



## EU Declaration of Conformity

|                                                                     |                                                                                                      |      |                                    |
|---------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------|------------------------------------|
| Manufacturer<br>according to Regulation 2017/745                    | Schülke & Mayr GmbH<br>Robert-Koch-Str. 2<br>22851 Norderstedt<br>Germany                            |      |                                    |
| Registration Number<br>acc. to Art. 31 2017/745                     | DE-MF-000005701                                                                                      |      |                                    |
| <b>Product Name</b>                                                 | <b>mikrozid<sup>®</sup> sensitive wipes</b>                                                          |      |                                    |
| Basic UDI-DI                                                        | 4032651BSC00000021A2                                                                                 |      |                                    |
| Code acc. to Art. 26 2017/745                                       | D99                                                                                                  |      |                                    |
| Intended Purpose                                                    | disinfectant and cleaner of medical device surfaces                                                  |      |                                    |
| Risk Class<br>according to Regulation 2017/745                      | II a                                                                                                 |      |                                    |
|                                                                     | Annex                                                                                                | VIII |                                    |
|                                                                     | rule                                                                                                 | 16   |                                    |
| Standards applied                                                   | EN ISO 13485<br>additional standards see technical documentation<br>Schülke & Mayr GmbH              |      |                                    |
| Notified Body                                                       | DQS Medizinprodukte GmbH<br>August-Schanz-Str. 21<br>60433 Frankfurt am Main<br>Germany<br>No.: 0297 |      |                                    |
| Conformity Assessment Procedure<br>according to Regulation 2017/745 | Annex                                                                                                | IX   | Chapter I, II section 4 and III    |
| Certificates                                                        | Annex                                                                                                | IX   | 004567 MDR2017Q<br>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