

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>gigazyme®</p>
<p>basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose</p>	<p>4032651-BSC00000003-CQ V0799 cleaning agent for manual reprocessing of medical devices</p>
<p>Risk Class according to Regulation 2017/745</p>	<p>I annex VIII rule 1</p>
<p>Standards applied</p>	<p>EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH</p>
<p>Conformity Assessment Procedure according to Regulation 2017/745</p>	<p>annex IV / V</p>
<p>Certificate</p>	<p>EN ISO 13485 004567 MP2016</p>
<p>Version</p>	<p>2-0</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 **09. Nov. 2021**

ppa.


 Dr. Uwe Berlekamp
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ppa.


 Jörn Ahlsdorff
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