

EU Declaration of Conformity

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 liquid

Basic UDI-DI

Code acc. to Art. 26 2017/745

Intended Purpose

4032651BSC00000022A4

16

D0799

disinfectant and cleaner of medical device surfaces

Risk Class

according to Regulation 2017/745

II a

Annex VIII

rule

Standards applied

Notified Body

EN ISO 13485

additional standards see technical documentation

Schülke & Mayr GmbH

DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main

ΙX

Germany No.: 0297

Conformity Assessment Procedure according to Regulation 2017/745

Annex

Chapter I, II section 4 and III

Certificates

Annex IX

004567 MDR2017Q

EN ISO 13485

004567 MDR2017B 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

15.06.2023

рра.

15.06.2023

рра.

Schülke & Mayr GmbH
Chief Commercial Officer

Schülke & Mayr GmbH

Chief Operating Officer