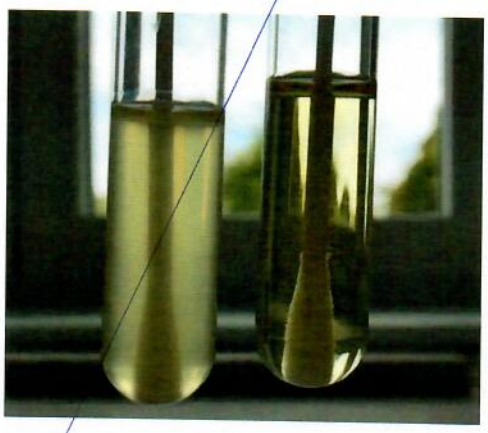
Nexa, s.r.o,

Sasinkova 9, 921 41 Piešťany

Assessment of the germicidal effect of germicide UV source and the possibility of its recognition as a medical device of class IIa according to the Slovak Government Regulation No 582/2008 Coll.

CLINICAL EVALUATION



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Date: September 2016

Objective of the work

Demonstrate that the tested germicidal UV source G ® 55W/SP of the manufacturer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany is a device capable of performing, by its physical action (emitted UV radiation) when it is used specifically in the healthcare sector (under precisely defined conditions), to effectively disinfect the other medical device — which would qualify for its recognition as a medical device of Class IIa according to Government Regulation No 582/2008 Coll., laying down details of the technical requirements and the procedures for assessing the conformity of medical devices, as amended.

N.B.: Rule 15 (4.3) of the Government Regulation provides that:

"All medical devices intended for disinfection, cleaning, rinsing or the hydration of eye lenses are in Class IIb.
All medical devices specifically intended for the disinfection of medical devices are in Class IIa, except medical devices intended specifically to be used for the disinfection of invasive medical devices, in which case they are in Class IIb.
This rule shall not apply to medical devices intended for the cleaning of medical devices other than contact lenses by physical means.'

Working hypothesis

UV germicidal lamp PROLUX G® 55W/SP manufacturer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany, the Slovak Republic, by its physical action in its effective impact, is able to effectively kill pathogenic micro-organisms and has the capacity to effectively kill a different medical device (under precisely defined conditions) — thus fulfilling the presumption for its recognition as a medical device of Class IIa according to Government Regulation No 582/2008 Coll., laying down details of the technical requirements and the procedures for assessing the conformity of medical devices, as amended.

Method of proof

In support of this working hypothesis, a laboratory attempt was made to simulate the environmental conditions of the health institution — using:

- the above mentioned specific type of UV germicidal source, in the form of a final product (medical technician) of the above specified manufacturer — with precisely defined physical characteristics (power consumption, radiant power, wavelength range of the emitted electromagnetic radiation);
- the accredited test method SOP OLD 41/10 of the MoE, RÚVZ Banská Bystrica, with the model Serratia marcescens CCM 4684 (Czech collection, Brno), in a nutrient broth.

The methodology, as a reference, followed by a statistically evaluated indicator (a trait), uses a deflection of the live bacterial culture pattern applied to the simulated surface of a medical device by exposure to UV radiation from that artificial source to which it is exposed.

Theoretical assumptions

Ultraviolet radiation (ultra violet) represents the human eye of the invisible part of the electro-magnetic wave, at a wavelength range from 100 to 400 nm. Is transmitted by the quantity of the electromagnetic field (photos).

According to the effects on biological processes in organisms, UV radiation is embedded in 3 spectrum bands: UVA (debt) with a wavelength of a wavelength range from 400 to 315 nm, an UVB (central), with a wavelength range of 315 to 280 nm and a UVC (short-wave), with a wavelength of wavelengths between 280 and 100 nm.

Ultraviolet radiation is characterised mainly by its wavelength "λ" (expressed in nanometres — nm) and by the oscillation frequency "f" in relation to λ = where $\frac{c}{f}$ "c" is the speed of the light. The less (shorter) wavelength the wavelength, the greater the frequency of its vibration, and the more energy it is, as the energy ("E") of its pictures is related to the frequency and the wavelength according to the relationship E = hf = h where " $\frac{c}{\lambda}$ h" is the Planck's constant.

The more environmentally rich (having a shorter wavelength and higher oscillations frequency) the electromagnetic radiation, the more dramatic (and more destructive) has an effect on bio-plasma, in a sequence of: infrared radiation — visible light — UV light radiation — gamma radiation — cosmic radiation.

From the literature it is known that sun radiation, in particular its shorter wavelength components (X-rays, gamma rays and ultraviolet rays), have a bacteriostatic effect on micro-organisms. However, a large part of these cuts are shade of the earth's magnetic field (gamma and X-ray radiation) and absorb part of the earth's residual cover (ozone layer — in particular UVC and partly UVB radiation).

Scientific knowledge about bacteriostatic and bactericidal effects in particular in the UVC radiation area and parallel advances in microbiological processes (in particular, in the area of the progressive knowledge of micro-organisms in the pathogenesis of communicable diseases in humans and animals), have led to efforts to create artificial ultraviolet radiation available in various areas (notably health, pharmacy, veterinary care, laboratory operations, food, water, airmanship) in the fight against pathogenic micro-organisms (especially bacteria).

The design of artificial UV resources has been/is different, but in principle always uses the principles of electric phenomena such as electric displacement in gases, electric arc and fluorescence. Artificial UV radiation uses the most common xenon discharge (xenon discharge lamps) and mercury (low/high pressure mercury vapour lamps) and/or other noble gas (e.g. argon).The outer packaging of such a UV source consists of a tube of fused silica (UV permeable) to which the relevant electrodes are fused.

Germicidal sources are produced as open or closed. The open shall have an unmatched UV discharge (no "bonnet"), and shall use the direct effect of the appropriately channelled UV radiation pattern to the treated target areas/objects and air to reach the required effect. The sealed sources, on the

other hand, are accompanied by a cover, which does not have any power, to which the UV-beam would have entered the surrounding environment; by means of a slot and pump, the recirculation of air from the room in question, which is exposed to the exposure of UV radiation produced by the discharge, is mounted on the inside of the equipment, which decontaminates them.

Scientific experiments have shown that the micro-organisms most effectively destroyed part of UVC radiation, situated at a wavelength range from 253,7 to 264 nm (maximum at about 260 nm); this relatively narrow area of UVC radiation was given the name of germicidal (UV-) radiation (Germ = germ, chickpeas = mushroom).For the above reasons, technological developments and the design of the micro-organisms eliminating artificial UV radiation sources have focused primarily on providing a germicidal component of UVC radiation to the surrounding environment. In relation to the germicidal effects of these sources on micro-organisms, it took the name of germicidal sources (archaologically also "germicidal lamps").Currently, mainly low pressure mercury vapour lamps are used for this purpose.

Ultraviolet radiation with a wavelength shorter than 300 nm (and therefore by germicidal UV radiation) is strongly absorbed by biological material.

A classic explanation of the mechanism for applying a germicidal UV radiation is its absorption in the prototype in which the production of a cytotoxic hydrogen peroxide (wet) is produced (in a humid climate).

Another explanation is the violation of chemical bonds in the macromolecules critical for the maintenance of the biological functions of the cells (in particular the violation of chemical bonds in the nucleic acids of the genetic mutations) — namely the impact of UV radiation on the energy of the photoones exceeding 4-5 eV.

Professional literature, as well as *Decree of the Ministry of Health No 553/2007 Coll., laying down details of the health protection requirements for the operation of health facilities, as amended*, the effective germicidal effect of ultraviolet radiation is attributed to the aforementioned wavelengths of its wavelengths (253,7-264 nm).When we fit these values to the Einecs in the above equation:

$$E = hf = h\frac{c}{\lambda}$$

in SI units, we receive the energy value E in J (joules).Whereas 1 eV = $1{,}602.10^{-19}$ J, h = $6{,}625.10^{-34}$ Os^{-1} and c = $2{,}998.10^{8ms-1}$ germicidal UV radiation with a wavelength λ = 253,7 nm has an energy of 4.8 eV and germicidal radiation with a wavelength λ = 264 nm has an energy of 4.69 eV. Thus, the UV-radiation of the above and shorter wavelengths is sufficiently large (greater than 4-5 eV) to cause the induction of mutations. The mutagenic effects of ultraviolet radiation were first demonstrated by the induction of mutations in bacteria and only later in somatic cells of eukaryontov.

The UV absorption in biological material takes place primarily in nucleic acids, proteins and enzymes characterised by a conjugated structure (carbon chains in which two double connections are separated by one single bond) and also most damaging to it; as these are strategic molecules in terms of cell survival, the UV radiation of the cells (after it is absorbed by the systems) is very intense.

Damage to the genome of UV cells is mainly related to the aromatic nature of all nucleic acids bases that are demonstrably better UV absorbers per unit mass than all other biological molecules.

The effects of radiation on the live matter are complex in nature and, when interpreting the biological effects of radiation, it is necessary to take into account not only the physical and chemical activities but also the biological reactions of the cells taking place in the diaspora from the primary effects of radiation through severe damage to the biological function of the cells up to their (eventual) death.

The mechanism of the radiation effect on bioenergy is generally explained on the basis of the theory of direct and theoretical indirect effect of radiation and derived theory of combined effect.

The theory of direct effect of radiation presupposes that the place of primary radiation injury of the controlled biological structure is identical to the place of intervention (i.e. the place where the radiation energy is absorbed) in which the relevant radiological chemical reactions are subsequently carried out. The biological effect is then dependent on the affected so called sensitive cell volume. That damage is determined by the latter's fate. The sensitive cell volume is located in the core, as a critical structure is considered to be chromosome DNA encoded by the genetic information.

The indirect effect theory assumes that the chemical reaction is not the primary primary energy absorption point but that the energy is transferred within the molecule and also between the molecules. The mutant mutation effect was found to be significantly amplified under the current presence of water and oxygen — due to the formation of chemically highly reactive peroxybosses, having high oxido-reducing effects and nucleic acids.

The theory of the combined effect of radiation assumes that both direct and indirect radiation effect mechanisms are applied to the resulting extent of cell injury.

Other authors are of the view that, on the one hand, germicidal and UV-radiation are both qualitative and quantitative.

- the qualitative effect is influenced by the levels of radiation absorbed which induce, in the cell, the photochemical changes, that they stimulate, restrict or damage the cell's life marches by accelerating them, or their reversible or irreversible status, to the generation of mutations, or to the death of the cells;
- quantitative action is explained by the intervention theory, which assumes that the dispersal of micro-organisms, as well as the spread of quantum radiation, is discontinuous, conditioned to a hole and over time. Therefore, it is not possible to set a threshold for the bactericidal effect of ultraviolet radiation, because it is subject to the law of probability. Also the smallest dose can be tackled by micro-organisms as well as some individuals can avoid the bactericidal effect of radiation at the maximum doses. In this way, it is explained that the reliability of the UV effect is not 100 % and can fluctuate.

Finally, it is also important to emphasise the great importance of the temporal factor of the exposure of radiation — considering that low intensity, short duration or intermittent radiation exposure to

the cell necessarily gives rise to less biological answers such as its highly incessant, continuous and uninterrupted irradiation.

As stated above, it is 265,0 nm that the wavelength of the UV radiation, which is the most efficient germicidal effect, is most effective. A serious majority of germicidal sources exhibits a maximum energy output in an area that approaches a wavelength of 253,7 nm; it shows about 85 % of germicide efficiency on the majority of bacteria, viruses and moulds.

Identifying precisely the necessary germicidal exposure times for single species or groups of micro-organisms is extremely difficult as they range from several seconds to 60-minute — because different micro-organisms are inherently different from their biological nature to UV radiation.

This is not only the determination of the necessary exposure time, but also the necessary radiation dose required to achieve the required germicidal effect, which is given by the product of radiated energy (power or radiant power) per unit unit (in μW.cm — $^{2)}$ and the radiation period (in seconds).E.g. the radiation intensity of 15 W in a UV light at 30 cm from the irradiated objective is approximately 400 μW.s.cm — $^{2.}$The conversion of units of intensity of radiation, and thus benefits, is as follows: 10 J.M $^{-2}$ = 1 mJ.M. $^{-2}$ = 1 mW.s.cm $^{-2}$ = 1000 μW.s.cm $^{-2}$.

The lethal dose for different micro-organisms varies depending on the different authors. For the vegetative forms of micro-organisms, the dose ranges from 830 to about 5500 μW.s.cm $^{-2}$, for spores of Bacillus subtilis in the interval of 10 000-50 000 μW.s.cm — $^{2, for}$ microresin spores in the range of 10 000-25 000 μW.s.cm — 2 and for $^{viruses\ in}$ the interval of 20 000-34 000 μW.s.cm — 2.Doses of germicidal sources necessary for the deactivation of 90 % micro-organisms as indicated by one of their manufacturers, shall be presented in Table 1.

The effect of UV-radiation does not only depend on the wavelength, intensity and exposure, but also on an individual "genetically given" sensitivity of micro-organisms. According to several authors, the most sensitive to UV radiation are pathogenic micro-organisms in the following order: haemolytic streptococci, Corynebacterium diphtheriae, staphylococcus, less sensitive saprophytes, are most resistant to savings micro-organisms.

As can be seen, our test used for our test — **Serratia marcescens** — 44 types of micro-organisms compared (table 1) in terms of their susceptibility to germicide UV radiation are ranked 9th — and thus belongs to a group of relatively sensitive substances.

Unfortunately, typically the use of UV radiation doses according to some authors is not sufficient to ensure the safe inactivation of the violins. Relatively resistant: virus Hepatitis B, Hepatitis C virus and human immunodeficiency virus in descending order. Other authors, on the other hand, provide a good elimination of the effects of this radiation on the virus and poliomyelitis.

Table No 1

Irradiation doses of ultraviolet radiation of type C necessary for the deactivation of 90 % of the micro-organisms

Micro-organism	Dose ($\mu W.s.cm^{-2}$)	Micro-organism	Dose ($\mu W.s.cm^{-2}$)
Legionella pneumophila	900	Streptococcus faecalis	4400
Campylobacter jejuni	1100	Bacillus anthracis	4520
Yersinia enterocolitica	1100	Pseudomonas aeruginosa	5500
Shigella paradysenteriae	1630	Polio virus	5800
Staphylococcus albus	1840	Mycobacterium tuberculosis	6000
Streptococcus viridans	2000	Micrococcus candidus	6050
Streptococcus hemolyticus	2160	Streptococcus lactus	6150
Shigella dysenteriae	2200	Bacillus subtilis	7100
Serratia marcescens	***2420***	Hepatitis A	7300
Klebsiella terrifani	2600	Salmonella typhimurium	8000
Staphylococcus aureus	2600	Rotavirus	8100
Proteus vulgaris	2640	Micrococcus sphaeroides	10 000
Escherichia coli	3000	Bacillus suptilis spóry	12 000
Shigella sonnei	3000	Clostridium tetani	12000
Salmonella paratyphi	3200	Penicillium expansum	13 000
Corynebacterium diphteriae	3370	Mucor racemosus B	17 000
Pseudomonas fluorescens	3500	Mucor racemosus A	17 000
Vibrio chlolerae (V.comma)	3500	Sarcina lutea	19 700
Influenza virus	3600	Penicillium digitatum	44 000
Salmonella enteritidis	4000	Aspergillus glaucus	44 000
Neisseria catarrhalis	4400	Aspergillus flavus	60 000
Spirillum rubrum	4400	Aspergillus niger	132 000

Source: Philips, 2006

It shall be specified that the high intensity and short exposure dose (principle of "impact") has a higher disinfection effect than the same dose with low intensity and long exposure.

Although the **broader** germicidal area of UV radiation is generally given in the range of 210-330 nm, for some viruses (dengue, St Louis encephalitis, foot-and-mouth disease, poliomyelitis) this range is extended up to 100-350 nm (for second exposures) and for others (virus partitre, herpesu, influence) into the range 100-200 nm (for minute exposures).

The vegetative forms of the different types of micro-organisms differ from their resistance to UV radiation (λ in the range of 250-270 nm) only relatively little. On the other hand, spores (Bacillus and micromycéty) also appear to be more resilient in the optimal germicidal efficiency of UV radiation (λ in the range 260-280 nm) against vegetative forms of micro-organisms. In addition, it is indicated that the Gram-positive micro-organisms are more resistant to UV radiation than the Gram-negative UV radiation.

Even more surprisingly, the knowledge about the germicidal effect of UV radiation at an interval with a very different wavelength (320-370 nm) has been detected in cases of gold of staphylococcus and mycobacteria present in the aerosol, both in in vitro and in vivo experiments.

According to other findings, also pigment micro-organisms, in particular black (some spores), or yellow (e.g. sartin) for them allegedly constitute a protective filter against UV radiation. In addition, some of the substances present in the bacterial environment (such as antioxidants, catalyst, pyruins) also have a protective effect on micro-organisms (from the point of view of UV irradiation).On the contrary, visible light can, in some UV radiation of damaged micro-organisms, initiate restorative mechanisms. UV radiation is also detrimental to small sub-teenagers.

Finally, the germicide efficiency of UV radiation depends on the physiological condition of the exposed cell, especially its age. It should also be borne in mind that the exposed radiation will be absorbed very quickly by the surface of the substances, so it does not penetrate into depth and therefore de facto only ground (it is not penetrating, as is the case for X-ray or gamma rays).

In the case of UV air, it operates only in the wild, non-protected micro-organisms, for micro-organisms adsorbed onto the surface of dust.

UV radiation is only applied to the cleaned surfaces that are exposed directly to the UV radiation and any screened physical barrier ("insulating" interlayer — such as dust, grease, other mechanical dirt and water) may affect the expected germicidal effects of radiation negatively. Therefore, germicidal sources cannot be used for disinfecting hollow articles (except when introduced/incorporated directly into their lumens — e.g. in ventilation ducts).In the aquatic environment, it shall be applied to micro-organisms only to a depth of 0,1 to 1 mm, according to others, entirely to clear water, up to a distance of approximately 30 cm.

The germicidal effect of UVC radiation depends also on other in-dock factors in the particular room/space in which they are used. The literature indicates that relative air humidity (optimal is 6065 %), temperature (optimal at 27 ° C), dust (ideally dust-free), air circulation, reflectance/quality

of the walls of the walls and equipment in the room. It is indicated that, with a view to killing micro-organisms at 72 % relative humidity, half of the radiation is required than 36 % of the relative humidity. It is also stated that, for a germicide efficiency of a source, the angle of the impact of the UV-beam produced by the source beam on the irradiated surfaces is of great importance; an effective exposure time on surfaces with a vertical impact of a beam is 10-15 minutes when the rays of the beam at a sharp angle weigh is longer.

Because the intensity of the electromagnetic radiation is reduced to the square of the distance from its source, the very large impact on the efficiency of a germicidal effect of UV radiation also has a source distance (UV tube) from the irradiation objective (e.g. medical device).According to a number of authors in the airspace with a minimum dust level and optimal humidity and temperature, the optimum germicum effect of germicide can be achieved at a distance of between 1,8 and 2.0 m; in our experiments, 100 % of germinium effects of tested sources have been demonstrated for the cultures of the chosen experimental microorgnicism (Serratia marcescens), even when placing 4.0 m at a distance.

It can be said that a number of factors influence the germicidal effects of UV radiation, that this radiation can certainly not be seen as a one-size-fits-all means of combating microorganisms, but only for a major helping method for the decontamination of the environment (areas and air) or a physical method of disinfection as well as a valid hygienic prescription (Decree of the Ministry of Health No č.553/2007 Coll., laying down details of the health protection requirements for the operation of health institutions, as amended).

Model microorganism — Serratia marcescens

It is a Gram-negative, facultative anaerobic rod and active, usually mobile, mostly (up to 1 subtype) that is incontestable bacteria of the Enterobacteriaceae family. It occurs in an outer environment (soil, water) rather than the host organism (mammals but also other animals).In the outer environment, its metabolism is oriented to the respiration, in the anaerobic fermentation environment. Generates a pigment that protects it in part from the effects of sunlight in an outdoor environment; in laboratories cultivated colonies have a typical brick red colour due to the pigment protiigosin (there are strains, however, not forming the pigment).P. marzipan is a relatively resilient micro-organisms — both in relation to both antibiotics and chemical disinfection. In human medicine it is declared as a given pathogenic microorganism, which is one of the significant agents of nosocomial (hospital) diseases, in particular immunocompromised patients (sepsis, pneumonia, urinary tract infections).In relation to germicidal UV radiation, a sensitive species is considered to be sensitive to an average sensitive species (Table 1).Ubikvitar is used as a model laboratory microorganism for the peaceful nature of its cultivation (for some agars, stock in the broth), the relative resistance and the pronounced (prima facie distinguishable) red colour of its colonies on agara.

In our experiment, the model microorganism used comes from a well-defined test culture of Serratia marcescens with CCM 4684 (Czech collection of bacteria Brno), which is grown in a nutrient broth number 2.

Experiment

The attempt was aimed at confirmation or rebuttal of the working hypothesis, that the UV germicidal source of PROLUX G® 55W/SP — the final product of the manufacturer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany, the Slovak Republic — is capable, by its physical action, in its effective impact, under precisely defined conditions, that can effectively kill pathogenic micro-organisms and, in such a way, ensure the disinfection of the medical device and, as a consequence, it could itself be a Class IIa medical device. The experiment was carried out in such a way as to simulate the disinfection of the medical device (in this case, the surface area of the operating table surface area) in the germicidal optical radiation environment produced by the above apparatus, namely:

a) repeated attempt at 09.05.2016 and 10.05.2016 in a hospital environment — at the Septic Room No 8 of the department of the central operating department of the Faculty of Central Operating Hospital, F.D. Roosevelt Námestie L. Svobodu 11, Banská Bystrica ('experiment in 1');

b) a simultaneous repeated control experiment on 09.05.2016 and 10.05.2016 in a laboratory environment — in the microbiology laboratory of the environment (room 109) of the Regional Public Health Authority located in Banská Bystrica, Cesta k nemocnici 25, Banská Bystrica ('experiment in 2').

According to the manufacturer's data, the tested germicidal source shows the following technical parameters:

- wavelength of produced UV-C radiation: 253.7 nm
- power supply: 230V/50 Hz
- input: 39-47 W / 0,18-0,20 A
- minimum amount of the installation of a UV-C source from the floor of the room: 2.2 m
- the efficient impact of the UVC source: 6 m

The manufacturer recommends to put into the body of the source UVC the UVC tube Philips TUV 55 LL (lifetime 18 000 hrs), or 55 W OFR. The condition of the life of the tubes is to build them electronics on a soft start principle.

A modified method for the testing of the performance of germicidal sources pursuant to Acta hygienica, epidemiica and micbiologica č.5/91, pp. 22 and 23, has been used to test the performance of the germicidal UV emitter in a microbiological laboratory; linked to the accredited standard procedure SOPs of the SOP 41/10 of the MoE — Determination of microbial contamination of objects and surfaces by the swab method.

This methodology, aiming at monitoring the effectiveness of physical disinfection with UV radiation, as a reference, followed by a statistically evaluated indicator (character), using an overdose of live bacterial culture by the effect of UV radiation from a given artificial source to which it is exposed.

As a test culture in the form of a simulated sample, for testing the vitality before and after irradiation (exposure) of germicidal UV radiation, the 24-hour broth of Serratia marcescens 4684 (Brno Czech collection) was propagated in a nutrient broth No 2, subjected to sterile physiological solution subsequently converted to densita 2 according to the Mc Farland scale, thus standardised and qualified for immediate fit for use, or storage in a refrigerator for a maximum of 4 hours.

As a simulated surface of a medical device (designed to disinfect germicide UV radiation), the surface of the bottom of the bottom of the sterile Petri dishes (48 hours prior to the experiment, which is still treated in the original plastic bags with a number of drops of the Persteril solution — with a view to obtaining certainty about their sterility) was used. In the specified test rooms (selected for trials in environments 1 and 2), a sterile petri dish immediately prior to initiation of the experiment, shall be opened on the test bench, on 09.05.2016 in both environments at 3 distances of the tested source (1.5 m, 2.0 m and 4.0 m), at each distance of the two three plates. On 10.5.2016, the experiment was repeated at the same distances in both environments, only the number of dishes for each of the trials increased to 4. The test cell was fixed above the table surface of the test surface, aiming to ensure an angle of 45 degrees to the surface of the test table produced by the germicidal UV beam.

During the duration of the experiments (from 09.05 to 10.05.2016) in environments 1 and 2, the persons involved were dressed in sterile working clothes, hats, tubes and gloves, in order to prevent any adverse microbiological contamination from the environment (which could distort the results of the trials).

Experiments carried out on 09.05.2016 and 10.05.2016 in both settings (1 and 2) were conducted in a standard (no specially untreated) environment at 22 °C and a relative air humidity of 80 %.

During the whole testing in both environments (1 and 2), a new (unworn) germicidal source is used in the most advanced design. The UV emitted has been measured by UV light meter UVC-254, output No Q616512, which has been properly calibrated (calibration letter No CT130116002 of 16.01.2015).The UV emitted has been measured after the energy ratio has stabilised in the germicidal emitter, i.e. after 5 minutes after starting at a wavelength of 253,7 nm. (Annex 1 — test report, Annex 2 — photographic documentation)

After having secured the experimental conditions of the experiment, 09.05.2016 and again 10.05.2016 with disposable sterile swabs (manufacturer fa MEUS, Italy), the test culture has been progressively applied to the sterile internal surface of the bottom of the applied petri dish, followed by a drying of the applied samples. Immediately after drying, in both runs (1 and 2) on 09.05.2016, as well as on a repeated experiment on 10.05.2016 disposable sterile swabs (just previously soaked in sterile isotonic saline), lightly pulled from the surface of the bottom of the Petri dishes used for testing for the purpose of testing the continued vitality of the test sample (each time using 2 swabs for each Petri dish) with their subsequent immediate immersion in two different liquid test culture media, namely nutrient broth No 2 (liquid in tube) and selenomethionine (liquid in a tube) and the subsequent prompt provision of culture in liquid soils in tubes in the microbial environmental biology RÚVZ Banská Bystrica (thermostate at 37 ° C ± 1 ° C for 10 days).All simulated samples taken at this stage of the experiments (dated 09.05.2016 and dated 10.05.2016) are in the attached test reports prepared by the Banská Bystrica RPHA, dated 23.05.2016, by the term **"prior to exposure"**.

After this phase of experiments in both environments (1 and 2), the Petri dish (the contaminated test culture) remains on the areas of the test bench — in exactly the same condition as they were at the beginning of the experiments in both days mentioned above. I.e. they were also kept unchanged (in terms of both the distances and the irradiated angle angle) against (then disabled) tested germicide with a UV radiate.

At the next stage (identical in the 1 and 2 environments), a germicidal UV source was tested on 09.05.2016 and 10.05.2016, as well as a target of 60 minutes for a covered petri dish contaminated by the petri dish. After this period, the test sources in the tests performed in environments 1 and 2 should be washed, followed by a repeat of the procedure for testing the continued vitality of the test sample (as described above), i.e. disposable sterile swabs (just previously soaked in sterile isotonic saline), by the light of the surface of the bed of Petri dishes contaminated with the previously irradiated test sample (each using 2 swabs for each Petri dish) with their subsequent immediate immersion in two different test culture media (nutrient broth No 2 — liquid in tubes) and (selenium soil — liquid in a tube) and subsequently by providing for the cultivation of such inoculated soils in tubes in the microbial environmental biology RÚVZ Banská Bystrica (thermostate at a temperature of 37 ^{0} C ± 1 ^{0} C for 10 days).All simulated samples taken at this stage of the experiment are in the attached test reports prepared by RÚVZ Banská Bystrica on 23.05.2016 by **"post-exposure"**.

For reasons of obtaining as much and as robust as possible results from the testing of a source, 09.05.2016 experiments in both settings (1 i 2) were repeated in two consecutive 60 minutes of irradiation cycles (I — first hour of radiation cycle and II — second hour of radiation).Two separate series of samples were exposed in both cycles (i.e. each individual sample was irradiated either only in the first or the second irradiation cycle).In a repeated experiment of 10.05.2016 petri dishes in both environments (Nos 1 and 2) were irradiated in only one 60 minute irradiation cycle. During the first irradiation cycle phase, during both experimental days (09.05 and 10.05).2016) in environments No.1 i 2 exposed 42 simulated samples, and during the second irradiation cycle, on 09.05.2016, 18 simulated samples were irradiated in environments Nos 1 and 2 (for capacity reasons of the laboratory).At the appropriate test plates, the experimental Petri dishes were placed in the same geometrical and spatial configurations in the same geometrical and spatial configurations in relation to the tested germicide source, both in terms of their distances (1.5 m, 2.0 m and 4.0 m) and the prescribed irradiation angle (45 ^{0}).All simulated samples taken during the first hour cycle of the radiation cycle (preexposure and postexposure) are in the attached test reports (prepared by RÚVZ Banská Bystrica on 23.05.2016), identified by **Roman I** and all the simulated samples taken on 09.05.2016 in a second hour of the radiation cycle (preexposure and postexposure) are marked with **Roman II**.

All sampled, and subsequently within the thermostate of the laboratory, 10 days, cultivated simulated samples from experiments in environments 1 i 2 of experimental days 09.05 and 10.05.2016 — both pre-exposure and postexposure, and from both hours of radiation — were checked on a daily basis during cultivation. According to the chosen experiment methodology, in the case of turbidity in any of the liquid soils (nutrient broth No 2 and selenium) of the signal to signal growth of a test microbial strain, with a subsequent 24 hour culture of cloudy culture media (blood agar No 2, MacConkey agar), a derived culture of cloudy culture media (agar) of fixed culture (agar) soils at 37 ^{0} C ± 1 ^{0} C is used. Subsequent cultivation on fixed (agar) soils in 100 % of cases of pre-exposure simulated samples demonstrated the presence of the Serratia marcescens test strain. After the period of 10 days referred to above, all visually unchanged liquid test media (with post-exposure simulated samples) have been given to the two fixed (agar) test soils under the chosen methodology and were also cultured in a thermostat for 24 hours at 37 ^{0} C ± 1 ^{0} C for the definitive exclusion of the presence of live Serratia marcescens in the post-exposure simulated samples; however, the presence of the test strain was not detected in either case (both agar soils remain sterile).

Results

As a preliminary point, it should be noted that the results of the experiment were even surprisingly clear — with the wording in favour of the introduction to this elaborate hypothesis — of course, under the given entry conditions and in that time sequence of experiments performed in environments No '1' and '2'.

As already indicated, in some cases:

1. All 21 simulated samples resulting from an experiment in an environment "1" (Operative part of the central operational office of FNsP F.D.Roosevelt in Banská Bystrica), at its stage prior to the first hourly exposure cycle of germicidal radiation of the tested source (located at distances 1.5 m, 2.0 m and 4.0 m from the irradiation target — samples 8 to 6170 collected on 09.05.2016 and sampled on 10.05.2016 to 6233 collected on 6162, were recorded after their application, to the bottom of the Petri dish and their subsequent swab and to the culture of nutrient broth No 2 (21 swabs) and the liquid selenide (21 samples) of the growth of the culture of the above test strain Serratia marcescens; I.e. in all 21 + 21 cases (100 %) the bacterial strain of the test bacterial strain in the samples marked as 'simulated sample — prior to exposure I') was laboratory demonstrated for the next stage of the experiment (test reports ref. CEV: 6162-6197/2016 and ref. CEV: 6222-6245/2016 — both issued on 23.05.2016 by the medical microbiology department of the RPHA, established in Banská Bystrica. This result has also been verified by a subsequent confirmatory recovery and a 24 hour culture of all 21 + 21 cloudy cultures on the above two fixed (agar) soils — where also in all 21 + 21 cases (100 %) the bacterial strain of the test bacterial strain showed the full viability of the test bacterial strain in the samples marked as 'simulated sample — prior to exposure I'.

2. All 21 simulated samples resulting from a control experiment in an environment of '2' (MŽP RÚVZ Banská Bystrica laboratory), at its stage prior to the first hourly exposure cycle of germicidal radiation of the tested source (1.5 m, 2.0 m and 4.0 m from the irradiation target — samples 6126 to 6134 collected on 09.05.2016 and 6198 to 6209 collected on 10.06.2016 after their application, to dry the bottom petri dish, their subsequent swab, and culture in live broth No 2 (21 swabs) and the liquid selenide (21 samples) of the growth of the culture of the above test strain Serratia marcescens; I.e. in all 21 + 21 cases (100 %) the bacterial strain of the test bacterial strain in the samples marked as 'simulated sample — prior to exposure I') was laboratory demonstrated for the next stage of the experiment (test reports ref. CEV: 6126-6161/2016 and ref. CEV: 6198-6221/2016 — both issued on 23.05.2016 by the medical microbiology department of the RPHA, established in Banská Bystrica).This result was also verified by a subsequent confirmatory recovery and a 24 hour culture of all 21 + 21 cloudy cultures on the above two solid (agar) soils — which also showed in all 21 + 21 cases (100 %) the bacterial strain of the test bacterial strain recorded in the samples labelled as "simulated sample — prior to exposure I".

3. All 21 simulated samples resulting from the "1" experiment (FNsP F.D. Roosevelt in Banská Bystrica), at its stage following a first step (o) of the radiation of germicidal radiation of the tested source (spaced at distances of 1.5 m, 2.0 m and 4.0 m from the irradiated target — samples 8 to 6179 collected on 9.5.2016 and sampled on 10.5.2016 to 6245 collected on 6171,

did not report after their application, to the bottom of the Petri dish, to their subsequent swab and to culture in nutrient broth No 2 (21 samples), to the culture of the above test strain of Serratia marcescens. In all 21 + 21 cases of soil remaining sterile (100 % of cases), laboratory evidence of the full devitalisation of the bacterial strain in the test samples marked as "simulated sample — after exposure I" has been demonstrated to be laboratory. CEV: 6162-6197/2016 and ref. CEV: 6222-6245/2016 — both issued on 23.05.2016 by the medical microbiology department of the RPHA, established in Banská Bystrica).This result was also verified by a subsequent confirmatory recovery and a 24 hour culture of all 21 + 21 (in this case uncloudy) *cultures on* the two solid (agar) soils, which also in all 21 + 21 cases (100 %) demonstrated a complete devitalisation (soil remained sterile) of the bacterial strain in the test samples marked as "simulated sample — after exposure I".

4. All 21 simulated samples resulting from a control experiment under '2' (MŽP RÚVZ Banská Bystrica laboratory), at its stage following a first test cycle (o) of the germicidal radiation of the tested source (spaced at distances of 1.5 m, 2.0 m and 4.0 m from the irradiation target — samples 6135 to 6143 collected on 9.5.2016 and sampled on 10.5.2016 to 6221 collected on 6210, did not report after their application, to the bottom of the Petri dish, to their subsequent swab, and to the culture of nutrient broth No 2 (21 swab samples), to the culture of the above test strain of Serratia marcescens. In all 21 + 21 cases of soil remaining sterile (100 % of cases), laboratory evidence of the full devitalisation of the bacterial strain in the test samples marked as "simulated sample — after exposure I" has been demonstrated to be laboratory. CEV: 6126-6161/2016 and ref. CEV: 6198-6221/2016 — both issued on 23.05.2016 by the medical microbiology department of the RPHA, established in Banská Bystrica).This result was verified also by a confirmatory recovery and a 24 hour culture of all 21 + 21 (in this case uncloudy) *cultures on* the above two solid (agar) soils — which also in all 21 + 21 cases (100 %) demonstrated a complete devitalisation (soil remained sterile) of the bacterial strain in the test samples marked as "simulated sample — after exposure I".

5. All 9 simulated samples resulting from an experiment in an environment "1" (Operative part of the central operational office of FNsP F.D. Roosevelt in Banská Bystrica), at its stage prior to the second hourly UV radiation of the tested source (located at distances 1.5 m, 2.0 m and 4.0 m from the irradiation objective — samples 8 to 6188 collected on 9.5.2016, showed after their application, to the bottom of the Petri dish, to their subsequent swab and to culture in live broth No 2 (9 swabs) and to the liquid selenide (9 swab samples) of the growth of the culture of the above test strain Serratia marcescens; I.e. in all 9 + 9 cases (100 %) the bacterial strain of the test bacterial strain was laboratory confirmed in the samples described as 'simulated sample — prior to exposure II') prepared for the next stage of the experiment (test report ref. CEV: 6162 — Case 6197/2016 — drawn up on 23.05.2016 by the medical microbiology unit of the RÚVZ, established in Banská Bystrica).This result was also verified by a subsequent confirmatory recovery and a 24 hour culture of all 9 + 9 cloudy cultures on the above two solid (agar) soils — which also showed in all 9 + 9 cases (100 %) the bacterial strain of the test bacterial strain recorded in the samples labelled as "simulated sample — prior to exposure II".

6. All 9 simulated samples resulting from a control experiment in an environment of '2' (MŽP RÚVZ Banská Bystrica laboratory), in its phase prior to the second hourly UV radiation of the tested

source (positioned at distances of 1.5 m, 2.0 m and 4.0 m from the irradiation objective — samples 6144 to 6152 taken on9.5.2016, exhibited after their application, to the bottom of the Petri dish, to their subsequent swab and to culture in nutrient broth No 2 (9 swab samples) and to the liquid selenide (9 swabs) growth of the above test strain Serratia marcescens; I.e. in all 9 + 9 cases (100 %) the bacterial strain of the test bacterial strain in the samples marked as 'simulated sample — prior to exposure II' was laboratory demonstrated for the next stage of the experiment (test report ref. CEV: 6126 — Case 6161/2016 — drawn up on 23.05.2016 by the medical microbiology unit of the RÚVZ, established in Banská Bystrica).This result was also verified by a subsequent confirmatory recovery and a 24 hour culture of all 9 + 9 cloudy cultures on the above two solid (agar) soils — which also showed in all 9 + 9 cases (100 %) the bacterial strain of the test bacterial strain recorded in the samples labelled as "simulated sample — prior to exposure II".

7. All 9 simulated samples resulting from an experiment in the "1" environment (FNP Sec. central operational unit of FNsP F.D. Roosevelt in Banská Bystrica), at its stage, following a second time cycle (o) of the germicidal radiation of the tested source (spaced at distances of 1.5 m, 2.0 m and 4.0 m from the irradiation objective) — samples 8 to 6197 collected on 9.5.2016, did not report after their application, to the bottom of the Petri dish, to their subsequent swab, and to the culture of nutrient broth No 2 (9 swab samples), to the culture of the above test strain of Serratia marcescens. In all 9 + 9 cases the soil remained sterile (100 % of cases), laboratory evidence of the full devitalisation of the bacterial strain in the test samples marked as "simulated sample — after exposure II" was demonstrated (test report ref. CEV: 6162 — Case 6197/2016 — both issued on 23.05.2016 by the medical microbiology unit of the RÚVZ, established in Banská Bystrica).This result was also verified by a subsequent confirmatory recovery and a 24 hour culture of all 9 + 9 (in this case uncloudy) *cultures on* the two solid (agar) soils, which also in all 9 + 9 cases (100 %) demonstrated a complete devitalisation (soil remained sterile) of the bacterial strain in the test samples marked as "simulated sample — after exposure II".

8. All 9 simulated samples resulting from a control experiment in an environment of '2' (MŽP RÚVZ Banská Bystrica laboratory), following a second time cycle (o) of the germicidal radiation of the tested source (spaced at distances of 1.5 m, 2.0 m and 4.0 m from the irradiation target — samples 6153 to 6161 collected on 9.5.2016, did not report after their application, to the bottom of the Petri dish, to their subsequent swab, and to the culture of nutrient broth No 2 (9 swab samples), to the culture of the above test strain of Serratia marcescens. In all 9 + 9 cases of land remained sterile (100 % of cases), laboratory evidence of the full devitalisation of the bacterial strain in the test samples marked as 'simulated sample — after exposure II' was demonstrated (test report ref. CEV: 6126 — Case 6161/2016 — drawn up on 23.05.2016 by the medical microbiology unit of the RÚVZ, established in Banská Bystrica). This result was also verified by a subsequent confirmatory recovery and a 24 hour culture of all 9 + 9 (in this case uncloudy) *cultures on* the two solid (agar) soils, which also in all 9 + 9 cases (100 %) demonstrated a complete devitalisation (soil remained sterile) of the bacterial strain in the test samples marked as "simulated sample — after exposure II".

9. In summary: None of the 60 + 60 simulated post-exposure samples (exposed either in the first or second hours of the UV cycle of the tested germick of the tested germick of the two test

environments — No.' 1 'i n.' 2) did not lead to the growth of the Serratia marcescens' test strain, even in the primary vaccinated liquid broth of both species (cultivated in the thermostate in the MoE RÚVZ Banská Bystrica laboratory for a period of 10 days) or even after a confirmation of the vaccination on the two rigid (agar) culture soils (cultivated in the thermostate in a thermostated laboratory for a further 24 hours).

Table n. 2 summarizes the results of the experiment briefly and transparently:

- Experimental phase - location/type of experimental environment - distance germ. source from target [m]	Number of samples showing the rise in liquid soils on liquid soils: a) nutrient broth No 2 b) Selenite land [ABS./%]	Number of reported growth samples on solid soils in turn: a) blood agar No 2, b) MacConkey agar [ABS./%]	Total [ABS./%]
prior to exposure — irradiation cycle I in hospital ("1") (1.5 m, 2.0 m, 4.0 m)	a) 21/100 % b) 21/100 %	a) 21/100 % b) 21/100 %	8 4/100 %
prior to exposure — irradiation cycle I in the Laboratory. RPHA ("2") (1.5 m, 2.0 m, 4.0 m)	a) 21/100 % b) 21/100 %	a) 21/100 % b) 21/100 %	84/100 %
prior to exposure irradiation cycle II in hospital ('1') (1.5 m, 2.0 m, 4.0 m)	a) 9/100 % b) 9/100 %	a) 9/100 % b) 9/100 %	36/100 %
prior to exposure irradiation cycle II in the Laboratory. RPHA ("2") (1.5 m, 2.0 m, 4.0 m)	a) 9/100 % b) 9/100 %	a) 9/100 % b) 9/100 %	36/100 %
after exposure irradiation cycle I in hospital ('1') (1.5 m, 2.0 m, 4.0 m)	a) 0/0 % b) 0/0 %	a) 0/0 % b) 0/0 %	0/0 %
after exposure irradiation cycle I in the Laboratory. RPHA ("2") (1.5 m, 2.0 m, 4.0 m)	a) 0/0 % b) 0/0 %	a) 0/0 % b) 0/0 %	0/0 %
after exposure irradiation cycle II	a) 0/0 % b) 0/0 %	a) 0/0 % b) 0/0 %	0/0 %

in hospital ('1') (1.5 m, 2.0 m, 4.0 m)			
after exposure irradiation cycle II in the Laboratory. RPHA ("2") (1.5 m, 2.0 m, 4.0 m)	a) 0/0 % b) 0/0 %	a) 0/0 % b) 0/0 %	0/0 %

Debate: The results obtained from the trials carried out are so (and not surprisingly) clear that, in the light of their 100 % capacity, it is not necessary to subject them to another calculation aimed at confirming the statistical significance of the test phenomenon (χ tests).

The aim of the work was to verify the working hypothesis that the UV germicidal source of PROLUX G® 55W/SP of the producer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany, the Slovak Republic, by its physical footprint in its effective reach, is able to effectively kill pathogenic micro-organisms and can, when used specifically in health care (under precisely defined conditions), effectively disinfect the other medical device — fulfilling the prerequisite for its recognition as a class of class IIa according to Government Regulation No 582/2008 Coll., laying down details of the technical requirements and procedures for the assessment of the conformity of medical devices, as amended.

From the point of view of statistical analysis in order to confirm/rebut the abovementioned working hypothesis on the basis of the results obtained from the experiments carried out, it was necessary, or sufficient, to confirm/invalidate the zero hypothesis, which reads as follows:

"The files of a specimen of Serratia marcescens CCM 4684 (Czech collection, Brno), of a well-defined test cell culture of Serratia marcescens (Brno) applied to the simulated surface of the medical device before irradiation, and following the irradiation of UV germicide source G ® 55W/SP of the manufacturer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany, Slovak Republic, do not show a **significant** difference in vitality, a process of disinfection of the other medical device has not been confirmed."

As the trial results clearly demonstrated that between the two sets it is a significant difference (characterised by values of 100 % of the vital test cultures of the micro-organism in the radiation file and 0 % of the vital samples of the assay culture of the micro-organism in the masterfile), for this reason, we reject the hypothesis and accept an alternative hypothesis that:

"The files of a specimen of Serratia marcescens CCM 4684 (Czech collection, Brno), of a well-defined test cell culture of Serratia marcescens (Brno) applied to the simulated surface of the medical device before irradiation, and following the irradiation of UV germicide source G ® 55W/SP of the manufacturer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany, Slovak Republic, displays a **significant** difference in vitality, a process of disinfection of the other medical device has been confirmed."

In so doing, we confirm the above working hypothesis that the UV germicidal source of PROLUX G® 55W/SP of the manufacturer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany, the Slovak Republic is capable, by its physical action in its effective impact, of an effective killing of viable microorganisms and is capable, when used specifically in the healthcare system (in precisely defined sub-headings), to effectively disinfect another medical device — thus fulfilling the presumption for its recognition as a

medical device of Class IIa according to Government Regulation No 582/2008 Coll., laying down details of the technical requirements and the procedures for assessing the conformity of medical devices, as amended.

It can be assumed that the experimental results could be different when using a less sensitive test culture of other types of bacteria, their spores, moulds, viruses etc. However, in our case an attempt has been made of the standard type of bacterium, the obligate used to test the effects of germics sources even in the past — as it is a typical representative of vegetative forms of micro-organisms present in the environment. This is a type of sporadic (as conditional pathogen) even in a nonzoomia environment, which, moreover, shows a comparable sensitivity to the germicidal, UV-radiation, as many other vegetative forms of vegetative forms conditional on pathogenic micro-organisms present in a hospital or other environment surrounding the human being.

In addition, in the case of Serratia marcescens, it is a laboratory easy to develop, well set and culture soils that are easily recognisable and the type of culture that is, for these reasons, in laboratory practice and which is used as a model taxon for the various research objectives.

The experiment conducted has convincingly confirmed both the correctness of the theoretical assumptions and the non-repudiation of the practical experience of the bactericidal effects of germicide UV radiation — if the apparatus in question is correctly used for this purpose.

The experiment has repeatedly demonstrated the justification for the specific use of germicide UV radiation (in this case, ***UV germicidal radiation emitted by PROLUX G® 55W/SP manufactured by Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany, Slovak Republic***) *as* one of the effective methods of physical disinfection. This method should, however, be of primary importance, since its effects are primarily superficial — strongly constrained by impurities, grease or humidity, on the surface of irradiated areas or objects, i.e. it is usable as a follow up method of disinfection applied to thoroughly mechanically cleaned and chemically disinfected target areas (including, for example, medical work surfaces and devices).It is important to bear in mind that disinfection of germicide by UV radiation in no way can replace sterilisation of target areas and devices, and that in practice it is to be applied only after normal **mechanical cleaning** and chemical disinfection of the target surface with disinfectant (for use in health care).

The test germicidal UV source is exclusively for the healthcare specific use mentioned above. The exposure of the target surfaces by a UV emitted must be targeted and coherent, operating and adjusting devices only to qualified and trained persons. It is also self-evident that, in order to achieve the required disinfection effect of the source, it is necessary to adhere strictly to the manufacturer's instructions concerning its placing and installation under realistic conditions, including safety instructions.

Conclusion:

The tested UV germicidal source PROLUX G® 55W/SP manufacturer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany, the Slovak Republic is, by its physical action, in its effective impact, is able to effectively kill pathogenic micro-organisms and is therefore in the environment of health institutions (under precisely defined conditions), which is specifically usable for the effective disinfection of the other medical devices, and is in a position to recognise it as a medical device of class IIa according to Government Regulation No 582/2008 Coll., laying down details of the technical requirements and procedures for the assessment of the conformity of medical devices, as amended. It should be used mainly for the needs of additional surface disinfection not only of selected medical devices, but also for both working and other indoor areas as well as indoor air.

MUDr. Stanislav Duba **RNDr. Karol Pukančík** **RNDr. Milota Fatkulinová**

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Nexa, s.r.o.
výroba, predaj, servis zdravotníckej techniky
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P.O. BOX E 15
IČO: 36 269 796, IČ DPH: SK2021542303
Zapísaná v OR OS TRNAVA vložka 12390/T odd. Sro

Used literature:

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- vyhláška Ministerstva zdravotníctva Slovenskej republiky z 15. augusta 2007, ktorou sa ustanovujú podrobnosti o požiadavkách na prevádzku zdravotníckych zariadení z hľadiska ochrany zdravia uverejnená pod. č. 553/2007 Z.z. (čiastka 231) v znení neskorších predpisov
- nariadenie vlády SR č. 582/2008 Z.z., ktorým sa ustanovujú podrobnosti o technických požiadavkách a postupoch posudzovania zhody zdravotníckych pomôcok v znení jeho novely
- oborová norma ON 84 84 5051 Predpisy pre aseptickú prácu z 18.06.1976

Annex 1 – Test report

REGIONÁLNY ÚRAD VEREJNÉHO ZDRAVOTNÍCTVA
SO SÍDLOM V BANSKEJ BYSTRICI
Cesta k nemocnici č.1, 975 56 Banská Bystrica

Oddelenie lekárskej mikrobiológie
Cesta k nemocnici č. 25, 975 56 Banská Bystrica

SNAS
Reg. No.159/S-156

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PROTOKOL O SKÚŠKACH

CEV: 6126 – 6161 /2016

Predmet skúšky:	**Stery z prostredia** (10 dňová kultivácia sterov skúšobnej kultúry podľa stanoveného ukazovateľa)
Rozbor vyžiadal:	Nexa, s.r.o. Sasinkova 9, Piešťany, výrobca testovaného žiariča PROLUX G K55W/SP
Miesto odberu:	RÚVZ Cesta k nemocnici č.25 Banská Bystrica Laboratórium MŽP, miestnosť č.109
Dátum odberu a doručenia vzorky do laboratória:	09. 05. 2016
Dátum ukončenia rozboru:	19. 05. 2016
Dátum vystavenia protokolu o skúškach:	23. 05. 2016
Protokol zhotovil:	Hüvös Ivaničová
Stanovený ukazovateľ:	dôkaz rastu skúšobnej kultúry v simulovanej vzorke pred expozíciou testovaným germicídnym žiaričom a po nej
Skúšobná kultúra (simulovaná vzorka):	24 hodinová kultúra zbierkového kmeňa (kultivovaná v živnom bujóne č.2) Serratia marcescens CRM 4684 -ČSM Brno, upravená sterilným fyziologickým roztokom podľa stupnice McFarlanda č.2
Použitá metóda:	A - ŠPP-OLM-41/10 MŽP

ČÍSLO CEV	MATERIÁL	VÝSLEDOK
6126	Simulovaná vzorka -pred expozíciou I. 1,5 m	Serratia marcescens
6127	Simulovaná vzorka -pred expozíciou I. 1,5 m	Serratia marcescens
6128	Simulovaná vzorka -pred expozíciou I. 1,5 m	Serratia marcescens
6129	Simulovaná vzorka -pred expozíciou I. 2,0 m	Serratia marcescens
6130	Simulovaná vzorka -pred expozíciou I. 2,0 m	Serratia marcescens
6131	Simulovaná vzorka -pred expozíciou I. 2,0 m	Serratia marcescens

6132	Simulovaná vzorka -pred expozíciou I. 4.0 m	Serratia marcescens
6133	Simulovaná vzorka -pred expozíciou I. 4,0 m	Serratia marcescens
6134	Simulovaná vzorka -pred expozíciou I. 4.0 m	Serratia marcescens
6135	Simulovaná vzorka -po expozícii I. 1,5 m	Pôdy ostali sterilné
6136	Simulovaná vzorka -po expozícii I. 1,5 m	Pôdy ostali sterilné
6137	Simulovaná vzorka -po expozícii I. 1,5 m	Pôdy ostali sterilné
6138	Simulovaná vzorka -po expozícii I. 2.0 m	Pôdy ostali sterilné
6139	Simulovaná vzorka -po expozícii I. 2,0 m	Pôdy ostali sterilné
6140	Simulovaná vzorka -po expozícii I. 2,0 m	Pôdy ostali sterilné
6141	Simulovaná vzorka -po expozícii I. 4,0 m	Pôdy ostali sterilné
6142	Simulovaná vzorka -po expozícii I. 4,0 m	Pôdy ostali sterilné
6143	Simulovaná vzorka -po expozícii I. 4,0 m	Pôdy ostali sterilné
6144	Simulovaná vzorka - pred expozíciou II 1,5 m	Serratia marcescens
6145	Simulovaná vzorka - pred expozíciou II 1,5 m	Serratia marcescens
6146	Simulovaná vzorka - pred expozíciou II 1,5 m	Serratia marcescens
6147	Simulovaná vzorka - pred expozíciou II 2,0 m	Serratia marcescens
6148	Simulovaná vzorka - pred expozíciou II 2,0 m	Serratia marcescens
6149	Simulovaná vzorka - pred expozíciou II 2,0 m	Serratia marcescens
6150	Simulovaná vzorka - pred expozíciou II 4,0 m	Serratia marcescens
6151	Simulovaná vzorka - pred expozíciou II 4,0 m	Serratia marcescens
6152	Simulovaná vzorka - pred expozíciou II 4,0 m	Serratia marcescens
6153	Simulovaná vzorka -po expozícii II 1,5 m	Pôdy ostali sterilné
6154	Simulovaná vzorka -po expozícii II 1,5 m	Pôdy ostali sterilné
6155	Simulovaná vzorka -po expozícii II 1,5 m	Pôdy ostali sterilné
6156	Simulovaná vzorka -po expozícii II 2,0 m	Pôdy ostali sterilné
6157	Simulovaná vzorka -po expozícii II 2,0 m	Pôdy ostali sterilné
6158	Simulovaná vzorka -po expozícii II 2,0 m	Pôdy ostali sterilné
6159	Simulovaná vzorka -po expozícii II 4,0 m	Pôdy ostali sterilné
6160	Simulovaná vzorka -po expozícii II 4,0 m	Pôdy ostali sterilné
6161	Simulovaná vzorka -po expozícii II 4,0 m	Pôdy ostali sterilné

Výsledky sa vzťahujú len na predmet skúšky
Protokol o skúškach sa môže kopírovať len vcelku, kopírovanie jeho častí je možné len s písomným súhlasom vedúceho OLM RÚVZ

Vysvetlivky: I – prvý hodinový cyklus žiarenia
II – druhý hodinový cyklus žiarenia
1.5m; 2.0m; 4.0m – vzdialenosť testovanej vzorky od germicídneho žiariča

Za správnosť zodpovedá: RNDr. Milota Fatkulinová

Nexa, s.r.o. výroba, predaj, servis zdravotníckej techniky Sasinkova 9, 921 41 PIEŠŤANY PO BOX E 15 IČO: 36 239 798, IČ DPH: SK2021542303 Zapísaná v Ok.s TRNAVA vložka 12330/T odd. Sro

Schválil:
RNDr. Jozef Strhársky, PhD.
vedúci oddelenia lekárskej mikrobiológie

Regionálny úrad verejného zdravotníctva so sídlom v Banskej Bystrici

.....Koniec protokolu.....

Form OLM_15b ver.1.4._01. 03.2014

REGIONÁLNY ÚRAD VEREJNÉHO ZDRAVOTNÍCTVA
SO SÍDLOM V BANSKEJ BYSTRICI
Cesta k nemocnici č.1, 975 56 Banská Bystrica
Oddelenie lekárskej mikrobiológie
Cesta k nemocnici č. 25, 975 56 Banská Bystrica

SNAS
Reg. No.159/S-156

Vedúci oddelenia: RNDr. Jozef Strhársky, PhD.
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(048) 4367 288
e-mail: milota.fatkulinova@vzbb.sk

PROTOKOL O SKÚŠKACH

CEV: 6162 – 6197 /2016

Predmet skúšky:	**Stery z prostredia** (10 dňová kultivácia sterov skúšobnej kultúry podľa stanoveného ukazovateľa)
Rozbor vyžiadal:	Nexa, s.r.o. Sasinkova 9, Piešťany, výrobca testovaného žiariča PROLUX G K55W/SP
Miesto odberu:	FNsP F.D.Roosevelta Banská Bystrica OCOS – septická sála č.8
Dátum odberu a doručenia vzorky do laboratória:	09. 05. 2016
Dátum ukončenia rozboru:	19. 05. 2016
Dátum vystavenia protokolu o skúškach:	23. 05. 2016
Protokol zhotovil:	Hüvös Ivaničová
Stanovený ukazovateľ:	dôkaz rastu skúšobnej kultúry v simulovanej vzorke pred expozíciou testovaným germicídnym žiaričom a po nej
Skúšobná kultúra (simulovaná vzorka):	24 hodinová kultúra zbierkového kmeňa (kultivovaná v živnom bujóne č.2) Serratia marcescens CRM 4684 -ČSM Brno, upravená sterilným fyziologickým roztokom podľa stupnice McFarlanda č.2
Použitá metóda:	A - ŠPP-OLM-41/10 MŽP

ČÍSLO CEV	MATERIÁL	VÝSLEDOK
6162	Simulovaná vzorka -pred expozíciou I. 1,5 m	Serratia marcescens
6163	Simulovaná vzorka -pred expozíciou I. 1,5 m	Serratia marcescens
6164	Simulovaná vzorka -pred expozíciou I. 1,5 m	Serratia marcescens
6165	Simulovaná vzorka -pred expozíciou I. 2,0 m	Serratia marcescens
6166	Simulovaná vzorka -pred expozíciou I. 2,0 m	Serratia marcescens

6167	Simulovaná vzorka -pred expozíciou I. 2,0 m	Serratia marcescens
6168	Simulovaná vzorka -pred expozíciou I. 4,0 m	Serratia marcescens
6169	Simulovaná vzorka -pred expozíciou I. 4,0 m	Serratia marcescens
6170	Simulovaná vzorka -pred expozíciou I. 4,0 m	Serratia marcescens
6171	Simulovaná vzorka -po expozícii I. 1,5 m	Pôdy ostali sterilné
6172	Simulovaná vzorka -po expozícii I. 1,5 m	Pôdy ostali sterilné
6173	Simulovaná vzorka -po expozícii I. 1,5 m	Pôdy ostali sterilné
6174	Simulovaná vzorka -po expozícii I. 2,0 m	Pôdy ostali sterilné
6175	Simulovaná vzorka -po expozícii I. 2,0 m	Pôdy ostali sterilné
6176	Simulovaná vzorka -po expozícii I. 2,0 m	Pôdy ostali sterilné
6177	Simulovaná vzorka -po expozícii I. 4,0 m	Pôdy ostali sterilné
6178	Simulovaná vzorka -po expozícii I. 4,0 m	Pôdy ostali sterilné
6179	Simulovaná vzorka -po expozícii I. 4,0 m	Pôdy ostali sterilné
6180	Simulovaná vzorka - pred expozíciou II 1,5 m	Serratia marcescens
6181	Simulovaná vzorka - pred expozíciou II 1,5 m	Serratia marcescens
6182	Simulovaná vzorka - pred expozíciou II 1,5 m	Serratia marcescens
6183	Simulovaná vzorka - pred expozíciou II 2.0 m	Serratia marcescens
6184	Simulovaná vzorka - pred expozíciou II 2,0 m	Serratia marcescens
6185	Simulovaná vzorka - pred expozíciou II 2,0 m	Serratia marcescens
6186	Simulovaná vzorka - pred expozíciou II 4,0 m	Serratia marcescens
6187	Simulovaná vzorka - pred expozíciou II 4,0 m	Serratia marcescens
6188	Simulovaná vzorka - pred expozíciou II 4,0 m	Serratia marcescens
6189	Simulovaná vzorka -po expozícii II 1,5 m	Pôdy ostali sterilné
6190	Simulovaná vzorka -po expozícii II 1,5 m	Pôdy ostali sterilné
6191	Simulovaná vzorka -po expozícii II 1,5 m	Pôdy ostali sterilné
6192	Simulovaná vzorka -po expozícii II 2,0 m	Pôdy ostali sterilné
6193	Simulovaná vzorka -po expozícii II 2,0 m	Pôdy ostali sterilné
6194	Simulovaná vzorka -po expozícii II 2.0 m	Pôdy ostali sterilné
6195	Simulovaná vzorka -po expozícii II 4.0 m	Pôdy ostali sterilné
6196	Simulovaná vzorka -po expozícii II 4.0 m	Pôdy ostali sterilné
6197	Simulovaná vzorka -po expozícii II 4,0 m	Pôdy ostali sterilné

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976 56 Banská Bystrica
Cesta k nemocnici 1
-21-

.....Koniec protokolu.....

Annex 2 – Photographic documentation