EU declaration of conformity

schülke

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

This Declaration is valid until an updated version has been issued, but not longer than
26.06.2024

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EU declaration of conformity

schülke

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

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

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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 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.

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Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

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
Effective date: 2022-02-01
Expiry date: 2024-12-03
Issue date: 2022-02-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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D-ZM-14169-01-02