

EC declaration of conformity

Declaration of Conformity

| | | | |
|---|---|----------------|------------|
| Medical Device name | gigasept[®] instru AF | | |
| Formulation No. | F04 | | |
| 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 | IX |
| Standards applied | EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH, Regulatory Affairs | | |
| Manufacturer according to Directive 93/42/EEC | Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany | | |
| Notified Body | DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany 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 | 1.0 | | |

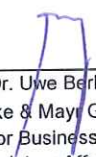
Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Council Directive 93/42/EEC concerning medical devices.

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


Norderstedt

28.04.2020

28.04.2020



ppa. Dr. Uwe Berlekamp
Schülke & Mayr GmbH
Director Business Lines, Research
& Regulatory Affairs



ppa. Dr. Thorsten August
Schülke & Mayr GmbH
Director Global Quality &
Health, Safety, Environment