

**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	IV / V	
Certificate	EN ISO 13485	004567 MP2016	
Version	2-0		

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 **09. Nov. 2021**

ppa.

  
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