

# Certificate

Full Quality Assurance System Approval  
Annex II excluding (4) of the Directive on Medical  
Devices



ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

**Müller-Omicron GmbH & Co. KG**  
Schlosserstraße 1, 51789 Lindlar, Germany

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

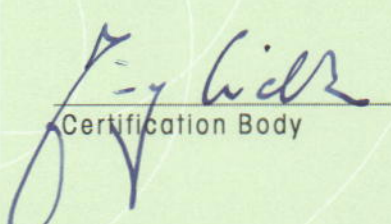
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

**Audit Report Number**  
**792-16-53**

**Registered under**  
**Z/16/03920E**

**Valid until**  
**September 18<sup>th</sup>, 2021**

Aachen, September 19<sup>th</sup>, 2016

  
Certification Body



Annex I of Certificate Z/16/03920E

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code
Single use devices	Surfaces disinfection	/
Single use devices	Disinfection of dental suction systems	/
Single use devices	Instruments disinfection	/
Single use devices	Impression disinfection	/

Special terms of validity:

None.