



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify 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.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills 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 Identification 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. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	004567 MR2
Certificate unique ID	170730505
Effective date	2018-12-19
Expiry date	2023-12-18
Frankfurt am Main	2018-12-19

### **DQS Medizinprodukte GmbH**

Sigrid Uhlemann  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

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



**Annex to certificate**  
**Certificate registration No.: 004567 MR2**  
**Certificate unique ID: 170730505**  
**Effective date: 2018-12-19**

## **Schülke & Mayr GmbH**

Robert-Koch-Straße 2  
22851 Norderstedt  
Germany

<b>Device</b>	<b>Class</b>
Surface disinfectant for medical devices	IIa
Disinfectant for automated reprocessing of bedpans	IIa
Disinfectant for automated and manual reprocessing of medical instruments	IIb
Wound care products	IIb