EU Declaration of Conformity

schülke

# EU Declaration of Conformity

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|---|---|
| Manufacturer<br>according to Regulation 2017/745 | Schülke & Mayr GmbH<br>Robert-Koch-Str. 2<br>22851 Norderstedt<br>Germany |
| Registration Number<br>acc. to Art. 31 2017/745 | DE-MF-000005701 |
| **Product Name** | **gigasept® Instru AF** |
| Basic UDI-DI<br>Code acc. to Art. 26 2017/745 | 4032651BSC00000037AH<br>Z12011385 |
| Intended Purpose | cleaning and disinfection agent for manual reprocessing of medical devices |
| Risk Class<br>according to Regulation 2017/745 | II a<br>Annex VIII<br>rule 16 |
| Standards applied | EN ISO 13485<br>additional standards see technical documentation<br>Schülke & Mayr GmbH |
| Notified Body | DQS Medizinprodukte GmbH<br>August-Schanz-Str. 21<br>60433 Frankfurt am Main<br>Germany<br>No.: 0297 |
| Conformity Assessment Procedure<br>according to Regulation 2017/745 | Annex IX Chapter I, II section 4 and III |
| Certificates | Annex IX 004567 MDR2017Q<br>004567 MDR2017B<br>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