



EC declaration of conformity

Medical Device name	thermosept® ED		
Formulation No.	F05		
Product group	Disinfectant, medical device instruments		
Product Category	05 - Hospital hardware		
Intended Purpose	instrument disinfection		
Risk Class	II b		
according to Directive 93/42/EEC	annex	IX	
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH, Regulatory Affairs		
Manufacturer	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
according to Directive 93/42/EEC			
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany Ident.No.: 0297		
Conformity Assessment Procedure	Annex II excluding section 4		
according to Council Directive 93/42/EEC			
Issued Certificates	Annex II 93/42/EEC	Cert. Reg. No.	004567 MR2
Version	7.0		


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

06.05.2019

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



ppa. Dr. Werner Weltgen
Director Quality and HSE
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This Declaration is valid until an updated version has been issued, but not longer than
18.12.2023