



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	mikrozid[®] sensitive wipes		
Basic UDI-DI	4032651BSC00000021A2		
Code acc. to Art. 26 2017/745	D99		
Intended Purpose	disinfectant and cleaner of medical device surfaces		
Risk Class according to Regulation 2017/745	II a		
	Annex	VIII	
	rule	16	
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH		
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297		
Conformity Assessment Procedure according to Regulation 2017/745	Annex	IX	Chapter I, II section 4 and III
Certificates	Annex	IX	004567 MDR2017Q 004567 MDR2017B
	EN ISO 13485		004567 MP2016
Version	1-0		

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

15.06.2023
ppa.

Dr. Sven Pflüging
Schülke & Mayr GmbH
Chief Commercial Officer

15.06.2023
ppa.

Lars Lemke
Schülke & Mayr GmbH
Chief Operating Officer