EU Quality Management 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, 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.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

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

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 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	1000215631
Effective date	2025-02-05
Expiry date	2028-05-03
Frankfurt am Main,	2025-02-05

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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

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 the certification can only be verified by the QR-code.

420.90Version 7.0

Heruntergeladen von Gast (IP 216.73.216.59) am 31.10.2026 um 06:56 Uhr · sana.swiss

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000215631

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)
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
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, 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, 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
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000035AD
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:	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

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Device category:	**MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigazyme X-tra
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 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 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 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

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Device category:	**MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	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, 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
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
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
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000026AC
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:	Terralin protect, TPH protect
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000027AE
Intended purpose:	Disinfectant and cleaner for medical device surfaces

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Device category:	**MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Thermosept NDR
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 Gigasept powerSET3 disinfection wipe
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
Risk classification:	IIb
Basic-UDI-DI:	4032651-BSC00000011-CP
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:	Triamin disinfection
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000047AL
Intended purpose:	Disinfectant for medical device surfaces

Device category:	**MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Perform pro
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000049AQ
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:	Dentavon ID, UnoDent Unoguard ID
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000048AN
Intended purpose:	Disinfection of dental impressions

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Device category:	**MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	thermosept ED
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000042AA
Intended purpose:	Didisinfectant for chemo-thermal reprocessing of medical devices

Device category:	**MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	gigasept FF new, DESIMATIC-ID PLUS
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000036AF, 4032651BSC00000036AF
Intended purpose:	Disinfectant for manual reprocessing of medical devices

Device category:	**MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Rotasept
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000029AJ
Intended purpose:	Disinfectant for manual reprocessing of medical devices - cleaning and disinfection of rotary dental instruments

Device category:	**MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	mikrozid PAA+ wipes
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000068AU
Intended purpose:	Ddisinfectant of medical device surfaces at the endpoint of reprocessing

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Product name:	octenisept gel, octenisept wound gel
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000032A7
Intended purpose:	Wound healing of acute wounds and slight burns

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Product name:	octenilin wound gel
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000031A5
Intended purpose:	Covering, moistening and cleaning of coated, contaminated and chronic skin wounds and burns

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Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Product name:	octenilin wound irrigation solution
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000030A3
Intended purpose:	Cleansing and moistening encrusted, contaminated and chronic skin wounds

Examinations and tests performed:
004567 A209710MED MDR2017Q dated 2022-09-09
004567 A209710MED MDR2017B dated 2023-04-19
004567 A209710MED MDR2017B Mikrozid® PAA wipes dated 2023-05-08
004567 A212073MED MDR2017B thermosept ED dated 2024-08-27
004567 A212073MED MDR2017B octenilin wound gel dated 2023-12-07

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	170779017	Addition of the Device category for the product Mikrozid® PAA wipes
02	2023-05-17	1000120979	Addition of "Triamin Disinfection" & Expansion of the product range with an additional trade name (gigasept powerSET3 disinfection wipe) for the existing product "gigasept powerTrio disinfection wipe
03	2023-10-26	1000142418	Addition of the product "perform pro und dentavon ID"
04	2023-12-15	1000150416	New certificate template
05	2024-07-04	1000164509	Addition of the product “thermosept ED” “gigasept FF new, DESIMATIC-ID PLUS” & Rotasept
06	2024-10-25	1000199401	Addition of the product “mikrozid PAA+ wipes”,“octenisept gel, octenisept wound gel”, “octenilin wound gel”and “octenilin wound irrigation solution”

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