Version 3 5

schülke

EC declaration of conformity

according to Annex II - excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

DECLARATION OF CONFORMITY

Medical Device	**gigasept® AF forte**
Manufacturer	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Ident.No.: 0297
Classification acc. to Directive 93/42/EEC, Annex IX, Rule 15	IIb
Product group	Disinfectant, surgical instrument
Product category	05 - Hospital hardware
Issued CE certificates	EN ISO 9001 – Cert. Reg. No. 004567 QM08 EN ISO 13485 – Cert. Reg. No. 004567 MP29 Annex II – Cert. Reg. No. 004567 MR2
Standards applied	Applied standards are listed in Sec. 2.4 of the technical documentation. Location of technical documentation: Schülke & Mayr GmbH, Reg. Affairs

We herewith declare that the described device corresponds to the essential requirements of the EEC directive concerning medical devices.

I, the undersigned declare that Schülke bears the sole responsibility for issuing this Declaration

Norderstedt, 29.07.2014

M. Schmidt
Regulatory Affairs Manager

Schülke & Mayr Ges.m.b.H
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This Declaration is valid until an updated version has been issued, but not longer than 1 year.