



EC-CERTIFICATE

(Full quality assurance system)

DQS Medizinprodukte GmbH

hereby certifies that the company

schülke -t

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 I devices the certificate is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. In case of class II 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

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

Product	class
Surface disinfectant for medical devices	Ila
Disinfectant for automated chemothermal and thermal reprocessing of bedpans	Ila
Disinfectant for automated and manual reprocessing of medical instruments	IIb
Wound care products	IIb

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 Acc. to Directive 93/42/EC Annex IX	Conformity Assessment 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

Datum 17.02.2012
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Product Name	Risk Class Acc. to Directive 93/42/EC Annex IX	Conformity Assessment 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

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Product Name	Risk Class Acc. to Directive 93/42/EC Annex IX	Conformity Assessment Procedure
quartamon [®] med	II a	Annex II
Reinigungsverstärker für 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

Datum 17.02.2012
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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 unikalumas Nr.	170518821
Išgaliojimo data	2011-06-14
Galioja iki	2016-06-13
Frankfurtas prie Maino	2011-06-14

/parašas/

Frank Graichen
Generalinis direktorius

/parašas/

Stefan Hofmann
Notifikuotos įstaigos vadovas

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49(0)69 96427-263, 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 basonų apdorojimui	IIa
Instrumentų dezinfektantas rankiniam ir automatiniam instrumentų apdorojimui	IIb
Žaizdų priežiūros priemonės	IIb

Šis priedas galioja tik su aukščiau nurodytu sertifikatu

Schulke&Mayr GmbH / 22840 Norderstedt

SUINTERESUOTIEMS ASMENIMS

Kontaktinis asmuo Melanie Schmidt

Tel./Faks. +49 40 521 00 – 543 / 577

El. paštas 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.

Produkto pavadinimas	Rizikos klasė Pagal 93/42/EC direktyvos IX priedą	Atitikties vertinimo procedūra
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
aspermatic®	IIa	Priedas II
aspermatic® 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
mikrozid® AF	IIa	Priedas II
mikrozid® AF aroma	IIa	Priedas II
mikrozid® AF Jumbo wipes	IIa	Priedas II
mikrozid® AF Liquid	IIa	Priedas II
mikrozid® AF Tissues	IIa	Priedas II
mikrozid® AF wipes	IIa	Priedas II
mikrozid® RF liquid	IIa	Priedas II
mikrozid® SA	IIa	Priedas II
mikrozid® sensitive Liquid	IIa	Priedas II
mikrozid® 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