



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	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	II / III
Certificate	EN ISO 13485	004567 MP2016
Version	3-0	

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 15.08.2024
ppa.


Dr. Rainer Wolber
Schülke & Mayr GmbH
Director Innovation & Regulatory
Affairs

15.08.2024
ppa.


Lars Lemke
Schülke & Mayr GmbH
Chief Operating Officer