

EC declaration of conformity

Declaration of Conformity

Medical Device name	octenilin[®] wound irrigation solution		
Formulation No.	F01		
Product group	sterile wound irrigation solution		
Product Category	05 - Hospital hardware		
Intended Purpose	Wound irrigation solution for moistening and cleansing encrusted, contaminated and chronic skin wounds.		
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	9.0		

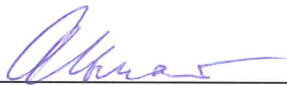
Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Council Directive 93/42/EEC concerning medical devices.

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


Norderstedt

06.05.2019

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Director Research & Regulatory Affairs
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