

	Technical Information	730-105-EN		V04
	Sterilization of contaminated waste and liquids in bottles	Created	16.05.2011	JM
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In microbiological or clinical-chemical laboratories, animal hospitals, research institutes or in the pharmaceutical and chemical industry etc. waste materials are produced that could be contaminated with pathogenic germs.

Such materials must be sterilized before they are disposed.

The type of contamination and the risk involved could be quite different. A risk classification exists that contains information how storage, transport etc. of the waste materials must be carried out.

There are large differences for the design of the sterilization process and the method of sterilization monitoring to be used for decontamination of the waste.

The source of the waste materials, the pre-treatment of the contaminated goods, different germs and their resistance against the sterilization process can be so variable that the process suitable for decontamination has to be adapted to each individual case.

Sterilization in steam sterilization processes, i.e. at 121°C or 134°C, is carried out successfully in general under the following three conditions:

- The sterilization time required for inactivation must be calculated after the time when all surfaces of the (waste) load to be sterilized have reached the target temperature (i.e. 134°C).
- The holding time only starts when the coldest part of the load has reached the set temperature (carry out validation with data loggers).
- During the sterilization time all surfaces to be sterilized have to be moistened with water or dropped in water.
- The necessary sterilization time must be determined and depends on the actual contamination (bioburden).

The bioburden is calculated from the summary of all F_{Bio} -values of all germs with a D-value > 1 min ($F_{\text{Bio}} = \lg \text{Pop} \times D_{121^\circ\text{C}}$). A rule of thumb says that for an F_{Bio} -value of 10 min at 121°C a sterilization time of 1 min is equivalent at 134°C. According to this i.e. for an $F_{\text{Bio}} = 100$ min at 121°C a sterilization time of 10 min. at 134°C is equivalent (calculated from the time the target temperature is reached on all surfaces).

Since waste materials have extremely different specifications and therefore have to be treated, transported and stored differently, also the detailed design and performance of the sterilization process have to be adapted.

In laboratories waste is often collected in PP-bags (PP = Polypropylene). If the content of these bags should be sterilized in a steam sterilization process, the bags must be open during sterilization and filled with 1 to 2 liter water before starting the sterilization program. During validation of the sterilization process the temperature gradient in the bags must be

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measured to determine how long the heat-up time of the waste material to be sterilized is. Heat-up time, sterilization time and cooling time add up to the complete sterilization time which at least has to be kept.

When sterilizing liquids, it must also be ensured that the heating, holding and cooling times are sufficient. For monitoring the success of the sterilization of liquid waste and liquids in bottles, we recommend the use of GKE Stearo ampoules, which are placed directly into the liquid to be sterilized. The result of this test, together with the temperature curve, already provides the information required for batch release.

For secure steam sterilization of packaged goods, that means also of waste materials in steam-permeable packages, the use of a sterilizer with an efficient fractionated vacuum is necessary. For monitoring sufficient air removal and steam penetration we recommend to use the GKE hollow device test system according EN 867-5 with the GKE Compact-PCD®, colour orange, with the corresponding indicator strips which are designed for an extended sterilization time of 18 min at 134°C. The result of these tests together with the pressure and temperature process data, which the sterilizer records with the installed measuring instruments, provides the necessary information to release the batch.