



# 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	1000199401
Effective date	2024-10-25
Expiry date	2028-05-03
Frankfurt am Main,	2024-10-25



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



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: DE-MF-000005701**  
**Certificate ID: 1000199401**

**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: Mikrozyd AF liquid, Mikrozyd AF wipes, Terralin liquid, Mikrozyd liquid, Mikrozyd 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: Mikrozyd sensitive liquid, Mikrozyd sensitive wipes, Mikrozyd alcohol free liquid, Mikrozyd 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: Mikrozyd universal liquid, Mikrozyd 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

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



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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

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



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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

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: Didisinfektant for chemo-thermal reprocessing of medical devices



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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

**Examinations and tests performed:**

004567 A209710MED MDR2017Q dated 2022-09-09  
004567 A209710MED MDR2017B dated 2023-04-19  
004567 A209710MED MDR2017B Mikroqid® PAA wipes dated 2023-05-08  
004567 A212073MED MDR2017B thermosept ED dated 2024-08-27

**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 Mikroqid® 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