

## 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
<b>Product Name</b>	<b>mikrozid® universal wipes</b>
Basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose	4032651BSC00000022A4 D0799 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 Pfleging  
Schülke & Mayr GmbH  
Chief Commercial Officer

15.06.2023  
ppa.

  
Lars Lemke  
Schülke & Mayr GmbH  
Chief Operating Officer