Declaration of Conformity

schülke

EC 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 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 28.04.2020

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

28.04.2020

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

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