Declaration of Conformity

schülke

EC declaration of conformity

Medical Device name		**gigasept® FF new**
Formulation No.		F07
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		8.0

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 17.10.2018

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

17.10.2018

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 17.10.2020