



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 170613406

Effective date 2015-10-18

Expiry date 2020-10-17

Frankfurt am Main 2015-10-18

DQS Medizinprodukte GmbH

Frank Graichen
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

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: 170613406

Effective date: 2015-10-18

Schülke & Mayr GmbH

Robert-Koch-Straße 2

22851 Norderstedt

Germany

Device	Class
Surface disinfectant for medical devices	Ila
Disinfectant for automated reprocessing of bedpans	Ila
Disinfectant for automated and manual reprocessing of medical instruments	Ilb
Wound care products	Ilb

Schülke & Mayr GmbH | 22840 Norderstedt | GERMANY

TO WHOM IT MAY CONCERN

Contact person: Natalya Ohler
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Date: 15/06/2016

Certified medical devices risk class IIa and IIb covered by Annex II Certificate

Dear Sir / Madam,

Hereby Schülke & Mayr GmbH confirms that the below mentioned are attributed to medical device class IIa and IIb according to Medical Devices Directive 93/42/EEC Annex IX Rule 15.

For this class of medical devices involvement of the notified body is required according to Directive 93/42/EEC. Following products fall under categories given on the EC- Certificate according to Annex II of Directive 93/42/EEC:

acryl des	grotanat liquid	octenilin wound irrigation solution
acryl des disinfection wipes	mikrozid AF liquid	octenisept Gel
antifect AF (N)	mikrozid AF wipes	octenisept wound gel
antifect FF	mikrozid AF wipes jumbo	perform
antifect N liquid	mikrozid AF wipes premium	perform ID
antifect extra	mikrozid alcohol free liquid	pursept AF
aspirmatic	mikrozid alcohol free wipes jumbo	pursept A Xpress
boots wound healing gel	mikrozid PAA wipes	pursept A Xpress wipes
dentavon	mikrozid sensitive liquid	pursept FD
dentavon liquid	mikrozid sensitive wipes	pursept wipes Xpress
esemfix	mikrozid sensitive wipes premium	quartamon med
gigasept AF	mikrozid wipes	rotasept
gigasept AF forte	mikrozid wipes jumbo	septinol SA
gigasept FF (new)	mikrozid universal wipes	terralin liquid
gigasept Granulate	mucalgin	terralin protect
gigasept Instru AF	mucadont AS	thermosept ED
gigasept med	mucadont IS	thermosept NDR
gigasept pearls	mucapur CD	TPH protect
gigasonic	mucocit T	
gigazyme Xtra	octenilin wound gel	

Schülke & Mayr GmbH

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Schülke & Mayr GmbH | 22840 Norderstedt | GERMANY

aspirmatic cleaner
gigazyme
grotanat granulat
Reinigungsverstärker für Gigasept FF
S&M labor
S&M labor flüssig
thermodent liquid
thermodent powder
thermodent alka clean
thermosept alka clean
thermosept alka clean forte
thermosept ER
thermosept RKF
thermosept RKF forte
thermosept RKN-zym
thermosept endocleaner

thermosept X-tra
Edisonite Classic
Edisonite Super
Edisonite Zympower
Mucadont Zymaktiv
Mucapur-AF
Mucapur-MF
Mucapur-MP
Mucapur-N
Mucapur-OxiMed
Mucapur Robotvario
Mucapur-RS
Mucasol
thermodent clear
thermodent neutralizer

thermosept BSK
thermosept KSK
thermosept NKP
thermosept NKZ
thermosept SEK
thermosept SKS
Mucadont Fluid
Mucapur-KS
Mucapur-N
Mucapur-S
Mucapur-Z
Pursept Wipes
schülke wipes safe and easy
schülke wipes

Following products are attributed to medical device class I according to Medical Devices Directive 93/42/EEC Annex IX Rule 1.

For this class of medical devices no involvement of any certified or notified body is required according to Directive 93/42/EEC. Therefore class I products are not listed on the EC- Certificate according Annex II of Directive 93/42/EEC and covered by ISO 13485 Certificate.

Sincerely Yours,
Schülke & Mayr GmbH

N. Ohler

i.A. (by order) Natalya Ohler
- Regulatory Affairs -



/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 visišką 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:

medicininių 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.	170613406
Išgaliojimo data	2015-10-18
Galioja iki	2020-10-17
Frankfurtas prie Maino	2015-10-18

/parašas/

Frank Graichen
Generalinis direktorius

/parašas/

Dr. Thomas Feldmann
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. 170613406
Sertifikato išdavimo data: 2015-10-18

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

Schulke&Mayr GmbH / 22840 Norderstedt

SUINTERESUOTIEMS ASMENIMS

Kontaktinis asmuo Natalya Ohler
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El. paštas Natalya.Ohler@schuelke.com
Data 2016.06.15

Sertifikuoti IIa ir IIb rizikos medicinos prietaisai nurodyti sertifikato priede

Suinteresuotiems asmenims,

Schulke&Mayr GmbH patvirtina, kad žemiau išvardinti IIa ir IIb medicinos prietaisai yra sertifikuoti pagal medicinos prietaisų Europos direktyvos 93/42/EC IX priedo 15 skirsnio reikalavimus.

Šių klasių medicinos prietaisams sertifikuoti reikalinga notifikuota įstaiga pagal 93/42/EEC direktyvą. Išvardinti produktai patenka į kategorijas nurodytas EC sertifikate pagal 93/42/EEC direktyvos II priedą.

acryl des	grotanat liquid	octenilin wound irrigation solution
acryl des disinfection wipes	mikrozid AF liquid	octenisept Gel
antifect AF (N)	mikrozid AF wipes	octenisept wound gel
antifect FF	mikrozid AF wipes jumbo	perform
antifect N liquid	mikrozid AF wipes premium	perform ID
antifect extra	mikrozid alcohol free liquid	pursept AF
aspirmatic	mikrozid alcohol free wipes jumbo	pursept A Xpress
boots wound healing gel	mikrozid PAA wipes	pursept A Xpress wipes
dentavon	mikrozid sensitive liquid	pursept FD
dentavon liquid	mikrozid sensitive wipes	pursept wipes Xpress
esemfix	mikrozid sensitive wipes premium	quartamon med
gigasept AF	mikrozid wipes	rotasept
gigasept AF forte	mikrozid wipes jumbo	septinol SA
gigasept FF (new)	mikrozid universal wipes	terralin liquid
gigasept Granulate	mucalgin	terralin protect
gigasept Instru AF	mucadont AS	thermosept ED
gigasept med	mucadont IS	thermosept NDR
gigasept pearls	mucapur CD	TPH protect
gigasonic	mucocit T	
gigazyme Xtra	octenilin wound gel	

aspirmatic cleaner	thermosept X-tra	thermosept BSK
gigazyme	Edisonite Classic	thermosept KSK
grotanat granulat	Edisonite Super	thermosept NKP
Reinigungsverstärker für Gigasept FF	Edisonite Zympower	thermosept NKZ
S&M labor	Mucadont Zymaktiv	thermosept SEK
S&M labor flussig	Mucapur-AF	thermosept SKS
thermodent liquid	Mucapur-MF	Mucadont Fluid
thermodent powder	Mucapur-MP	Mucapur KS
thermodent alka clean	Mucapur-N	Mucapur N
thermosept alka clean	Mucapur-OxiMed	Mucapur S
thermosept alka clean forte	Mucapur Robotvario	Mucapur Z
thermosept ER	Mucapur-RS	Pursept Wipes
thermosept RKF	Mucasol	schulke wipes safe and easy
thermosept RKF forte	thermodent clear	schulke wipes
thermosept RKN-zym	thermodent neutralizer	
thermosept endocleaner		

Išvardinti produktai yra priskiriami Ia klasei pagal medicinos prietaisų Europos direktyvos 93/42/EC IX priedo 1 skirsnį.

Šių klasių medicinos prietaisams sertifikuoti reikalinga notifikuota įstaiga pagal 93/42/EEC direktyvą. Nors I klasės produktai ir nenurodyti EC sertifikate pagal Europos direktyvos 93/42/EC II priedą, jie atitinka ISO 13485 standartą.

Pagarbiai,
Schulke&Mayr GmbH
/parašas/
/spaudas/
i.A. Natalya Ohler
Reguliavimo tarnyba

/Rekvizitai/