

## EC declaration of conformity

Declaration of Conformity

<b>Medical Device name</b>	rotasept®		
<b>Formulation No.</b>	F07		
<b>Product group</b>	Disinfectant, medical device instruments		
<b>Product Category</b>	05 - Hospital hardware		
<b>Intended Purpose</b>	instrument disinfection		
<b>Risk Class</b>	II b		
<b>according to Directive 93/42/EEC</b>	<b>annex</b>	IX	
<b>Standards applied</b>	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH, Regulatory Affairs		
<b>Manufacturer</b>	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
<b>Notified Body</b>	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany Ident.No.: 0297		
<b>Conformity Assessment Procedure</b>	Annex II excluding section 4		
<b>according to Council Directive 93/42/EEC</b>			
<b>Issued Certificates</b>	Annex II 93/42/EEC	Cert. Reg. No.	004567 MR2
<b>Version</b>	8.0		

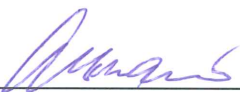
Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Council Directive 93/42/EEC concerning medical devices.


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

Norderstedt

06.05.2019

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\_\_\_\_\_  
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Director Research & Regulatory Affairs  
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