Clinical evaluation report of medical device class IIa – Germicidal lamp type PROLUX G®

The germicidal effect of PROLUXG® K55W/SP producer Nexa, s.r.o., Sasinkova 9, 921 41 Piešťany and 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 procedures for the assessment of conformity of medical devices, as amended

- **expert report**

Presentation by the authors (MUDr. Stanislav Duba, RNDr. Karol Pukančík, RNDr. Milota Fatkulinová) describes in detail the nature of electromagnetic radiation, its decontamination effects depending on its wavelength, the angle of incident exposure, the sensitivity/susceptibility of micro-organisms to UV light and local microclimatic conditions (relative humidity of the environment, air temperature) in which the UV radiation operates.

The authors describe in detail the nature and dynamics of application of the different types of electromagnetic radiation. Special attention shall be paid to the dose of exposure of the UV radiation of type C, which is necessary for the deactivation of 90 % of the live micro-organisms (Table. no. I.). In this table, the testing of species Serratia marcescens obtained the 9th place, where the living microorganisms were disabled/killed at a dose of 2420 $\mu W.s.cm^{-2}$.

The above mentioned group of authors, using the accredited test method ŠPP OLM 41/10 MŽP, RÚVZ Banská Bystrica, on the micro-organism body Serratia marcescens CCM 4684/collection strain 4684, propagated in a nutrient broth and treated with sterile physiological saline according to McFarlandsa No.2, under precisely defined physical conditions (electric power input, radiant power, wavelength range of emitted electromagnetic radiation, temperature, relative air humidity and angle of irradiation), tested a germicide (bactericide) performance of **PROLUX G®** K55W/SP manufacturered by, Nexa, s.r.o., production, sales and service of medical devices, Sasinkova 9, 921 41 Piešťany, Slovakia. The exemplary microorganism used (propagated and modified as described above) has been applied to an imitation of a medical device (sterile ground of a petri dish), left on it until dry and so prepared for the irradiation by the germicidal lamp. This was a collection strain of the micro-organism Serratia marcescens from the Czech microorganism collection, Brno. It is a movable, facultatively anaerobic non-spore bacteria of the Enterobacteriaceae family, which has good cultivation properties and belongs to the sensitive group of micro-organisms to UV light. In human medicine it is a conditional pathogen. It often occurs as etiological agent of hospital-associated (nosocomial) diseases, which also affected its choice for this test. The above test strain of Serratia marcescens (model microorganism) is often used for different testings due to its easy cultivation, the red colouration of its colonies on culture agar and the relative resistance not only to antibiotics but also to disinfectants. The laboratory experiment simulated the environmental conditions of a healthcare institution - sampling from the test area of the surfaces of Petri dishes was carried out in a hospital environment at the central operating department (Septic Room No 8) of the Faculty Hospital with a polyclinic, F. D. Roosevelt, Banská Bystrica, on 09.05.2016 and 10.05.2016 prior to their exposure to the indicated UV source and after the exposure to UVC radiation (**'Environment 1'**).

A similar experiment was carried out in parallel on 09.05.2016 and 10.05.2016 in the microbial biology laboratory (Room No 109 of the Regional Public Health Authority located in Banská Bystrica, Cesta k nemocnici 25, Banská Bystrica - 'Environment 2').

The test strain of the micro-organism (24-hour broth culture of the collection strain) has been subjected to a precise and strict definition of the conditions applied to an imitation of a medical device (sterile ground of a petri dish) until its drying. Subsequently, this medical device was exposed to physical exposure to UVC radiation from a specified UV source of 1 hour in order to achieve effective disinfection by it. The exposure was made from 1.5 m, 2 m and 4 m distances, each time at 45° angle of the application of germicidal rays, in a room with a temperature of 22°C and a relative air humidity of 80%.

During the testing in environments 1 and 2, brand new germicidal lamps manufactured by Nexa s.r.o. were used. A calibrated measuring device LUTRON UVC-254 serial n. Q616512 was used to measure the UVC radiation (after 5 minutes from switching on the device) at a wavelength of 253.7 nm. Subsequent sampling was carried out under strict aseptic conditions into two different liquid cultivation media - nutrient broth No.2 and liquid selenide. All samples and were cultivated under the same conditions in the environmental microbiology laboratory of the RÚVZ Banská Bystrica.

The proof of the mortality of the live micro-organisms of the collection of Serrate strain of Serratia marcescens CCM 4684 was carried out during the 1-hour interval from the realisation of the exposure of the test bacterial culture until the completion of the 10-day cultivation of these samples. Consequently, death of the strains of the test organisms was statistically evaluated and determined.

The authors describe in detail the procedure and the parameters for the use of germicidal radiation in both environments (environment 1 and environment 2). The predicted bactericidal effect of UVC radiation of the tested UV source has been built on the fact that UVC radiation of the wavelength range 253.7 nm has the strongest disinfection capacity and is well absorbed by the cells of micro-organisms. The absorbed quantities of UVC radiation result in intracellular qualitative changes, which are detrimental to the gene pool of the bacterial cell, and may lead to its subsequent death.

An optimal germicidal wavelength of UV radiation is 253.7 nm - a lethal effect of 90% of the bacteria. UVC radiation penetrates the outer cell membrane of the micro-organisms, passes through the body of the cell, reaches its DNA and changes it, thereby seriously damaging the genetic information of the micro-organism. The effect of the UVC radiation on the micro-organisms is directly proportional to the length, intensity and continuity of its exposure on the cells of the micro-organisms. Determining precise exposure periods of UVC with a germicidal effect on bacterial species is relatively difficult, due to the different natural sensitivity of bacteria.

It can be concluded that this test, aimed at evaluating the efficiency of the UV source, is carried out on its own merits after an appropriate provision of the necessary working conditions.
As mentioned above, the testing of UV germicidal lamp PROLUX G® K55W/SP has been conducted in two settings, in environment N.1 (operational hall No.8 OCOS FNsP F.D. Roosevelt in Banská Bystrica) and in environment N.2 (environmental microbiology laboratory RÚVZ Banská Bystrica, room N. 109), during two consecutive days - 09.05.2016 and 10.05.2016.

The same geometrical and physical parameters / radiation conditions for the simulated medical devices (the bottom of the Petri dishes) were maintained in both environments (i.e. the same places and times of

radiation, an identical UV germicidal source and the distance of the Petri dishes (1.5 m, 2.0 m and 4.0 m) from the testing source, the angle of received germicidal radiation, room temperature at 22°C and 80% air humidity.

Prior to the realisation of the UV light test, a disposable sterile swab (MEUS's products, Italy) was applied to the bottom of the sterile Petri dishes, under exactly the same conditions, and left until the drying of the test culture of the test bacterial strain Serratia marcescens.

During the first phase of the testing (before the exposition to UVC) - swabs were taken from the area of all walls of the Petri dishes (imitating a medical device) for the purpose of proving the presence and vitality of inoculated used test strain Serratia marcescens.

During the second phase of the testing (after the exposition to UVC) analogy sampling has been carried out by way of swabs taken from the area of all walls of the Petri dishes containing dried cultures of the test bacterial strain. Samples taken (stern sample swabs) were always immersed in liquid culture media (nutrient broth No. 2 and selenomethionine); the cultivation of all the samples was carried out in the environmental microbiology laboratory RÚVZ Banská Bystrica, Cesta k nemocnici 25, in a thermostat at a temperature of ± 37 ± 1 °C for a period of 10 days after which they were assessed.

The results of the experiment can be summarised as follows:

1. From the experiment conducted on 09.05.2016 and 10.05.2016 in environment 1 (operational room No 8, OCOS FNsP F.D. Roosevelt in Banská Bystrica), the 'simulated exposure sample before exposition 1' was preceded by 21 samples, which were cultured in two culture media (nutrient broth and selenomethionine). All 21 samples (inoculated into nutrient broth 2) and 21 steration samples (inoculated into selenomethionine) reported the presence of the viable bacterial strain of *Serratia marcescens.*

2. Samples taken on 09.05.2016 and 10.05.2016 from environment 2 (MŽP RÚVZ Banská Bystrica laboratory), before the first hourly exposure cycle to UV radiation (in total number of 21), showed, after being cultivated in two culture media (nutrient broth No. 2 and liquid selenite) growth, i.e. the presence and full vitality of the trial strain Serratia marcescens. Together, this consisted of 21 + 21 smear samples. This was a "simulated sample prior to exposure 1".

3. On the other hand, (in accordance with the stated working hypothesis), all 21 samples taken from the experiment of 09.05.2016 and 10.05.2016 in the environment 1 (operating room N. 8, dept. of central operating rooms FNsP F.D. Roosevelt in Banská Bystrica) after a cycle of one-hour exposure to UVC radiation from the tested device, there was ***no*** report of any growth of micro-organisms after their cultivation in liquid nutrient broth No 2 and in liquid selenomethionine. This indicates that they are devitalised following the UVC radiation application of the given wavelength, time of exposure, angle of the radiation and distance of the UV light from the irradiated target area (1.5 m, 2.0 m and 4.0 m). This concerned the "simulated sample after exposure I".

4. Equally, all 21 control samples taken from the experiment conducted in environment 2 (Laboratory of Environmental Microbiology of RÚVZ Banská Bystrica) on 09.05.2016 and 10.05.2016, 'simulated sample after exposure I' - after the first one-hour cycle of the exposure to UVC radiation from the tested device, it has ***not shown***, after their cultivation in liquid

nutrient broth No 2 and in liquid selenomethionine any test strain growth. This shows their full devitalisation in the exposed environment.
It can therefore be concluded that the identical outcome has also been identified in the context of the implementation of the second one-hour exposure cycle of simulated samples - in a clinical evaluation marked as:

5. "Simulated samples - prior to exposure II", a total of 9 + 9 simulated experiment samples from environment 1 (operating room No. 8 OCOS FNsP F.D.Roosevelt in Banská Bystrica), prior to the second one-hour exposition to UV radiation - a 100 % presence of the vital cultures of the trial strain of Serratia marcescens was confirmed.

6. Similarly, 9 + 9 "simulated samples before exposure II" from environment 2 (environmental microbiology laboratory RÚVZ Banská Bystrica) - a 100 % presence of the vital cultures of the trial strain of Serratia marcescens was confirmed.

7. Also, after the second one-hour cycle of exposure to UVC radiation in environment 1 (operating room N. 8 OCOS FNsP F.D. Roosevelt in Banská Bystrica), all 9 + 9 "simulated exposure samples after exposure II" ***did not*** report the growth of microbial cultures and thus the effects of UV radiation from the tested device have resulted in their devitalisation.

8. Likewise, after the second one-hour cycle of exposure to UVC radiation in environment 2 (environmental microbiology laboratory RÚVZ Banská Bystrica), after applying all 9 + 9 "simulated exposure samples after exposure II", all culture soils have remained sterile, which confirms a complete devitalisation of the used test strain Serratia marcescens.

It can be noted that the trials described above and their results (aimed at testing the effectiveness of the germicidal UV lamp **PROLUX G®** K55W/SP manufactured by Nexa, s.r.o. were carried out in well-defined (above-mentioned) environments 1 and 2, using suitably assembled simulations of samples - each time before and after the exposure to UVC radiation from the device - under strictly defined (and always repeatable) standard conditions.

It can therefore be clearly concluded that it has been demonstrated that all samples taken for cultivation from the test surface of the imitation medical device prior to exposure to UVC germicidal radiation have confirmed the presence of the vital strain of Serratia marcescens. Without the evidence of a sound vitality of the test bacterial strain, it would logically not be possible to prove the germicidal effect of the tested germicidal source, which consists of devitalisation of the micro-organisms used in this experiment.

It has been conclusively demonstrated, at standard and repeatable conditions, that in neither of the total of 60 + 60 post-exposure samples exposed to UVC germicidal radiation of **PROLUX G®** K55W/SP manufactured by Nexa, s r.o., Piešťany - in both environments 1 and 2 - after hourly exposure to UVC radiation, no presence (cultivation activity) of the used test strain Serratia marcescens has been shown.

The above results have confirmed the germicidal (bactericidal) effect of the **PROLUX G®** K55W/SP device, and at the same time the potential to recognise it as a class IIa medical device, provided that it should be primarily used for decontamination of medical devices and the indoor environment (air and surface) of operational theatres as well as medical sites with increased requirements for sterility of the environment (so-called clean rooms in the health care areas, or medical premises with controlled cleanliness of the environment).

Medical devices and surfaces shall, however, be subjected to thorough mechanical and chemical treatments prior to the application of UV radiation, and their surface shall exhibit no presence of impurities and droplets of water which reduces the effect of UVC radiation. It should also be noted that the effect of the test source lies in the physical disinfection (not sterilisation) of the target entities.
The test was carried out with UV germicidal lamps **PROLUX G®** K55W/SP manufactured by Nexa, s r.o., Sasinkova 9, 921 41 Piešťany, which, according to the manufacturer, has the following technical parameters:

wavelength of produced UVC radiation: 253.7 nm
power supply: 230V/50Hz
power: 39-47 W/0.18 - 0.20 A
minimum height of installation of the UVC source from the floor of the room: 2.2 m
effective reach of the UVC source: 6 m
lifetime of UVC source: 18000 hours

The manufacturer of this UV source recommends to install a UVC tube Philips TUV 55W LL into the body of the device, which has a lifetime of 18 000 hours or a HNS OSRAM 55W OFR, whose lifetime is equal to 18 000 hours even when using the HF technology with a soft start.
Naturally, it is important to monitor the duration of the actual use of the germicidal source in relation to its lifetime and to ensure its operation solely by trained professionals in accordance with the manufacturer's instructions.

Nexa, s.r.o. výroba, predaj, servis zdravotníckej techniky Sasinkova 9, 921 41 PIEŠŤANY P.O.BOX E 15 IČO: 36 236 798, IČ DPH: SK2021542303 Zapísaná v OR OS TRNAVA vložka 12330/T odd. Sro

Conclusion

The results obtained from the testing of the germicidal lamp **PROLUX G®** K55W/SP, the final product manufactured by Nexa s.r.o., Slovakia; confirmed that by its physical effect and within its effective reach, the device is capable of killing micro-organisms, including pathogenic micro-organisms, at the precise conditions defined by the manufacturer.

Given the above, the germicidal lamp **PROLUX G®** K55W/SP manufactured by Nexa, s.r.o., production, sale and service of medical technology, Sasinkova 9, 921 41 Piešťany fulfils the conditions for classification as a medical device in Class IIa according to Government Regulation No 582/2008 laying down details of the technical requirements and procedures for the assessment of the conformity of medical devices, as amended.

The above conclusions refer exclusively to the tested type of germicidal lamp, provided that the conditions for use and maintenance as specified by the manufacturer are observed. The above knowledge and conclusions cannot be applied unconditionally to other types of germicidal lamps, with other performance characteristics, or similar products from other manufacturers of germicidal lamps.

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Reviewer/opponent: MUDr. Silvia Sventeková, epidemiologist

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