



# 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  
Managing Director

Stefan Hofmann  
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, [medical.devices@dqs.de](mailto:medical.devices@dqs.de)

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**  
**Certificate unique ID: 170518821**  
**Effective date: 2011-06-14**

## **Schülke & Mayr GmbH**

Robert-Koch-Straße 2  
22851 Norderstedt  
Germany

| <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          |

This annex is only valid in connection with the above-mentioned certificate.

Schülke & Mayr GmbH | 22840 Norderstedt

## TO WHOM IT MAY CONCERN

Ansprechpartner Melanie Schmidt  
 Telefon/Fax + 49 40 521 00 – 543 / 577  
 E-mail melanie.schmidt@schuelke.com  
 Datum 17.02.2012

### Certified medical devices

To whom it may concern,

please find below a list of all medical devices certified according to the requirements of the relevant European Directive for Medical Devices, Directive 93/42/EC.

| Product Name                  | Risk Class<br>Acc. to Directive 93/42/EC Annex IX | Conformity Assessment<br>Procedure |
|-------------------------------|---|------------------------------------|
| acryldes®                     | II a  | Annex II                           |
| acryldes® Desinfektionstücher | II a  | Annex II                           |
| antifect® AF                  | II a  | Annex II                           |
| antifect® AF (N)              | II a  | Annex II                           |
| antifect® extra               | II a  | Annex II                           |
| antifect® FD 10               | II a  | Annex II                           |
| antifect® FF                  | II a  | Annex II                           |
| antifect® N Liquid            | II a  | Annex II                           |
| areades®                      | II a  | Annex II                           |
| areades® B                    | II a  | Annex II                           |
| aspirmatic®                   | II a  | Annex II                           |
| aspirmatic® Cleaner           | I   | Annex II VII                       |
| biotensid® Fläche             | II a  | Annex II                           |
| buraton® 10 F                 | II a  | Annex II                           |
| dentavon®                     | II a  | Annex II                           |

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| Product Name               | Risk Class<br>Acc. to Directive 93/42/EC Annex IX | Conformity Assessment<br>Procedure |
|----------------------------|---|------------------------------------|
| dentavon® Liquid           | II a  | Annex II                           |
| dodarcana® N               | II a  | Annex II                           |
| dodarcana® rapid Neu       | II a  | Annex II                           |
| esemfix®                   | II a  | Annex II                           |
| gigasept®                  | II b  | Annex II                           |
| gigasept® AF               | II b  | Annex II                           |
| gigasept® AF forte         | II b  | Annex II                           |
| gigasept® FF               | II b  | Annex II                           |
| gigasept® FF (neu)         | II b  | Annex II                           |
| gigasept® med              | II b  | Annex II                           |
| gigasept® Instru AF        | II b  | Annex II                           |
| gigasonic®                 | II b  | Annex II                           |
| gigazyme®                  | I   | Annex II VII                       |
| grotanat® flüssig          | II b  | Annex II                           |
| grotanat® Granulat         | I   | Annex II VII                       |
| lysetol® FF                | II b  | Annex II                           |
| lysetol® med               | II b  | Annex II                           |
| lysetol® V                 | II b  | Annex II                           |
| mikrozid® AF               | II a  | Annex II                           |
| mikrozid® AF aroma         | II a  | Annex II                           |
| mikrozid® AF Jumbo wipe    | II a  | Annex II                           |
| mikrozid® AF Liquid        | II a  | Annex II                           |
| mikrozid® AF Tissues       | II a  | Annex II                           |
| mikrozid® AF wipes         | II a  | Annex II                           |
| mikrozid® RF liquid        | II a  | Annex II                           |
| mikrozid® SA               | II a  | Annex II                           |
| mikrozid® sensitive Liquid | II a  | Annex II                           |
| mikrozid® sensitive wipes  | II a  | Annex II                           |
| octenilin® Wundgel         | II b  | Annex II                           |
| octenilin® Wundspüllösung  | II b  | Annex II                           |
| octenisept® Wundgel        | II b  | Annex II                           |
| perform®                   | II a  | Annex II                           |
| perform® ID                | II a  | Annex II                           |

Datum 17.02.2012

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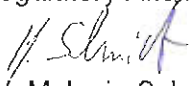
| Product Name                             | Risk Class<br>Acc. to Directive 93/42/EC Annex IX | Conformity Assessment<br>Procedure |
|--|---|------------------------------------|
| quartamon® med                           | II a  | Annex II                           |
| Reinigungsverstärker für<br>Gigasept® FF | I   | Annex VII                          |
| rotasept®                                | II b  | Annex II                           |
| S&M® labor                               | I   | Annex VII                          |
| S&M® labor flüssig                       | I   | Annex VII                          |
| septinol® SA                             | II a  | Annex II                           |
| terralin® Liquid                         | II a  | Annex II                           |
| terralin® protect                        | II a  | Annex II                           |
| thermoDent® alka clean                   | I   | Annex VII                          |
| thermoDent® clear                        | I   | Annex VII                          |
| thermoDent® liquid                       | I   | Annex VII                          |
| thermoDent® neutralizer                  | I   | Annex VII                          |
| thermoDent® powder                       | I   | Annex VII                          |
| thermosept® AF                           | II b  | Annex II                           |
| thermosept® alka clean                   | I   | Annex VII                          |
| thermosept® alka clean forte             | I   | Annex VII                          |
| thermosept® BD                           | II a  | Annex II                           |
| thermosept® BSK                          | I   | Annex VII                          |
| thermosept® DK                           | II b  | Annex II                           |
| thermosept® ED                           | II b  | Annex II                           |
| thermosept® ER                           | I   | Annex VII                          |
| thermosept® KSK                          | I   | Annex VII                          |
| thermosept® NDR                          | II a  | Annex II                           |
| Thermosept® NKP                          | I   | Annex VII                          |
| thermosept® RKA                          | I   | Annex VII                          |
| thermosept® RKF                          | I   | Annex VII                          |
| thermosept® RKF forte                    | I   | Annex VII                          |
| thermosept® RKI                          | I   | Annex VII                          |
| thermosept® RKN-zym                      | I   | Annex VII                          |
| TPH® protect                             | II a  | Annex II                           |

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Yours sincerely

**Schülke & Mayr GmbH**

Regulatory Affairs

  
i.V. Melanie Schmidt

/vertimas iš anglų k./

## **EC – SERTIFIKATAS**

(Visiška kokybės užtikrinimo sistema)

DQS Medizinprodukte GmbH  
patvirtina, kad kompanija

/logotipas/

### **Schulke & Mayr GmbH**

Robert – Koch – Straße 2  
22851 Norderstedt  
Vokietija

Igyvendino ir išlaiko visiška kokybės užtikrinimo sistemą, kuri taikoma produktams, kiekviename etape nuo projektavimo iki galutinės kontrolės.

Ataskaitoje aprašytas auditas, atliktas DQS, patvirtino, kad ši kokybės valdymo sistema atitinka:

### **Medicinos prietaisų 93/42/EEC direktyvos II priedo sąlygas**

Taikoma žemiau išvardintiems medicininiams prietaisams:

medicininį prietaisų dezinfekcijos priemonės ir žaizdų priežiūros produktai, išvardinti priede.

Pagal direktyvos II priedo 5 skyriaus sąlygas, šių prietaisų gamyba turi būti kontroliuojama. Notifikuotos įstaigos (Nr. 0297) CE ženklavimas gali būti patvirtintas prietaisams išvardintiems šiame sertifikate. EC patikros sertifikatas pagal II priedą, 4 skirsnį išduodamas III klasės prietaisams, apimančius šį sertifikatą. I s klasės prietaisams sertifikatas skiriamas tik tuo atveju, jeigu gamyboje yra užtikrinamos sterilios sąlygos. I m klasės prietaisams sertifikatas skiriamas tik tuo atveju jeigu gaminami produktai atitinka metrologinius reikalavimus.

|                               |            |
|-------------------------------|------------|
| Sertifikato registracijos Nr. | 004567 MR2 |
| Sertifikato unikalus Nr.      | 170518821  |
| Išgaliojimo data              | 2011-06-14 |
| Galioja iki                   | 2016-06-13 |
| Frankfurtas prie Maino        | 2011-06-14 |

/parašas/

/parašas/

Frank Graichen  
Generalinis direktorius

Stefan Hofmann  
Notifikuotos įstaigos vadovas

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49(0)69 96427-263, [medical.devices@dqs.de](mailto:medical.devices@dqs.de)

**DQS Medizinprodukte GmbH yra medicinos prietaisų notifikavimo įstaiga Nr. 0297, pagal 93/42/EEC direktyvą.**

/vertimas iš anglų k./

Priedas prie sertifikato  
Sertifikato registracijos Nr.: 004567 MR2  
Sertifikato unikalus Nr. 170518821  
Sertifikato išdavimo data: 2011-06-14

## **Schulke & Mayr GmbH**

Robert – Koch – Straße 2  
22851 Norderstedt  
Vokietija

| Produktai   | Klasė |
|---|-------|
| Paviršių dezinfektantas   | IIa   |
| Terminės ir cheminės dezinfekcijos priemonė<br>basonų apdorojimui               | IIa   |
| Instrumentų dezinfektantas rankiniam ir<br>automatiniam instrumentų apdorojimui | IIb   |
| Žaizdų priežiūros priemonės   | IIb   |

Šis priedas galioja tik su aukščiau nurodytu sertifikatu



Schulke&amp;Mayr GmbH / 22840 Norderstedt

**SUINTERESUOTIEMS ASMENIMS**

Kontaktinis asmuo Melanie Schmidt

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El. paštas [melanie.schmidt@schuelke.com](mailto:melanie.schmidt@schuelke.com)

Data 2012.02.17

**Sertifikuoti medicinos prietaisai**

Suinteresuotiems asmenims,

Žemiau išvardinti medicinos prietaisai yra sertifikuoti pagal medicinos prietaisų Europos direktyvos 93/42/EC reikalavimus.

| <b>Produkto pavadinimas</b>   | <b>Rizikos klasė</b><br>Pagal 93/42/EC direktyvos IX priedą | <b>Atitikties vertinimo procedūra</b> |
|-------------------------------|---|---------------------------------------|
| acryldes®                     | IIa   | Priedas II                            |
| acryldes® Desinfectionstucher | IIa   | Priedas II                            |
| antifect® AF                  | IIa   | Priedas II                            |
| antifect® AF (N)              | IIa   | Priedas II                            |
| antifect® extra               | IIa   | Priedas II                            |
| antifect® FD 10               | IIa   | Priedas II                            |
| antifect® FF                  | IIa   | Priedas II                            |
| antifect® N Liquid            | IIa   | Priedas II                            |
| areades®                      | IIa   | Priedas II                            |
| areades® B                    | IIa   | Priedas II                            |
| aspirmatic®                   | IIa   | Priedas II                            |
| aspirmatic® Cleaner           | I   | Priedas II VII                        |
| biotensid® Flache             | IIa   | Priedas II                            |
| buraton® 10 F                 | IIa   | Priedas II                            |
| dentavon®                     | IIa   | Priedas II                            |
| dentavon® Liquid              | IIa   | Priedas II                            |
| dodarcana® N                  | IIa   | Priedas II                            |
| dodarcana® rapid Neu          | IIa   | Priedas II                            |
| esemfix®                      | IIa   | Priedas II                            |
| gigasept®                     | IIb   | Priedas II                            |
| gigasept® AF                  | IIb   | Priedas II                            |
| gigasept® AF forte            | IIb   | Priedas II                            |
| gigasept® FF                  | IIb   | Priedas II                            |
| gigasept® FF (neu)            | IIb   | Priedas II                            |
| gigasept® med                 | IIb   | Priedas II                            |
| gigasept® Instru AF           | IIb   | Priedas II                            |
| gigasonic®                    | IIb   | Priedas II                            |
| gigazyme®                     | I   | Priedas II VII                        |
| grotanat® flussig             | IIb   | Priedas II                            |
| grotanat® Granulat            | I   | Priedas II VII                        |
| lysetol® FF                   | IIb   | Priedas II                            |
| lysetol® med                  | IIb   | Priedas II                            |

|                                       |     |             |
|---------------------------------------|-----|-------------|
| lysetol® V                            | IIb | Priedas II  |
| mikrozyd® AF                          | IIa | Priedas II  |
| mikrozyd® AF aroma                    | IIa | Priedas II  |
| mikrozyd® AF Jumbo wipes              | IIa | Priedas II  |
| mikrozyd® AF Liquid                   | IIa | Priedas II  |
| mikrozyd® AF Tissues                  | IIa | Priedas II  |
| mikrozyd® AF wipes                    | IIa | Priedas II  |
| mikrozyd® RF liquid                   | IIa | Priedas II  |
| mikrozyd® SA                          | IIa | Priedas II  |
| mikrozyd® sensitive Liquid            | IIa | Priedas II  |
| mikrozyd® sensitive wipes             | IIa | Priedas II  |
| octenilin® Wundgel                    | IIb | Priedas II  |
| octenilin® Wundspullosung             | IIb | Priedas II  |
| octenisept® Wundgel                   | IIb | Priedas II  |
| perform®                              | IIa | Priedas II  |
| perform® ID                           | IIa | Priedas II  |
| quartamon® med                        | IIa | Priedas II  |
| Reinigungsverstärker für Gigasept® FF | I   | Priedas VII |
| rotasept®                             | IIb | Priedas II  |
| S&M® labor                            | I   | Priedas VII |
| S&M® labor flusig                     | I   | Priedas VII |
| septinol® SA                          | IIa | Priedas II  |
| terralin® Liquid                      | IIa | Priedas II  |
| terralin® protect                     | IIa | Priedas II  |
| thermoDent® alka clean                | I   | Priedas VII |
| thermoDent® clear                     | I   | Priedas VII |
| thermoDent® liquid                    | I   | Priedas VII |
| thermoDent® neutralizer               | I   | Priedas VII |
| thermoDent® powder                    | I   | Priedas VII |
| thermosept® AF                        | IIb | Priedas II  |
| thermosept® alka clean                | I   | Priedas VII |
| thermosept® alka clean forte          | I   | Priedas VII |
| thermosept® BD                        | IIa | Priedas II  |
| thermosept® BSK                       | I   | Priedas VII |
| thermosept® DK                        | IIb | Priedas II  |
| thermosept® ED                        | IIb | Priedas II  |
| thermosept® ER                        | I   | Priedas VII |
| thermosept® KSK                       | I   | Priedas VII |
| thermosept® NDR                       | IIa | Priedas II  |
| Thermosept® NKP                       | I   | Priedas VII |
| thermosept® RKA                       | I   | Priedas VII |
| thermosept® RKF                       | I   | Priedas VII |
| thermosept® RKF forte                 | I   | Priedas VII |
| thermosept® RKI                       | I   | Priedas VII |
| thermosept® RKN-zym                   | I   | Priedas VII |
| TPH® protect                          | IIa | Priedas II  |

Data 2012.02.17

Pagarbiai,  
**Schulke&Mayr GmbH**  
Reguliavimo tarnyba  
/parašas/  
i.V. Melanie Schmidt