

EC declaration of conformity

Declaration of Conformity

Medical Device name	octenisept® gel
Formulation No.	F01
Product group	dressing occlusive, hydrogel
Product Category	05 - Hospital hardware
Intended Purpose	Hydrogel for moistening and protection of acute wounds (such as grazes and cuts) and slight burns (also sunburn).
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	4.0

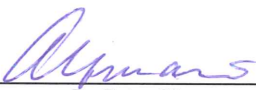
Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Council Directive 93/42/EEC concerning medical devices.

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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