

EC declaration of conformity

Medical Device name		DESIFOR - ONE multi wipes	
Formulation No.		F01	
Product group		Disinfectant, medical device surfaces	
Product Category		05 - Hospital hardware	
Intended Purpose		surface disinfectant	
Risk Class		II a	
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		2.0	

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

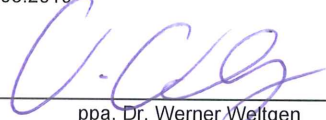
Norderstedt

25.03.2019



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25.03.2019



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