

EU Declaration of Conformity

<p>Manufacturer according to Regulation 2017/745</p>	<p>Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany</p>
<p>Registration Number acc. to Art. 31 2017/745</p>	<p>DE-MF-000005701</p>
<p>Product Name</p>	<p>mikrozid® universal liquid</p>
<p>Basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose</p>	<p>4032651BSC0000022A4 D0799 disinfectant and cleaner of medical device surfaces</p>
<p>Risk Class according to Regulation 2017/745</p>	<p>II a Annex VIII rule 16</p>
<p>Standards applied</p>	<p>EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH</p>
<p>Notified Body</p>	<p>DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297</p>
<p>Conformity Assessment Procedure according to Regulation 2017/745</p>	<p>Annex IX Chapter I, II section 4 and III</p>
<p>Certificates</p>	<p>Annex IX 004567 MDR2017Q 004567 MDR2017B EN ISO 13485 004567 MP2016</p>
<p>Version</p>	<p>1-0</p>

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