

EU Declaration of Conformity



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Manufacturer
according to Regulation 2017/745

Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt
Germany

Registration Number
acc. to Art. 31 2017/745

DE-MF-000005701

Product Name

mikrozid® universal p liquid

Basic UDI-DI
Code acc. to Art. 26 2017/745

4032651BSC00000070AF

Intended Purpose

D0799

disinfectant and cleaner of medical device surfaces

Risk Class
according to Regulation 2017/745

II a

Annex VIII

rule 16

Standards applied

EN ISO 13485

additional standards see technical documentation

Schülke & Mayr GmbH

Notified Body

DQS Medizinprodukte GmbH

August-Schanz-Str. 21

60433 Frankfurt am Main

Germany

No.: 0297

Conformity Assessment Procedure
according to Regulation 2017/745

Annex IX

Chapter I, II section 4 and III

Certificates

Annex IX

004567 MDR2017Q

EN ISO 13485

004567 MP2016

Version

1-0

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this declaration

Norderstedt

13.11.2025

ppa.

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ppa.

Dr. Rainer Wolber
Schülke & Mayr GmbH
Chief Technology Officer

Lars Lemke
Schülke & Mayr GmbH
Chief Operating Officer

This Declaration is valid until an updated version has been issued, but not longer than
03.05.2028