Mag. Dr. rer.nat.
Tillo MIORINI
c/o Institute for applied Hygiene, Graz / Austria

Generally sworn and court certified expert for
- Hospital-hygiene, Operational hygiene and Microbiology

Univ. Prof. Mag. Dr. rer.nat.
Franz F. REINTHALER
c/o Institute for Hygiene, Microbiology and Preventive Medicine
Medical University, Graz / Austria

Generally sworn and court certified expert for
- Clinical Microbiology und Hygiene
- Microbiology, especially for mould and fungi
- Waste from the medical field

Expertise

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

for
Christof Systems GmbH

Graz, September 2019

Christof Systems GmbH
Plabutscherstraße 115
8051 Graz, Austria

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

GU 825/19

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 on the one hand have been measured in different positions in the subject matter to be disinfected on the other hand the germ-reduction counts have been determined using bio indicators.

The equipment itself and the standard program for the disinfection of medical waste had been tested at an earlier date on the basis of a previous model (expertise dated December 1995).

1 Introduction

1.1 Excursus: Disposal of canulae and other pointed and sharp objects

According ÖNORM S2104 these waste products are classified as "Waste products, which may be a risk for infection or injury within the medical ambience but need not to be disposed as dangerous waste" (ÖNORM S 2104; pt. 4.3).
In the standard this kind of waste is declared as "Waste with risk of injury" explicating as follows: To avoid injuries for the collection and storage of waste with risk of injury containers must be used which meet the following criteria:

- puncture safe according to British Standard BS 7320:1990 or according to French Standard NF X30-500
- break-proof
- permanently lockable

For safety reasons it is recommended to fill these containers to a maximum of ¾.
Once filled they must be closed tightly and permanently. Containers made of cardboard must not be used for these waste products.
Once closed and tightly locked these containers might be discarded without previous disinfection, but they must not end up in a mechanical-biological site for waste treatment. Therefore an incineration plant is the only possible way of disposal of these items.
In the last years in Austria some problems occurred insofar as the company which had been in charge for this kind of waste refused to take the waste pointing out that they will not accept waste containing pathogens of the risk group 3 (e.g. *Mycobacterium tuberculosis*) and 4 (e.g. Ebolavirus) according to the ordinance regarding biological working material.
For this reason Christof Systems GmbH designed an additional process for hollow needles (canulae and similar items) for the disinfector for medical waste sinTion ®.

1.1 General requirements on decontamination processes for infectious waste

As a principle of epidemics control one has to consider that a decontamination process for infectious waste must avoid any spread of pathogens and the contamination is limited to the primary object respectively.
All inner and outer surfaces of the waste must meet the process parameters, which have to cover the activity area A (killing of vegetative bacteria including Mycobacteria, as well as fungi and fungal spores), B (inactivation of viruses) and C (killing of Anthrax spores).

2 Technical data of the machine

2.1 Identification

Fig. 1: Decontamination apparatus for medical waste sinTion ®

The tests were carried out in the premises of Christof System GmbH using a machine under test carrying the factory number 7218001.

The space to take up the decontamination goods consists of a plastic-lined cylindrical metal chamber which is closable by means of a mechanical lid and is impermeable for steam and microwaves (manufacturer information).

The usable space (diameter 450 mm, height 675 mm) is inclined by 30 ° and lined with polypropylene, silicone rubber and polytetrafluorethylene.

The device is equipped with a vacuum test program as well as with 2 programs for the decontamination of waste:

1. Decontamination of mixed infectious waste by means of a combined microwave-steam disinfection process (metal objects excluded)
2. Decontamination of used hollow needles (canulae) by means of a fractionated vacuum steam disinfection process (needle program)

2.1.1 Process parameters "needle program"

Prozess phase	Pressure	Temperature	Time
Vacuum 1	150 mbar		
Steam 1	1200 mbar		
Vacuum 2	250 mbar		
Steam 2	2000 mbar		
Vauum 3	250 mbar		
Steam 3	3050 mbar		
Holding phase	3050 mbar	134 °C	20 Minuten
Vacuum 4	500 mbar		
Ventilation			30 Sekunden

Batch number, process parameters, holding time as well as date and time are documented on a paper strip. The overall batch time is about 50 minutes.

The removal of air and steam during the vacuum phases is done over a bacteria-filter, which is exposed to steam and thus disinfected in every process (manufacturer information).

Further technical data can be found in the operating manual.

2.1.2 Container for used needles

For the collection of the used needles a plastic container of square section [21 x 21 cm, h = (incl. lid) 32 cm]. Following the manufacturer´s instructions only these containers may be used for the disposal of used syringes/needles. Once closed, the container can be opened only by force however it is untight enough to let pass air and steam through the remaining slots.

Fig. 2: Container for used needles

3 Testing conditions

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

The following configurations were tested:
Tests 1-3: Load with a full container with closed lid
Test 4: Load with a full container with open lid
Test 5: Small load with a container containing mixed goods (Needles, gloves, pulp), representing a worst case-load

3.1 Bio-Indicators

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).

Excursus: The equivalence of this experimental setup (closed test tubes with spore suspension) with syringes which are contaminated with liquid and /or blood as a worst case scenario was demonstrated in laboratory experiments: Measurements of temperature were carried out in hollow glassware first with water and secondly with coagulated sheep blood. The tests showed that the temperature in blood in comparison to water (in the temperature range between 90 and 100 °C) is delayed for about 2 minutes.
Since the safety margin of the programmed process parameters (134 °C/ 20 minutes) is many times higher than this time span this is of no relevance in practice.

Fig. 3: Test tube with spore suspension

Fig. 4: Bio indicator acc. DIN 58949-4

Additionally bio indicators according to 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)

2 test tubes with spore suspension and 2 bio indicators were used per test run.

3.1.1 Recultivation of the test organisms

Dilution series with 0.9 % saline solution were made and 0.1 ml of the dilution stages -1 and -2 were spreaded on CS-agar. The petri dishes were incubated at 33 °C ± 3 K for 7 days. In case of bacterial growth the colonies were examined for presence of test organisms.
The original spore suspension was used as a positive control. The spore-count was determined in an analogue way.
The bio indicators were shaken out in CS-solution and incubated at 37 °C for 7 days. In case of turbidity the presence of test organisms was clarified by means of inoculation to blood agar and microscopy.
An untreated bio indicator was used as positive control.

3.2 Physical testing

3.2.1 Measuring system

The temperature and pressure was measured by means of data loggers (EBI 10 T 421 und EBI 10 TP 200, Ebro).
The temperature sensors of the EBI 10 T-logger were positioned in the fully loaded container for hollow needles. The temperature-pressure-logger was positioned in the chamber.

No.	Position	colour in the diagram
T1	container bottom	dark green
T2	container center right	red
T3	chamber	light green
Pressure	chamber	blue

T1-3: Temperature sensor

Fig. 5: Positioning of the datalogger

4 Results

4.1 Microbiological tests

4.1.1 Controls of the bio indicators

The colony count of the untreated spore suspension was determined by 2.4 x 10^6 (log 6,38)

All of the untreated bio indicators according to DIN 58949-4 showed bacterial growth after incubation.

4.1.2 Tests 1-5

spore suspension/ bio indicators	position	reduction factor (log)
SpS	container bottom	≥ 6,38
SpS	container center	≥ 6,38
BI	container bottom	≥ 5
BI	container center	≥ 5

* SpS: spore suspension BI: bio indicator

4.1 Physical testing

The results of the physical testing are shown in the Annex. It can be seen that the process follows the preset parameters and works reproducible.

5 Assessment of test results

The principles of assessment for a sufficient efficacy of disinfection of microbial contaminated (infectious) waste are defined in DIN 58949 -3 as follows: Reduction of the spore count of *Bacillus atrophaeus* of at least 5 log, which has to be achieved in all parts of the waste (inner and outer surfaces).

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

6 Summary

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.

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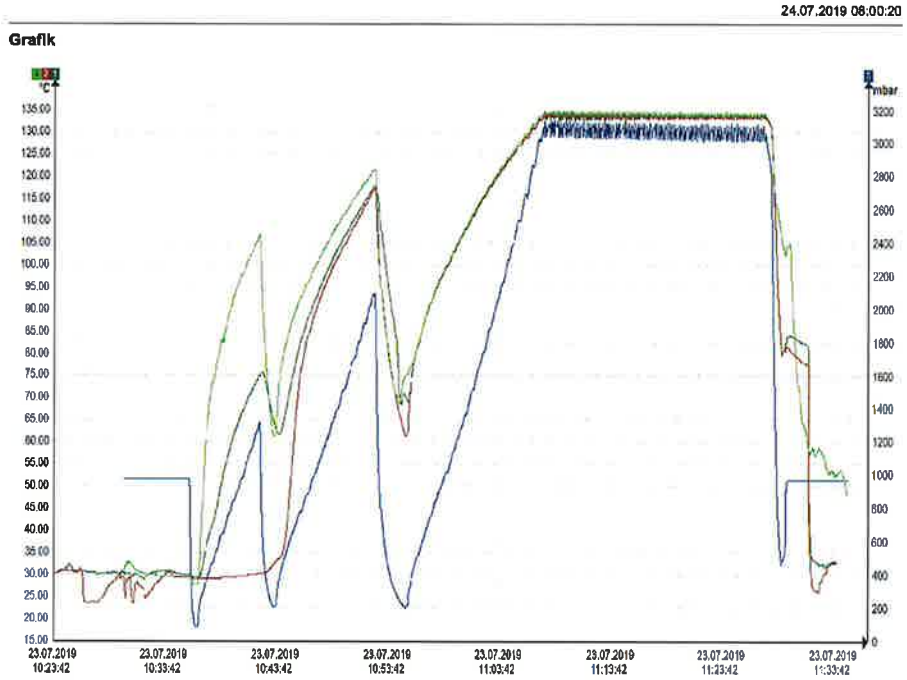
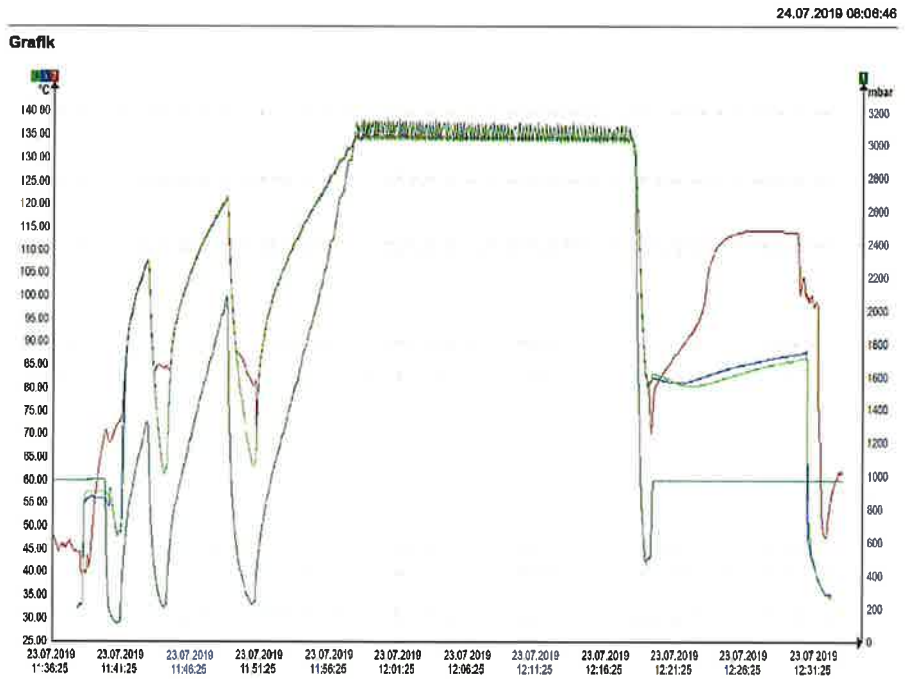
7 Annex

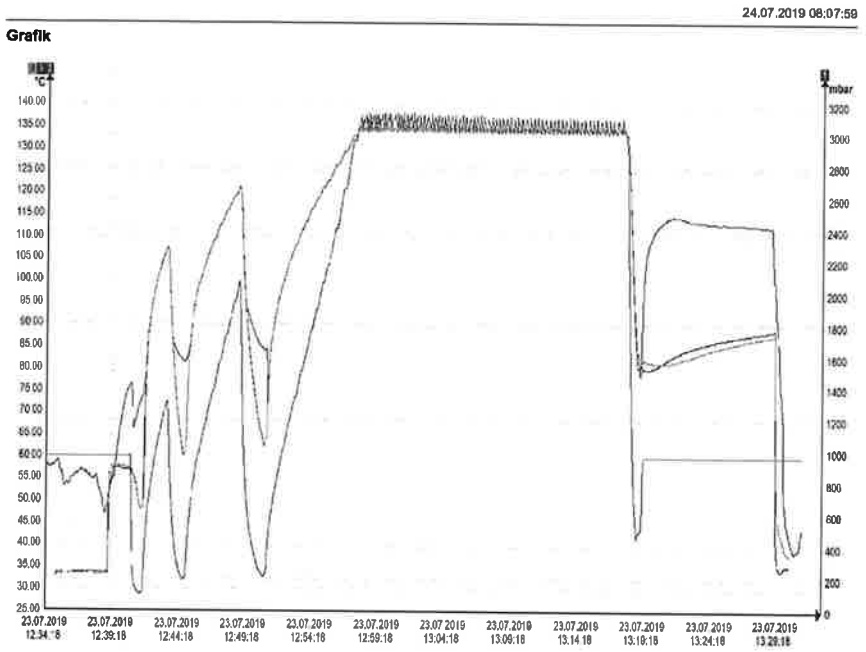
7.1 Test records



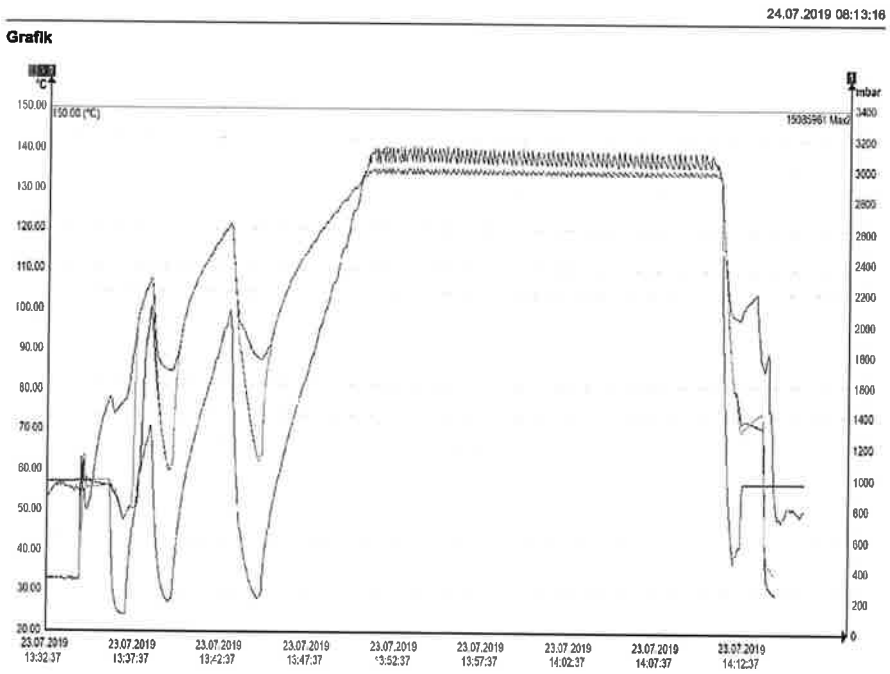
Test 1: Load with a full container and closed lid



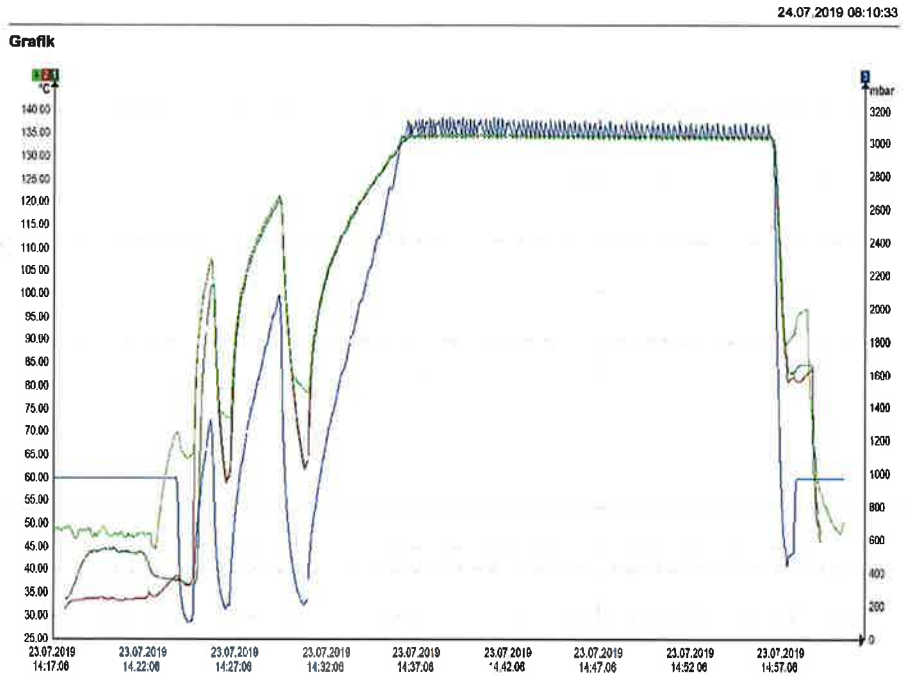
Test 2: Load with a full container and closed lid



Test 3: Load with a full container and closed lid



Test 4: Load with a full container and open lid



Test 5: Small load with a container containing mixed goods (Needles, gloves, pulp), representing a worst case-load