: 01-11680 Date: 26.10.2023. Крагујевац

# "CENTROREJTING" DOO BELGRADE-ČUKARICA to Mrs Ana Stanić, director

Dear Mrs. Stanic,

In accordance with Article 4 of the Agreement on Professional Cooperation concluded between the Faculty and the company you represent, dated October 2, 2023, we are attaching an expert opinion, signed by professors of the Faculty of Medical Sciences of the University of Kragujevac, who possess professional knowledge and qualifications for this type of project.

In the hope that we will continue to cooperate successfully in the future.

With respect,

DEAN

Prof. Dr. Vladimir Jakovljević

seal Faculty of Medical Sciences University of Kragujevac Faculty of Medical Sciences, University of Kragujevac Svetozara Markovića 69, 34000 Kragujevac Phone +381 34 306 800 Kragujevac, 24.10.2023. Official stamp of the Faculty of Medical Sciences, University of Kragujevac No. 01 11548/1

### EXPERT OPINION Assessment of documentation UNIT FOR AIR DECONTAMINATION "POTOK 150-M-01"

## 1. INTRODUCTION

The Faculty of Medical Sciences of the University of Kragujevac received the subject request no. 01-8303 from August 29, 2023. sent by Centrorejting d.o.o. Belgrade-Čukarica, ul. Branka Radičevića 7g, Belgrade, ID number 21276367, PIB 109965996, for the purpose of providing an expert opinion on the submitted documentation related to the "POTOK 150-M-01" technology, based on the documentation originally submitted by Centrorejting d.o.o. Belgrade. With his decision, the dean of the Faculty of Medical Sciences of the University of Kragujevac determined the employees of the faculty, prof. Dr. Dejan Baskić and Prof. Dr. Dragan Milovanović, to prepare an expert opinion.

#### 2. SUBJECT DOCUMENTATION

The subject documentation was submitted in electronic and printed form, in the form of uncertified copies of the original documents. It contains documents in the original languages (Serbian, English, French, Spanish, Russian), and some translations into Serbian made by court translators for English or Spanish. During the review of the documentation, its professional-methodological validity was assessed. Detailed, structured reports that were carried out in the respective institutions, signed and/or certified with the seal of the institution, were analyzed according to the principles of critical, scientific, and expert review. The rest of the documentation was analyzed using a descriptive method. Documentation that was judged to be invalid and/or the validity could not be reliably determined was not analyzed.

## 2.1 DEVICE DESCRIPTION

The description of the POTOK 150-M-01 technology is stated in the document created by the applicant Centrorejting d.o.o., Belgrade. The document states that the principle of the POTOK 150-M-01 technology is based on the exposure of microorganisms and viruses to an electric field of constant strength and variable polarity, which destroys the cells of microorganisms and/or their proteins. The remains of destroyed cells and particles are then retained in an electrostatic filter where they are completely removed. When exposing microorganism cells to an electric field inside the decontamination unit, the value and polarity of the electric potential on the surface and inside the cell change many times. As a result, the cell membrane is subjected to multiple deformations which create openings on the membrane through which the cytoplasm exits the cell. Local damage in the cell membrane caused by the external electric field causes disruption of the cellular homeostasis of the microorganism and its death.

Under the influence of a constant electric field, the positively charged units of nucleic acids move toward the negatively charged electrode, while the negatively charged units move toward the positively charged electrode. As a result, the molecular bonds in nucleic acids and proteins break, which disrupts their secondary and tertiary structure. This not only leads to the destruction of the cell membrane but also causes irreversible degradation of the protein structures of membrane-less microorganisms, regardless of their type, size, and resistance to chemical disinfectants.

The electrostatic filtration process is based on a unique high-porosity material with an open cell system. Dielectric porous plates placed between the electrodes allow the deposition of destroyed microorganisms and aerosols, retaining even the finest particles of  $0.1 - 0.3 \,\mu$ m in size. Further operation of the device leads to the destruction of filtered components of inactivated cells because organic

molecules are unstable and break down into simpler compounds (CO2 and N2O).

The concentration of the final products of cell decay is less than  $1 \text{ ng/m}^3$ , which is significantly lower than the sensitivity of many modern devices. This material has a high dust retention capacity, and its characteristics do not change throughout its working life.

### 3. EVALUATION OF DOCUMENTATION

#### 3.1 STRUCTURED TEST REPORTS, SIGNED AND/OR INSTITUTIONALLY CERTIFIED

3.1.1 PROGRESS REPORT II, PHASE I, POTOK 150-M01 TEST PROGRAM. Harvard School of Public Health, Department of Environmental Health, Environmental Science and Engineering Program. 4 February 2003. (A copy of the original text and a copy of the certified translation of the court translator into English).

The document is 2 pages long and the results are summarized in 5 paragraphs. The original results are said to be attached in a 5-page document, which includes tables and statistical analysis (document not filed). Microbiological aerosols were used in the tests, by dispersing selected compounds from an aqueous suspension. Air samples were collected by means of cascade impactors, upstream and downstream of the tested unit. The analysis of living microorganisms included the determination of their total number in air samples as well as the particle size of microorganisms, which we consider to be measures of the efficiency of the unit for removing the air passing through it. Test conditions included low and high electrical settings of the unit (device) at the specified airflow (77 and 100 cubic feet per minute - CFM). The results showed that under the test conditions, there was a destruction of 94.4% to 99.5% of Bacillus subtilis spores, a reduction in the number of live Serrada marcescens bacteria, depending on the conditions of the experiment from 92.4% to 99.4%, removal of *Staphylococcus aureus* from 97.0% to 99.8 % and effectiveness in terms of impact on Pseudomonas aeruginosa from 98.0% to 99.5%, also depending on the test conditions. The description of results for Aspergillus niger spores did not include exact numerical data, with efficacy differing for spores aerosolized from aqueous suspensions and for dry spores dispersed in an air stream (the cause of these differences is unknown). The paper concludes that the results at the characteristic airflow rate (77 CFM) and high electrical setting were excellent and could probably be improved by increasing the electrical voltage within the experiment and increasing the residence time by enlarging the treatment chamber.

Evaluation of the report. The applied methods are valid and the test results are presented clearly and transparently. It was shown that the use of the "Potok 150-M-0T" air decontamination unit, in the described test conditions, leads to a reduction of the total number of microorganisms in the tested air samples in the range of 92.4-99.8%, depending on the type of microorganism and test conditions.

3.1.2 ESTUDIO DEL TEST REALIZADO A "AIR-CLENER UNIT POTOK 150". Departmento de Microbiología. Facultad de Farmacia. Universidad de Granada, 1995. (Study of the "Air cleaner unit Potok 150". Department of Microbiology, Faculty of Pharmacy, University of Granada, Spain, 1995.).

A copy of the original report is 7 pages long (pages 9-15 in the submitted document), contains a description of the method, results (3 tables and one picture-graph), and a conclusion, signed by two people (microbiology professors) and certified with the seal of the institution. A certified and signed translation into Serbian, a court translator for Spanish and English, was submitted. In reports, the equipment used is described. The test was conducted for a Potok 150 unit, using an atomizer (generating 2  $\mu$ m aerosol particles), a closed room (chamber) with a volume of 40 m<sup>3</sup>, the test organism *Micrococcus luteus* (ATCC 13513), with approximately 108 cells per mL. Before the operation of the device, an analysis of the concentration (number) of microorganisms present in the ambient air was performed, and the test itself was performed in two phases, the first - SP (without the use of the Potok unit) and the second - CP (with the use of the Potok unit). Petri dishes with a substrate (open) were placed at 4 locations in the room, at intervals of 30 and 60 minutes, and the total test lasted 270 minutes. The initial number of colonies measured in the ambient air was from 9-13, depending on the location.

In the first minute of the test itself without the use of the apparatus (phase 1), the number of colonies

was from 2128-2240, and during the test, also without the use of the apparatus, it progressively decreased, up to 11-18 colonies in the substrate after 270 minutes, depending on the location. In this test, the aerosolization suspension contained  $1.94 \times 10^8$  cells per mL. In the first minute of the second phase of the test, with the use of the apparatus, the number of colonies was from 2640-2840, and during the test, also without the use of the apparatus, it progressively decreased, to 0-1 colonies in the substrate after 270 minutes, depending on the location. In this test, the aerosolization suspension contained 2.25 x 10<sup>8</sup> cells per mL. Figure 1 shows the dynamics of the number of colonies, with and without the use of the Potok device (without variability marks). It is concluded that the use of the Potok 150 unit causes the microbiota present in the air to be reduced by approximately 1/200 in 90 minutes, while the normal reduction without the use of the unit is about 1/20 in the same period. The authors state that the result implies that it is possible to use the Potok 150 unit to create an environment without microorganisms, in a not too long time, and to maintain the environment in the specified conditions while the unit is in operation.

Evaluation of the report. The applied methods are valid and the test results are presented clearly and transparently. It was shown that the use of the air decontamination unit "Potok 150-M-01", under the described test conditions, leads to a reduction of the total number of tested microorganisms in the air, by about 10 times more (1/200 vs 1/20) compared to the reduction that occurs in the same period without using the "Potok 150-M-01" device.

3.1.3 TEST REPORT. Korea Conformity Laboratories, Gongdan-ro, Gunpo-si, Gyeonggi-do, Korea. The Center for Green Complex Technologies, 2018.

A copy of the original document in English is 4 pages long (pages 21-24 of the submitted document), signed by three persons (the examiner, the technical manager, and the president). A translation into Serbian certified and signed by a court translator for the English language was also submitted. Potok 150-M-01, an air decontamination device, was tested in a test room (chamber) of 8 m<sup>3</sup>, with Escherichia coli strain ATCC 25922, during 3 hours of operation, with the sampling method KS 1 2008:2013 Mod., using Feller's conversion tables for measuring results. The investigated outcome was the concentration of microorganisms measured in colony-forming units per unit volume (CFU/m<sup>3</sup>), under conditions of temperature of  $23.2 \pm 0.2$ °C and relative humidity of the ambient air of  $50.3 \pm 2.0$ %. The results showed that before the operation of the device, the measured concentration was 1.1 x 10<sup>4</sup> CFU/m<sup>3</sup> and after the operation, it was <10 CFU/m<sup>3</sup>, which is a reduction of 99.9%.

Evaluation of the report. The applied methods are valid and the test results are presented clearly and transparently. It was shown that the use of the "Potok 150-M-01" air decontamination unit, in the described test conditions, leads to a reduction of the total number of tested microorganisms in the air by 99.9%.

3.1.4 EXPERTISE ON TESTING EFFECTIVENESS OF "POTOK" AIR DECONTAMINATION EQUIPMENT, DISTRIBUTED BY G AND G INSTRUMENTS LTD. National Public Health Institute 1097 Budapest, Alber Florian ut 2-6. Reg. no. KOZ-7298-3/2017. (Certified and signed copy of the original document in English, copy of the certified and signed translation of the court translator into English).

The original document is 10 pages long and contains an introduction, background, objectives, sampling and test plan, test results and conclusions, executive summary, and appendix. The study aimed to determine the concentration of aerosol particles with an aerodynamic diameter of 1, 2.5, and 10 pm (PM<sub>1</sub>; PM<sub>2.5</sub>; PM<sub>10</sub>), volatile organic substances, aldehydes, and biological agents (bacteria and fungi) in the air before and after using the device. Sampling and testing were performed with a Grimm 1.108 aerosol spectrometer, a Tenax TA thermal desorption tube (according to ISO 16017-1:2001 standard), a tube with silica gel coated with sodium iodide and 2,4-dinitrophenylhydrazine, and liquid chromatography (according to ISO 16000-3: 2011 standard), and a sampling device according to Andersen (MAS 100). The temporal dynamics of sampling as well as supplementary methods such as sampling for the determination of allergenic fungi are described. The results are expressed through the number of growing colonies - CFU (colony-forming-units /  $m^3$ ), adapted according to the Feller table

intended for the tested device. Temperature and humidity are determined using a suitable device (IAQ-CALC indoor AIR Quality Meters 7545 TSI Inc.).

The methods are based on the following recommendations and standards: 1995 LIII Act on the Protection of the Environment, 306/2010 (XII.23) Government Decree on Air Protection, 4/201 1.(1.14.) VM Regulation on limit values for airborne loads and emission limit values for stationary sources of air pollutants, MSZ 21460-1: 1988 Hungarian Standard. Definitions of air protection. Definitions of general terms, MSZ ISO 4225: 1995 Air quality. General consideration. Concept and definitions, WHO Guidelines for indoor air quality, selected pollutants, 2010. A sketch of the testing room is given, with the locations of sampling, the tested device, and the control devices used in the test.

The results are presented in the text, tables, and figures. During the test, the aerodynamic diameter of aerosol particles decreased, depending on the size and concentration, in the range of 8.4  $\mu$ g/m<sup>3</sup> (basal value before turning on the device, for  $PM_{10}$ ) to 1.1  $\mu$ g/m<sup>3</sup> (after 3 hours of device operation for  $PM_{10}$ ). The concentration of volatile organic substances and aldehydes did not decrease during the operation of the apparatus, nor did the temperature and humidity of the air in the examined room. The total number of bacterial colonies decreased from the initial values of 470 CFU/m<sup>3</sup> to 150 CFU/m<sup>3</sup> (after 3 hours of operation of the tested device and one change of the entire ambient air), 40 CFU/m<sup>3</sup> (4 hours and 2 changes of the entire ambient air ) and 80 CFU/m<sup>3</sup>, which is a reduction of 83% compared to the initial value (5 hours and 3 changes of the entire ambient air). The total number of fungi (bud) decreased from the initial values of 85 CFU/m<sup>3</sup> to 75 CFU/m<sup>3</sup> (after 3 hours of operation of the tested device and one change of all ambient air), 45 CFU/m<sup>3</sup> (4 hours and 2 changes of all of ambient air) and 25 CFU/m<sup>3</sup>, which is a reduction of 70% compared to the initial value (5 hours and 3 changes of the entire ambient air). In the conclusion of the document, it is stated that the tested device "Potok" effectively reduces the concentration of small aerosol particles and the total number of bacteria and fungi in the ambient air of the room during normal use. There was no influence on the ambient (atmospheric) concentration of volatile organic substances and aldehydes. In addition, the device is recommended for the intended application and assigned a corresponding certificate with a serial number (2017/4). The appendix to the report contains a tabular representation of the tested fungal species, along with the measurement time, sample label, and total number of fungi (CFU/m<sup>3</sup>).

Evaluation of the report. The applied methods are valid and the test results are presented clearly and transparently. The test was conducted in accordance with several international and local standards (protocols) in this area. It has been shown that the use of the "Potok 150-M-01" air decontamination unit, in the described test conditions, leads to a reduction of the total number of tested microorganisms (bacteria and fungi) in the air, in the range of 70-80%, depending on the type of microorganisms and test conditions. The use of the device, under the given conditions, did not lead to changes in the concentrations of potentially harmful substances under investigation.

3.1.5 A JOINT PROJECT OF THE FRAUNHOFER INSTITUTES IPA, IGB AND IBP. (2022). Certification of the effectiveness of a mobile air purifier to reduce aerosol concentrations in closed indoor areas. Stuttgart.

The report was prepared by Sana-Medizintechnisches Servisezentrum GmbH, Leinfelden-Echterdingen, Germany. The volume is 29 pages, version 1, July 18, 2022. In the Introduction chapter, the scientific knowledge of the infectivity of the coronavirus, as well as the importance of air purifiers, from the aspect of the tested product, are listed. The following two chapters are devoted to the tasks and objectives related to the evaluation of the effectiveness of the air purifier under investigation and its ability to inactivate surrogate viruses in the air. The Materials and Methods chapter describes the test conditions, aerosol generator, selection of surrogate virus (HCoV-229E, BCV, Phi6), aerosol concentration, humidity and temperature, organic volatile substances, ozone generator, aldehydes, and ketones, as well as the used test methodology (detection of surrogate viruses in the air, evaluation procedures, validation method). The next chapter is the results including the following: measurement of viral infectivity or reduction of viral concentration, the concentration of viral particles at three-time points, dynamics of temperature and humidity values during the test, dynamics of ozone concentration over time,

VOC/SVOC analysis for the presence of unwanted side substances that arise from the operation of the device (including ambient ketones and aldehydes). In conclusion, it is stated that the test procedure was performed according to the procedure described in VDI-EE 4300 part 14.

The average reduction is shown in three measuring points, for the reduction of three particle sizes (>0.2  $\mu$ m, >0.5  $\mu$ m, >1.0  $\mu$ m), for reduction during continuous aerosolization, and for reduction in relation to the initial level. Results ranged from < Log<sup>-1</sup> to < Log<sup>-2</sup>. The reduction of viral concentration (PFU/m<sup>3</sup>) in three-time points was maximum < Log<sup>-3</sup> (99.4%) after 3 hours.

Evaluation of the report. The applied methods are valid, and the test results are presented clearly and transparently, even in the part related to efficiency measures. During the test, ambient concentrations of potentially harmful substances (ozone, volatile, and semi-volatile organic substances) were determined, immediately before and during the use of the Potok 150-M-01 device, and the available report did not interpret the results of the measured concentrations of those compounds. The examination was carried out in accordance with certain international or local standards in this area. It was shown that the use of the air decontamination unit "Potok 150-M-01", under the described test conditions, led to a reduction of the total number of tested microorganisms (surrogate viruses) in the air, maximum  $< Log^{-3}$  (99.4%).

## 3.2 SHORT REPORTS, SIGNED AND/OR INSTITUTIONALLY CERTIFIED

3.2.1 Federal Government Budgetary Institution "National Research Center for Epidemiology and Microbiology named after Honorary Academician N.F. Gamaleya" of the Ministry of Health of the Russian Federation

Investigation of the effect of high-voltage constant electric fields of the air decontamination unit "Potok 150-M-01" on the viability of a surrogate virus for SARS-CoV-2, MS2 bacteriophage. It was found that the technology of high-voltage constant electric fields of the air decontamination unit "Potok 150-M-01" provides air decontamination by reducing the concentrations of live MS2 bacteriophage, a surrogate virus for SARS-CoV-2, by 99.99% in 26 minutes.

3.2.2 Russian Academy of Medical Sciences, State Institution Gamaleya Research Institute of Epidemiology and Microbiology

Report on the results of microbiological studies of the Potok 150-M-01 air disinfection unit. The Potok 150-M-01 unit, after operating for 60-90 minutes in a room with a volume of up to 100 m<sup>3</sup>, both in the absence of people and when people are working, reduces air contamination to 0 CFU/m<sup>3</sup> from an initial concentration of 109 CFU/m<sup>3</sup>. Inactivation of microorganisms from the air was >99.99%.

3.2.3 Central Research Institute of Epidemiology, Russian Federation

On the practical use of ADU Potok-150-M-01 for air decontamination and fine filtration in the premises of the Central Research Institute Rospotrebnadzor in the context of the spread of COVID-19. In order to prevent viral pathogens, including COVID-19, from circulating in the premises, the CMD of the Institute decontaminated the air in several (15) laboratory rooms with a total area of over 2,000 m<sup>2</sup> (20 m<sup>2</sup> to 850 m<sup>2</sup>) and more than 200 employees per shift using the system for decontamination and fine filtration ADU Potok-150-M-01. During the entire period of using the system, the work of the Center was practically continuous, without registered cases of infection and forced self-isolation among the working staff.

3.2.4 Influenza Research Institute, Russian Federation

Expert report on the non-selective effect of the air decontamination unit "Potok 150-M-01" on all types of microorganisms in the air. Air decontamination technology in the air decontamination unit "Potok 150-M-01" is non-selective. The effect of this unit on microorganisms does not depend on their structure and degree of resistance to disinfectants. Considering the above, it can be considered appropriate to recommend the device of the air decontamination unit "Potok 150-M-01" for the inactivation (destruction) of all types of microorganisms in the air, such as bacteria, including *Escherichia coli*,

Enterococcus spp., Proteus mirabilis, Pseudomonas aeruginosa, Staphilococcus spp., Streptococcus spp., molds and yeasts, including Aspergillus niger, Mucor ramosissimus, Saccharomices cerevisiae, and viruses, including Influenzavirus, Grippus avium, Coronaviridae.

3.2.5 Bioton, Limited Liability Company, Russian Federation, Novosibirsk

Potok- 150-M-0.1 ADU with an airflow of 135 m<sup>3</sup>/h in one pass of a highly concentrated aerosol containing the bird flu virus, with an average MMAD of particles of 1.5  $\mu$ m provides an aerosol filtration efficiency by weight of up to 98.33% and effectiveness of bird flu virus inactivation up to 99.63%. Test results suggest that the Potok-150-M-0.1 ADU recirculation type provides high aerosol filtration efficiency and effectiveness in the inactivation of the avian influenza virus.

## 3.2.6 Bioton, Limited Liability Company, Russian Federation, Novosibirsk

Report on the effectiveness of the Potok 150-M-01 unit in air disinfection and inactivation of vaccinia virus. At a volume flow of 100 m<sup>3</sup>/h in the ADU Potok-150-M-0.1 "II" operating mode, the efficiency of aerosol filtration by particle weight is 98.9%, while the effectiveness of vaccinia virus inactivation is 99.6%. Test results suggest that the Potok-150-M-01 ADU recirculation type provides high aerosol filtration efficiency and effectiveness in the inactivation of the avian influenza virus.

## 3.2.7 Russian Academy of Medical Sciences, Central Research Institute for Tuberculosis

During 1993 and 1997, in the Department of Microbiology CTR1 of the Russian Academy of Medical Sciences, research was conducted on the inactivation of non-specific microflora and *Mycobacterium tuberculosis* using the Potok 150 M air disinfection unit. The Potok 150 M unit, through continuous 4-hour operation, ensures complete sterilization of the air from *Staphylococcus epidermidis*, *Klebsiella* species, as well as non-fermenting gram-negative bacteria of the *Pseudomonas* species. The filtration element of the Potok 150 M unit showed high air disinfection efficiency and 99.8% inactivation of the standard strain of *Mycobacterium bovis* BCG under demanding test conditions.

#### 3.2.8 N.N. Blokhin Russian Cancer Research Center

Report on the outcome of the assessment of the effectiveness of air decontamination using Potok 150 M-01 units in the premises of the Research Institute for Pediatric Oncology and Hematology FSBI N.N. Blokhin RCRC of the Ministry of Health of Russia. Tests performed on the 7th day after starting the Potok 150-M-01 units showed that the total number of microorganisms in the air in the ward decreased from 218 to 20 CFU/m<sup>3</sup>. On the 14th day, while the air decontamination unit was still operating, the airborne microorganisms in the ward were not detected. The conducted study showed that the application of the Potok 150 M-01 air decontamination device reduced the total number of microbes in the air of the isolated department from 218 CFU/m<sup>3</sup> to zero.

3.2.9 BioResources and Ecology Research Center and G.K. Skryabin Research Institute for Biochemistry and Microbial Physiology, Russian Academy of Sciences

Potok 150-M-01 ADU provides efficient (near 100%, NLT 99.99% considering experimental uncertainty) single-pass inactivation of highly concentrated lyophilized aerosol containing *Pseudomonas fluorescens, Micrococcus luteus*, and *Saccharomyces* in a contact time of about 0.5 seconds.

#### 3.3 RECOMMENDATIONS, SIGNED AND/OR INSTITUTIONALLY CERTIFIED

3.3.1 Moscow Healthcare Department State Budgetary Institution Scientific and Practical Center for Children with Craniofacial Abnormalities and Congenital Nervous System Diseases

Overview of the air decontamination system with Potok 150-M-01 units. The results of testing of sanitary and microbiological indicators regularly conducted by the Epidemiological Service of the

Center confirm the effectiveness of the system. Bacteriological indicators of microbial contamination for the entire period of work do not exceed the norms established by sanitary regulations and standards 2.1.3.2630-10 4.

3.3.2 Moscow Healthcare Department, State Budgetary Institution of Healthcare of the City of Moscow, Botkin City Clinical Hospital

The results of measuring the degree of air contamination in clean rooms are in accordance with sanitary and epidemiological regulations. During the entire period of operation, there were no failures of the Potok 150-M-01 system, and the equipment worked reliably and efficiently. Air decontamination units Potok 150-M-01 fully comply with GOST R 52539-2006 and SanPiN 2.1.3.2630-10.

3.3.3 Moscow Healthcare Department, State Budgetary Institution of Healthcare of the City of Moscow, City Clinical Hospital No. 24

The Potok 150-M-01 system provides the necessary air cleanliness that complies with SanPin 2.1.3.2630-10 "Sanitary and epidemiological requirements for organizations performing medical activities", which is confirmed by regular studies of washing and air samples in operating rooms, conducted by Rospotrebnadzor FBIS

3.3.4 Ministry of Defense of the Russian Federation, The Burdenko Central Military Clinical Hospital

Potok 150-M-01 air decontamination unit has all permits and approvals for its use:

- Certificate of Registry with the Ministry of Health of the Russian Federation No. 022a2000/1902-05 of July 26, 2005;

– Certificate of Registry  $\Phi$ C-2006/271 of September 14, 2006, for medical technology: Decontamination of Air in Medical Rooms Using Potok 150-M-01 Unit;

- Sanitary and Epidemiological Statement 77 фц 12.945.П.000461.11.04 of November 25, 2004;2

- Certificate of Conformity issued by State Committee for Standards and Metrology of Russia;

- Practical Guidelines MUK 4.2.1089-02;

- Practical Guidelines for Use of Potok 150-M-01 Air Decontamination Units in Healthcare Facilities of the Russian Federation Medical Corps developed by Chief Center of Government Sanitary and Epidemiological Oversight with the Ministry of Defense of the Russian Federation.

## 4. CONCLUSIONS

By analyzing the available subject documentation, as previously described, and considering that the authors of the original test reports are responsible for the accuracy of the data, the following is concluded:

- o A considerable number of tests of the air decontamination unit "POTOK 150-M-01" were conducted in relevant institutions, mostly in Russia, and partly in Germany, Hungary, Korea, Spain, and the United States of America;
- o Tests presented in the form of structured reports were carried out in accordance with many international and local standards and protocols in the subject area, the methodology and results were presented clearly and transparently, and the conclusions corresponded to the established results;
- o Evaluation of the test documentation, which was presented in the form of short reports and recommendations, suggests that their results are largely consistent with the results described in the structured test reports of the "POTOK 150-M-01" unit;
- o The use of the air decontamination unit "POTOK 150-M-01" leads to a marked, multiple reduction in the number of different tested microorganisms (bacteria, fungi, surrogate viruses) in the surrounding air, with the magnitude of the effect depending on various factors such as the type of microorganisms and other relevant test conditions, especially including the operating parameters of the tested device and the test period;
- o The operation of the "POTOK 150-M-01" unit results in the decontamination of ambient air in those environmental conditions and operating parameters of the device itself that are equivalent to the conditions of conducted research with satisfactory professional and methodological validity.

Kragujevac, 24.10.2023.

/signature/ Prof. dr Dejan Baskić Full professor of Pharmaceutical Microbiology Specialist in Microbiology and Immunology

/signature/ Prof. dr Dragan Milovanović Full professor of Pharmacology and Toxicology Specialist in Clinical Pharmacology, specialist in clinical pharmacology - pharmacotherapy