

Dry heat sterilization of respirators for protection

To whom it may concern:

Memmert GmbH + Co.KG dry heat sterilizers type S do perform dry heat sterilization cycles which comply to the state of the art.

This as a given, respirators (as any other kind of medical item) can be sterilized using Memmert sterilizers type S as long as:

- ▶ the materials the respirators are composed of are compatible to the applied sterilization process parameters, i.e. are compatible to the temperature over time.
- ▶ the bioburden of the respirators are established.
- ▶ the applied sterilization process is validated*), mainly with respect to the load of respirators and the chosen loading configuration.

*) For requirements for validation of dry heat sterilization processes see EN ISO 20857:2013 (Sterilization of health care products. Dry heat. Requirements for the development, validation and routine control of a sterilization process for medical devices)

Recommendations for parameters of dry heat sterilization cycles

The well-established recommendations for parameters of dry heat sterilization cycles (= time / temperature integral) are:

- ▶ 180°C for 30 minutes according to WHO
- or
- ▶ 160°C for 120 minutes according to European Pharmacopoeia

Basically Memmert sterilizers type S are able to perform these sterilization cycles as any other tailored sterilization cycle by routine (time variable, temperature up to 250°C) as a result of sterilization process validation by routine. However, with respect to the well-established parameters and in order to implement more of a safety margin we recommend using:

- ▶ 180°C for 60 minutes
- or
- ▶ 160°C for 240 minutes

Meaning a 100% exceed of time span in combination with the named temperatures.


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Final Audit Report

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