

EU declaration of conformity

schülke -t

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 Code acc. to Art. 26 2017/745 Intended Purpose	4032651-BSC00000004-CT V0799 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

EU declaration of conformity

schülke -t

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 Code acc. to Art. 26 2017/745	4032651-BSC00000005-CW 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.

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

schülke -t


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 61	
basic UDI-DI Code acc. to Art. 26 2017/745	4032651-BSC00000006-CZ 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.

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