

## **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® PAA wipes

Basic UDI-DI

Code acc. to Art. 26 2017/745

Intended Purpose

Risk Class

according to Regulation 2017/745

Standards applied

4032651-BSC00000011-CP

D050103

disinfectant of medical device surfaces at the endpoint of reprocessing

II b

Annex VIII

rule 16

EN ISO 13485

additional standards see technical documentation

Schülke & Mayr GmbH

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

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Germany No.: 0297

Conformity Assessment Procedure according to Regulation 2017/745

Annex

Chapter I, II section 4, III

Certificates

Notified Body

Annex

004567 MDR2017Q 004567 MDR2017B

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

05.06.2023

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05.06.2023

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Dr. Sven Pfleging
Schülke & Mayr GmbH
Chief Commercial Officer

Lars Lemke Schülke & Mayr GmbH Chief Operating Officer