



Compliance with ISO 20857:2010

Ladies and gentlemen,

If a manufacturer (in this case, Memmert GmbH + Co. KG) designs and manufactures its product in accordance with the requirements of standards (in this case, ISO 20857: 2010 - Sterilisation of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilisation process for medical devices), the customer can assume that this product meets the essential requirements of the relevant standard and its corresponding guideline.

Depending on the composite components and functions of a product, there may be some exceptions that are still compliant with standards.

Heating concept for the hot air sterilisers of the type series SN, SF, SNplus and SFplus

The heating concept for the hot air sterilisers is based on four-sided all-round heating. Due to this heating concept, forced ventilation air circulation in the interior is not necessary. The models in the SF series have a fan, which results in better heat transfer to the sterilisation material. This is especially recommended if there is a risk of cold esters.

Switched off or reduced fan speed

The appliances achieve a sufficiently good temperature distribution when the fan speed is switched off or reduced. Documentation of the air volume flow is therefore not required and point 6.2.8.1 paragraph d of ISO 20857:2010 does not apply here.

Monitoring the requested parameters

Monitoring of the temperature, exposure time and speed of temperature change is implemented by required parameters. There is also cyclic recording.

The requirements of standard 20857 are implemented in point 6.2.8.1, paragraphs a, b and e. Thus, the hot air sterilisers from Memmert GmbH + Co. KG meet the requirements of ISO 20857:2010.

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Statement_air volume flow sterilisers_EN_D39775

Final Audit Report

2019-12-05

Created:	2019-12-05
By:	Martin Dümler (mduemler@memmert.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAO_wl6mhj8Ev49BdvmZ4wlhayK3r1lyVk

"Statement_air volume flow sterilisers_EN_D39775" History

-  Document created by Martin Dümler (mduemler@memmert.com)
2019-12-05 - 12:50:48 PM GMT- IP address: 195.145.231.106
-  Document emailed to Philipp Schwarm (pschwarm@memmert.com) for signature
2019-12-05 - 12:51:15 PM GMT
-  Email viewed by Philipp Schwarm (pschwarm@memmert.com)
2019-12-05 - 5:04:50 PM GMT- IP address: 195.145.231.106
-  Document e-signed by Philipp Schwarm (pschwarm@memmert.com)
Signature Date: 2019-12-05 - 5:05:12 PM GMT - Time Source: server- IP address: 195.145.231.106
-  Signed document emailed to Philipp Schwarm (pschwarm@memmert.com) and Martin Dümler (mduemler@memmert.com)
2019-12-05 - 5:05:12 PM GMT