

EU declaration of conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany	
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701	
Product name	MEtherm 50	
basic UDI-DI	4032651-BSC00000004-CT	
Code acc. to Art. 26 2017/745	V0799	
Intended Purpose	cleaning agent for automated reprocessing of medical devices	
Risk Class according to Regulation 2017/745	I	
	annex	VIII
	rule	1
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH	
Conformity Assessment Procedure according to Regulation 2017/745	annex	IV / V
Certificate	EN ISO 13485	004567 MP2016
Version	2-0	


Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this Declaration

Norderstedt **09. Nov. 2021**
ppa.


Dr. Uwe Berlekamp
Schülke & Mayr GmbH
Director Business Line Healthcare

ppa.


Jörn Ahlsdorff
Schülke & Mayr GmbH
Director Industrial Operations
International Industrial Operations

EU declaration of conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany	
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701	
Product name	MEtherm 55	
basic UDI-DI	4032651-BSC00000005-CW	
Code acc. to Art. 26 2017/745	V9099	
Intended Purpose	Neutralizing Agent	
Risk Class according to Regulation 2017/745	I	
	annex	VIII
	rule	1
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH	
Conformity Assessment Procedure according to Regulation 2017/745	annex	IV / V
Certificate	EN ISO 13485	004567 MP2016
Version	2-0	


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Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany	
Registration Number acc. to Art. 31 2017/745	DE-MF-000005701	
Product name	MEtherm 61	
basic UDI-DI	4032651-BSC00000006-CZ	
Code acc. to Art. 26 2017/745	V9099	
Intended Purpose	Rinsing Agent	
Risk Class according to Regulation 2017/745	I annex rule	VIII 1
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH	
Conformity Assessment Procedure according to Regulation 2017/745	annex	IV / V
Certificate	EN ISO 13485	004567 MP2016
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Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1082891-1

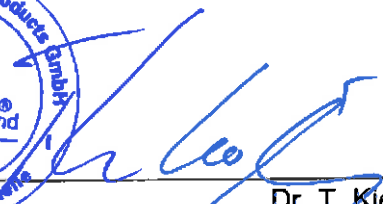
Organization: MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

Scope: Design and development, manufacture, installation, service and distribution of steam and dry heat sterilizers (incl. accessories), washer-disinfectors (incl. accessories), distribution of cleaners for washer-disinfectors as well as disinfectants and sterilization packaging

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3347683-90
Effective date: 2022-02-01
Expiry date: 2024-12-03
Issue date: 2022-02-01




Dr. T. Kießling
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1082891-1

Organization: MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o MELAG Medizintechnik GmbH & Co. KG Geneststr. 6-10 10829 Berlin Germany	Design and development, manufacture, installation, service and distribution
/02	c/o MELAG Medizintechnik GmbH & Co. KG Geneststr. 2 10829 Berlin Germany	Design and development, manufacture, installation, service and distribution

Report No.: 3347683-90
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Issue date: 2022-02-01



The seal of TÜV Rheinland LGA Products GmbH, featuring a stylized triangle and the text "TÜV Rheinland LGA Products GmbH", "TÜVRheinland", and "Zertifizierungsstelle".
A blue ink signature of Dr. T. Kießling.
Dr. T. Kießling
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany