EU Declaration of Conformity

schülke

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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	**gigasept® Instru AF**
Basic UDI-DI	4032651BSC00000037AH
Code acc. to Art. 26 2017/745	Z12011385
Intended Purpose	cleaning and disinfection agent for manual reprocessing of medical devices
Risk Class according to Regulation 2017/745	II a Annex VIII rule 16
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297
Conformity Assessment Procedure according to Regulation 2017/745	Annex IX Chapter I, II section 4 and III
Certificates	Annex IX 004567 MDR2017Q 004567 MDR2017B EN ISO 13485 004567 MP2016
Version	1-0

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 15.06.2023
ppa.

Dr. Sven Pfleging
Schülke & Mayr GmbH
Chief Commercial Officer

15.06.2023
ppa.

Lars Lemke
Schülke & Mayr GmbH
Chief Operating Officer

This Declaration is valid until an updated version has been issued, but not longer than 03.05.2028