Declaration of Conformity

schülke

# EC declaration of conformity

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| **Medical Device name** | | **gigasept® AF forte** |
| **Formulation No.** | | F01 |
| **Product group** | | Disinfectant, medical device instruments |
| **Product Category** | | 05 - Hospital hardware |
| **Intended Purpose** | | instrument disinfection |
| **Risk Class according to Directive 93/42/EEC** | **annex** | II b<br>IX |
| **Standards applied** | | EN ISO 13485<br>additional standards see technical documentation<br>Schülke & Mayr GmbH, Regulatory Affairs |
| **Manufacturer according to Directive 93/42/EEC** | | Schülke & Mayr GmbH<br>Robert-Koch-Str. 2<br>22851 Norderstedt<br>Germany |
| **Notified Body** | | DQS Medizinprodukte GmbH<br>August-Schanz-Str. 21<br>60433 Frankfurt am Main<br>Germany<br>Ident.No.: 0297 |
| **Conformity Assessment Procedure according to Council Directive 93/42/EEC** | | Annex II excluding section 4 |
| **Issued Certificates** | | Annex II 93/42/EEC Cert. Reg. No. 004567 MR2 |
| **Version** | | 6.0 |

Schülke & Mayr GmbH herewith declares that the device covered by this declation is in conformity with the Council Directive 93/42/EEC concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this Declaration

Norderstedt 06.05.2019

ppa. Dr. Peter Oltmanns
Director Research & Regulatory Affairs
Schülke & Mayr GmbH

06.05.2019

ppa. Dr. Werner Weltgen
Director Quality and HSE
Schülke & Mayr GmbH

This Declaration is valid until an updated version has been issued, but not longer than 18.12.2023