

**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>gigazyme®</b>	
Basic UDI-DI	4032651-BSC00000003-CQ	
Code acc. to Art. 26 2017/745	V0799	
Intended Purpose	cleaning agent for manual reprocessing of medical devices	
Risk Class according to Regulation 2017/745	I	
	annex	VIII
	rule	1
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH	
Conformity Assessment Procedure according to Regulation 2017/745	Annex	II / III
Certificate	EN ISO 13485	004567 MP2016
Version	3-0	

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      15.08.2024  
ppa.

15.08.2024  
ppa.

  
Dr. Rainer Wolber  
Schülke & Mayr GmbH  
Director Innovation & Regulatory  
Affairs

  
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