EU Quality Management Certificate

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Digitally signed by Ghereg Victor
Date: 2024.04.19 14:51:41 EEST
Reason: MoldSign Signature
Location: Moldova

SRN: DE-MF-000005701

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	004567 MDR2017Q
Certificate ID	1000120979
Effective date	2023-05-17
Expiry date	2028-05-03
Frankfurt am Main,	2023-05-17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120979

Device categories covered by this certificate:

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Cleaning and disinfection agent for chemo-thermal reprocessing

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Cleaning and disinfection agent for manual reprocessing of medical devices

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Disinfectant for suction unit surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Disinfectant medical devices

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Disinfection of dental mouldings

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIb
Intended purpose:	Disinfectant of medical device surfaces at the endpoint of reprocessing

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120979

Examinations and tests performed:
004567 A209710MED MDR2017Q dated 2022-09-09

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-05-04	170779017	Addition of the Device category for the product Mikrozid® PAA wipes

EU Technical Documentation Assessment Certificate

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

SRN: DE-MF-000005701

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Devices of class IIa and IIb listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	004567 MDR2017B
Certificate ID	1000120967
Effective date	2023-05-17
Expiry date	2028-05-03
Frankfurt am Main,	2023-05-17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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DQS Medizinprodukte GmbH

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Head of Certification Body
(non-active medical devices)

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Device categories and variants covered by this certificate:

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Antifect AF (N)
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000016A9
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Antifect extra
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000017AB
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Aspirmatic
Models:	Aspirmatic, UnoDent Aspisept Daily, PremEco AS
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000018AD
Intended purpose:	Disinfectant for suction unit surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Dentavon
Models:	Dentavon, Perform ID, UnoDent Unoguard
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000019AF
Intended purpose:	Disinfection of dental mouldings

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigasept AF forte
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000035AD
Intended purpose:	Cleaning and disinfection agent for manual reprocessing of medical devices

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigasept instru AF
Models:	Gigasept instru AF, UnoDent Surgical Instru. Cleanser
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000037AH
Intended purpose:	Cleaning and disinfection agent for manual reprocessing of medical devices

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigazyme X-tra
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000039AM
Intended purpose:	Cleaning and disinfection agent for manual reprocessing of medical devices

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mikrozid AF
Models:	Mikrozid AF liquid, Mikrozid AF wipes, Terralin liquid, Mikrozid liquid, Mikrozid wipes, Antifect N liquid, Prem Eco Plus, UnoDent Unosept, UnoDent Unowipes, Terralin AF wipes
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC000000209Y
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mikrozid sensitive
Models:	Mikrozid sensitive liquid, Mikrozid sensitive wipes, Mikrozid alcohol free liquid, Mikrozid alcohol free wipes, Terralin sensitive wipes
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000021A2
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mikrozid universal
Models:	Mikrozid universal liquid, Mikrozid universal wipes, DESIFOR-ONE multi wipes, Pursept A Xpress S, Pursept UniSprint Wipes, Terralin universal wipes
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000022A4
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mucalgin
Models:	Mucalgin, Mucalgin dental
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000028AG
Intended purpose:	Disinfection of dental mouldings

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Perform
Models:	Perform, DESIFOR-ONE PROTECT
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000023A6
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Puresept
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651-BSC000000129Z
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Pursept AF
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000024A8
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Quartamon med
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000026AC
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Terralin protect
Models:	Terralin protect, TPH protect
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000027AE
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Thermosept NDR
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000043AC
Intended purpose:	Cleaning and disinfection agent for chemo-thermal reprocessing

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigasept® powerTrio disinfection wipe
Models:	n/a
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000014A5
Intended purpose:	Disinfectant of medical device surfaces at the endpoint of reprocessing

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mikrozid® PAA wipes
Models:	n/a
Risk classification:	IIb
Basic-UDI-DI:	4032651-BSC00000011-CP
Intended purpose:	Disinfectant of medical device surfaces at the endpoint of reprocessing

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Examinations and tests performed:
004567 A209710MED MDR2017B dated 2023-04-19
004567 A209710MED MDR2017B Mikrozid® PAA wipes dated 2023-05-08

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-05-04	170779018	Addition of Product Mikrozid® PAA wipes and new trade names Terralin AF , sensitive, universal wipes

schülke

sm 2 Universal – suitable for 500 ml to 1,000 ml bottles

sm 2 500 – suitable for 500 ml bottles

For the application of hand disinfectants, wash and care lotions.

sm 2 Universal / sm 2 500

Our plus:

- no recontamination or evaporation due to unique pump design and integrated bottle closure
- valve protected from contact and contamination
- container can be completely emptied due to a flexible suction hose
- adjustable stroke from 1 ml – 3 ml
- easy cleaning as dispenser and pump can be completely disassembled
- simple mounting

Description

Simple and exact metering of hand disinfectants, wash and care lotions

- the required quantities are provided by the adjustable stroke from about 1 ml to 3 ml per stroke.
- pump system and discharge valve have been harmonized so that the different viscosities of the preparations are taken into account
- Hermetic sealing due to unique outlet valve: no drips, no leakage, no drying up, no evaporation, no recontamination.

Changing product

In case of a product change only the one-way bottle must be replaced and the detachable pumping system must be rinsed. The bottle label is the dispenser label.

Cleaning

The wall dispenser can be dismantled and disassembled without tools. Smooth and polished surfaces allow easy cleaning.

Discharge valve

The design of the discharge valve does not allow the product to flow out before the big opening is unclosed. Therefore no sharp yet can build up. An additional seal at the lower end of the discharge opening prevents leaking in case of closed valve.

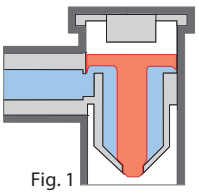


Fig. 1

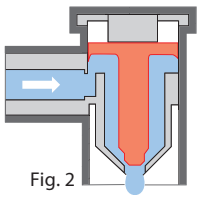


Fig. 2

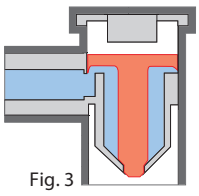


Fig. 3

Operating lever

Can be operated by the elbow or lower arm. The lever can be turned up for simple replacement of the pump and for metering adjustment.

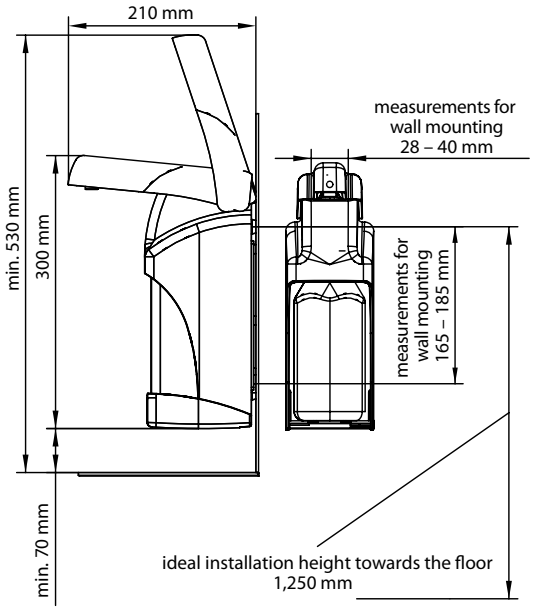
sm 2 universal / sm 2 500

Mounting instructions

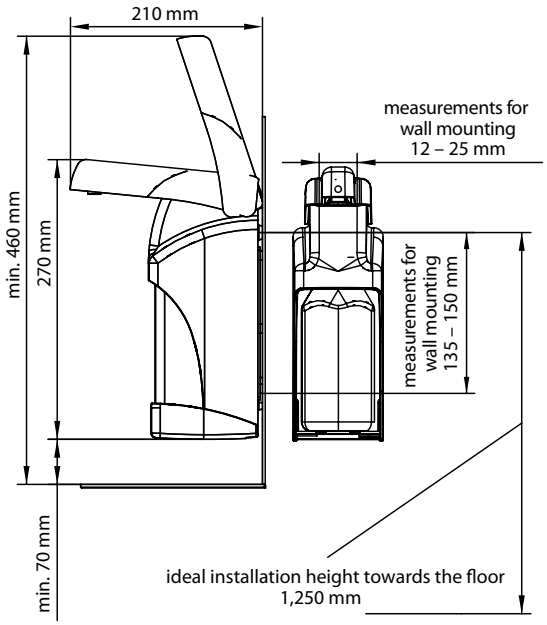
Standard mounting:

- 2 elongated holes above and below
- best static fixing for dispenser: T-fixing which fits in all tile joints
- hole pattern at the back of all common dispenser mountings

Mounting measurements sm 2 Universal:



Mounting measurements sm 2 500:



Technical data

Dispenser box:	500 ml – 1,000 ml (sm 2 Universal) 500 ml (sm 2 500)
Adjustable metering:	about 1 ml to 3 ml
Level indicator:	permanent due to transparent box
Materials:	casing made of ABS plastic, metal parts of stainless steel

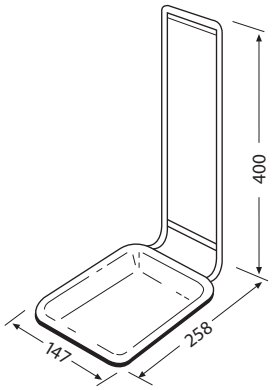
Packaging units

Packaging units	Art. no.
☐ **sm 2 Universal** (450 / 500 ml – 1,000 ml)	668 500
☐ **sm 2 500** (450 – 500 ml)	668 600

Accessories

Accessories	Art. no.
Dish fixing for sm 2 Universal / sm 2 500 complet	668 510
Replacement pump	668 540

Dish mounting



EMAS GEPRÜFTES UMWELTMANAGEMENT REG.-NR. D-150-00003

DQS MED Quality Management ISO 13485

DQS MED Quality Management ISO 9001:2008

Schülke & Mayr GmbH ist zertifiziert gemäß DIN EN ISO 9001, DIN EN ISO 14001 und DIN EN ISO 13485 **(Reg.-Nr. 004567-MP23)** und verfügt über ein validiertes Umweltmanagementsystem gem. Öko-Audit-Verordnung **(Reg.-Nr. D-150-00003)**.

Schülke & Mayr GmbH
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II / 08.20 / A / intern

Agenția Națională pentru Sănătatea Publică

CERTIFICAT
DE ÎNREGISTRARE DE STAT/AVIZARE SANITARĂ AL PRODUSULUI BIOCID

Nr. **00183** data/luna/anul **05.03.2021**

Solicitant: For titular **SC"Endo –Chirurgie" SRL**

Adresa juridică: ***str. Meșterul Manole, 9 mun. Chișinău, Republica Moldova***

Nr. de identificare de stat – codul fiscal 1009600033242

În conformitate cu HG nr. 344 din 10.06.20 și în baza ordinului ANSP **nr. 34 din 02.03.2021**
(nr., data/luna/anul)

emis în baza documentației înaintate, s-a decis că următorul produs biocid poate fi fabricat sau **comercializat și utilizat** în Republica Moldova, conform prevederilor legislației în vigoare.

Denumirea comercială a produsului: Desderman®pure

1. Date de identificare ale produsului:

1.1 Categoria de produs: **biocid**

- *Grupa principală:* **1**
- *Tip de produs:* **1**

1.2Utilizare: Dezinfectarea igienică și chirurgicală a mâinilor

1.3 Forma de condiționare și ambalare: **Lichid, ambalaj – flacoane/canistre polimer, de 60 ml, 100 ml, 150 ml, 500ml, 1l, 5l.**

1.4 Conținut în substanțe active: Etanol 96%- 78,20%
bifenil -2 –ol -0,10%

1.5 Categorii de utilizatori: **Profesionali, industrial**

1.6 Informații privind reglementările aplicabile: **HG nr. 344 din 10.06.2020,**

2. Date de identificare ale producătorului:

2.1 Firma: **„SchUlke&Mayr GmbH", Germania**

2.2 Adresa: **22840 Norderstedt, Germania**

Valabilitatea certificatului de înregistrare data/luna/anul **05.03.2028**

Compoziția, parametrii de calitate ai produsului și domeniul de utilizare sunt cei prevăzuți în documentația tehnică, care a stat la baza eliberării prezentului certificat, conform Raportului de evaluare nr. **170** din **25.02.2021**

Orice modificare a datelor de identificare a produsului biocid, duce în mod automat la anularea certificatului de înregistrare.

Director interimar **Vasile GUȘTIUC**