



# EC-CERTIFICATE

(Full quality assurance system)

## DQS Medizinprodukte GmbH

hereby certifies that the company

**schülke** 

## Schülke & Mayr GmbH

Robert-Koch-Straße 2  
22851 Norderstedt  
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

An audit, documented in a report, performed by DQS, has verified that this quality assurance system fulfils the requirements of

### Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Disinfectant for medical devices and wound care products as listed in annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. In case of class Is devices the certificate is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. In case of class Im devices the certificate is restricted to the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate registration No.	004567 MR2
Certificate unique ID	170518821
Effective date	2011-06-14
Expiry date	2016-06-13
Frankfurt am Main	2011-06-14

Frank Graichen  
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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Notified Body Number 0297.



**Annex to Certificate**  
**Certificate registration No.: 004567 MR2**  
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<b>Product</b>	<b>class</b>
Surface disinfectant for medical devices	IIa
Disinfectant for automated chemothermal and thermal reprocessing of bedpans	IIa
Disinfectant for automated and manual reprocessing of medical instruments	IIb
Wound care products	IIb