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
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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(active medical devices)

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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

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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

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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

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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

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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