

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
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ppa.

 Jörn Ahlsdorff
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