

EU Declaration of Conformity

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|---|--|-------|------------------------------------|
| 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® AF wipes | | |
| Basic UDI-DI Code acc. to Art. 26 2017/745 | 4032651BSC000000209Y D0799 | | |
| 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 Pflöging
Schülke & Mayr GmbH
Chief Commercial Officer

15.06.2023
ppa.


Lars Lemke
Schülke & Mayr GmbH
Chief Operating Officer