



# 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, 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	170773612
Effective date	2021-02-01
Expiry date	2023-12-18
Frankfurt am Main	2021-02-01

**DQS Medizinprodukte GmbH**

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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

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### Device

### Class

acryl-des® Gebrauchslösung	Ila
acryl-des® Desinfektionstücher	Ila
antifect® AF (N)	Ila
antifect® N liquid	Ila
antifect® extra	Ila
aspirmatic®	Ila
boots wound healing gel	Ilb
dentavon®	Ila
dentavon® liquid	Ila
gigasept® AF	Ilb
gigasept® AF forte	Ilb
gigasept® FF (neu)	Ilb
gigasept® Instru AF	Ilb
gigasept® med	Ilb
gigasept® pearls	Ilb
gigasonic®	Ilb
gigazyme® Xtra	Ilb
mikrozyd® AF liquid	Ila
mikrozyd® AF wipes	Ila
mikrozyd® alcohol free liquid	Ila
mikrozyd® alcohol free wipes jumbo	Ila
mikrozyd® liquid	Ila
mikrozyd® PAA wipes	Ilb
mikrozyd® sensitive liquid	Ila
mikrozyd® sensitive wipes	Ila
mikrozyd® universal liquid	Ila
mikrozyd® universal wipes	Ila
mikrozyd® wipes	Ila
mucalgin®	Ila
mucapur® CD	Ila
mucocit® T	Ilb
octenilin® wound gel	Ilb
octenilin® wound irrigation solution	Ilb
octenisan® md nasal gel	Ila
octenisept® Gel	Ilb
octenisept® wound gel	Ilb





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Device	Class
perform®	Ila
pursept® AF	Ila
pursept® A Xpress liquid	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
Pursept A Xpress S	Ila
ProCare Protect universal wipes	Ila
UnoDent Alcohol-free Wipes	Ila