

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		
Product name	gigazyme[®]		
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.


Dr. Uwe Berlekamp
Schülke & Mayr GmbH
Director Business Line Healthcare

ppa.


Jörn Ahlsdorff
Schülke & Mayr GmbH
Director Industrial Operations
International Industrial Operations