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Expertise (Abstract)

Testing of the effectiveness of a decontamination process for used hollow needles (canulae) in the disinfector for medical waste *sinTion* ®

(for Christof Systems GmbH)

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According to orders the microbiological/physical testing of a specially designed steam decontamination process for used canulae in the disinfector for medical waste sinTion ® was carried out in July 2019.

In step with actual practice the relevant physical parameters have been measured in different positions in the subject matter to be disinfected using the machine under test carrying the factory number 7218001. On the same spots the germ-reduction counts have been determined using bio indicators.

Following the manufacturer´s instructions a plastic container of square section [21 x 21 cm, h = (incl. lid) 32 cm] was used for the collection of the used needles.

The Testing was carried out following DIN 58949-3:2012 "Steam-disinfection apparatus – Part 3: Testing of efficacy".

Test tubes with screw-caps were used as a surrogate for hollow needles /syringes. They contained 0.5 ml of a suspension of spores of *Bacillus atrophaeus* (ATTC 9372) with a bacterial count of 2.8 x 10^7 / ml each (SIMICON SPE8101-7, Ch. Nr. 7 SU 20918/7-8).

Additionally bio indicators according DIN 58949-4 were used, namely germ carriers with spores of *Bacillus atrophaeus* (ATTC 9372) with a bacterial count of 1.6 x 10^5/ ml each (Simicon DS, Ch. Nr. 910518)

The results of the physical testing showed that the process follows the preset parameters and works reproducible.

The preset process parameters of 3050 mbar corresponding with the steam temperature of 134.1 °C and a holding time of 20 minutes make sure that the disinfection of microbial contaminated waste even under worst case conditions is achieved.

The controls of the device are able to meet the process parameters over the entire holding time.

None of the used test pieces showed growth of the test organisms.

The process under test (needle program) meets the requirements according DIN 58949-3 and as well meets the requirements of ÖNORM S 2104 regarding disinfection of waste.

The steam-disinfection process in the disinfector for medical waste sinTion® designed for the decontamination of used canulae (needle program) is able to kill all microorganisms corresponding to the resistance groups A, B and C under worst case conditions.