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.

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