TRANSLATION FROM GERMAN

ROBERT KOCH INSTITUT

Certified Duplication

Robert Koch-Institute | Nordufer 20 | 13353 Berlin

Maschinenbau und Handels GmbH
Plabutscher Str. 115

A-8051 Graz

Regarding: Acceptance of the waste disinfection process system CMB into the list of the Robert Koch-Institute according to §10 c BSeuchG
Here: Your request from 1997-07-25 with the additions from 1997-10-07, 1998-05-08, 1999-10-15, 1999-11-02 and 2000-01-28

Dear Mr. Christof,

We hereby inform you that in the above mentioned list in the category:

3.4 disinfection of waste

the **system CMB**

has been added.

The requirements stipulated by RKI at the time of entry regarding type and packaging of waste have to be met.

Operating data:

1. Program for unspecified hospital waste

Air evacuation
amount of evacuation phases: 4
required pressure during evacuation phases:

1st phase:	150 mbar
2nd phase:	200 mbar
3rd phase:	300 mbar
4th phase:	300 mbar

required pressure for the intermediate steam bursts:

1st intermediate steam burst: 1500 mbar
2nd intermediate steam burst: 1800 mbar
3rd intermediate steam burst: 2100 mbar

Disinfection
pressure in the disinfection chamber: 2100 mbar
exposure time: 6 min

2. Program for liquid waste

Air evacuation
amount of evacuation phases: 1
required pressure during evacuation phases:
1st phase: 150 mbar

Disinfection
pressure in the disinfection chamber: 2250 mbar
exposure time: 12 min

3. Program for liquid waste in bags

Air evacuation
amount of evacuation phases: 2
required pressure during evacuation phases:
1st phase: 150 mbar
2nd phase: 300 mbar
required pressure for the intermediate steam burst:
1st intermediate steam burst: 1200 mbar

Disinfection
pressure in the disinfection chamber: 2100 mbar
exposure time: 12 min

Tested and approved apparatus type: sinTion 1.1

Regarding type and packaging of waste, the user manual must contain the following instructions:

The waste has to be put into the disinfection chamber using the designated bags (Co. Schöller-Bleckmann Medizintechnik GmbH, ID-Nr. MS526960). The bags may only be opened after being put into the device. The bag has to be opened in such a manner that eliminates the risk of infection. Device components that may have been contaminated with waste of the category C and are out of reach of the disinfection process (outside of the disinfection chamber), have to be disinfected using a disinfectant from the above mentioned list. The material that has to be disinfected must be directly accessible by the steam; this includes microbial contaminated cavities of the items (e.g. bottles), unless they contain water. The total volume of liquid per container or bottle must not exceed 0,5 l. If the waste includes containers with more than 500 ml of liquids, thick-walled vacuum flasks or other wastes, of which the thermal characteristics during treatment with saturated steam are unknown, the required compensation time has to be calculated and the exposure time adjusted accordingly. Cooling time has to be determined in such

a manner, that there is no risk of an explosion due to boiling retardation during the emptying of the disinfection chamber.

Canulae and other metal parts must not be put into the device individually. Disinfection of such items in the sinTion 1.1. may only be carried out using a sharp-proof, thermostable container that is filled with water.

Special instructions:

Program for liquid waste and liquid waste in bags:
The maximum load constitutes 10 liters.

Program for unspecified hospital waste:
The maximum load constitutes 6 kg. The bags must be at least ¾ filled.

Furthermore, the following general instructions for fractionated vacuum processes apply:
The process requires saturated steam that has to be largely free of air and foreign gases. The disinfection chamber has to be vacuum-tight. The required absolute pressures during the vacuum phases as well as during the intermediate steam bursts have to be maintained and may deviate only by +10 mbar and -10 mbar, respectively. The waste water and exhaust air generated during the process have to be re-treated in a manner, that they do not pose any risks. Besides, the requirements laid down in DIN 58949 part 2 apply. The disinfection devices have to be loaded and operated in accordance with the user manual and have to be maintained on a regular basis as well as checked for proper functioning (see DIN 58949 part 3 and part 6).

The registration will be published in the 14th edition of the disinfectants list of the Robert Koch-Institute in the "Bundesgesundheitsblatt":

The registration will be revoked, if

a) Facts come to light, that would have caused the Robert Koch-Institute to reject registration;
b) Facts come to light, for which registration no longer seems justified, especially, if the process is not suitable according to § 10 c BSeuchG.

We have to be notified of modifications in the construction of the registered apparatus type that could influence the values determined during the examination, prior to their execution.

An appeal may be filed against this decision. It has to be protested within a month of announcement of this decision either in written form or recorded for transcript at the Robert Koch-Institute, Nordufer 20, 13353 Berlin.

A fee notification is issued separately.

Yours sincerely
On behalf of

2019-11-04

Dr. Ingeborg Schwebke

ROBERT KOCH INSTITUT