



EC-CERTIFICATE

(Full quality assurance system)



This is to certify 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.

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, wound care products and gel 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 | 170742365 |
| Effective date | 2020-06-09 |
| Expiry date | 2023-12-18 |
| Frankfurt am Main | 2020-06-09 |

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

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: 170742365
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| Device | Class |
|--------------------------------------|--------------|
| acryl-des® Gebrauchslösung | IIa |
| acryl-des® Desinfektionstücher | IIa |
| antifect® AF (N) | IIa |
| antifect® N liquid | IIa |
| antifect® extra | IIa |
| aspirmatic® | IIa |
| boots wound healing gel | IIb |
| dentavon® | IIa |
| dentavon® liquid | IIa |
| Essential+ Wipes | IIa |
| gigasept® AF | IIb |
| gigasept® AF forte | IIb |
| gigasept® FF (neu) | IIb |
| gigasept® Instru AF | IIb |
| gigasept® med | IIb |
| gigasept® pearls | IIb |
| gigasonic® | IIb |
| gigazyme® Xtra | IIb |
| mikrozid® AF liquid | IIa |
| mikrozid® AF wipes | IIa |
| mikrozid® alcohol free liquid | IIa |
| mikrozid® alcohol free wipes jumbo | IIa |
| mikrozid® liquid | IIa |
| mikrozid® PAA wipes | IIb |
| mikrozid® sensitive liquid | IIa |
| mikrozid® sensitive wipes | IIa |
| mikrozid® universal liquid | IIa |
| mikrozid® universal wipes | IIa |
| mikrozid® wipes | IIa |
| mucalgin® | IIa |
| mucadont® IS | IIb |
| mucapur® CD | IIa |
| muccit® T | IIb |
| octenilin® wound gel | IIb |
| octenilin® wound irrigation solution | IIb |
| octenisan® md nasal gel | IIa |
| octenisept® Gel | IIb |
| octenisept® wound gel | IIb |



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| Device | Class |
|--------------------------|--------------|
| perform® | Ila |
| pursept® AF | Ila |
| pursept® A Xpress liquid | Ila |
| pursept® A Xpress wipes | Ila |
| quartamon® med | Ila |
| rotasept® | Ilb |
| septinol® SA | Ila |
| terralin® liquid | Ila |
| terralin® protect | Ila |
| thermosept® ED | Ilb |
| thermosept® NDR | Ila |
| TPH® protect | Ila |
| SteraClar Daily | Ila |
| SteraDif Powder | Ila |
| SteraPex | Ilb |
| SteraPex Rotary | Ilb |
| SteraClens Alcohol Free | Ila |
| SteraClens | Ila |
| SteriWipe+ Alcohol Free | Ila |
| SteriWipe+ | Ila |
| DESIMATIC-ID PLUS | Ilb |
| DESIFOR-ONE multi wipes | Ila |
| DESIFOR-ONE PROTECT | Ila |
| B3 | Ila |



EC-SERIFIKATAS

(Visiška kokybės užtikrinimo sistema)



Patvirtina, kad kompanija

schülk -

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Vokietija

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

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

Medicinos prietaisų 93/42/EEC direktyvos II priedo sąlygas

Taikoma žemiau išvardintiems medicininiams prietaisams:

medicinių prietaisų dezinfekcijos priemonės, žaizdų priežiūros produktai ir gelis, išvardinti priede.

Pagal direktyvos II priedo 5 skyriaus sąlygas, šių prietaisų gamyba turi būti kontroliuojama. Notifikuotos įstaigos (Nr. 0297) CE ženklintas 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. 170742365

Įsigaliojimo data 2020-06-09

Galioja iki 2023-12-18

Frankfurtas prie Maino 2020-06-09

DQS Medizinprodukte GmbH

/parašas/

Sigrid Uhlemann
Generalinis direktorius

/parašas/

Dr. Thomas Feldmann
Notifikuotos įstaigos vadovas

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

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



Priedas prie sertifikato
Sertifikato registracijos Nr.: 004567 MR2
Sertifikato unikalus Nr.: 170742365
Sertifikato išdavimo data: 2020-06-09

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Vokietija

Produktai

Klasė

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|--------------------------------------|-----|
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| gigasept® med | IIb |
| gigasept® pearls | IIb |
| gigasonic® | IIb |
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| mikrozyd® AF liquid | IIa |
| mikrozyd® AF wipes | IIa |
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| mikrozyd® alcohol free wipes jumbo | IIa |
| mikrozyd® liquid | IIa |
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| mikrozyd® universal wipes | IIa |
| mikrozyd® wipes | IIa |
| mucalgin® | IIa |
| mucadont® IS | IIb |
| mucapur® CD | IIa |
| mucocit® T | IIb |
| octenilin® wound gel | IIb |
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| rotasept® | Ilb |
| septinol® SA | Ila |
| terralin® liquid | Ila |
| terralin® protect | Ila |
| thermosept® ED | Ilb |
| thermosept® NDR | Ila |
| TPH® protect | Ila |
| SteraClar Daily | Ila |
| SteraDif Powder | Ila |
| SteraPex | Ilb |
| SteraPex Rotary | Ilb |
| SteraClens Alcohol Free | Ila |
| SteraClens | Ila |
| SteriWipe+ Alcohol Free | Ila |
| SteriWipe+ | Ila |
| DESIMATIC-ID PLUS | Ilb |
| DESIFOR-ONE multi wipes | Ila |
| DESIFOR-ONE PROTECT | Ila |
| B3 | Ila |