



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

aspirmatic® cleaner

basic UDI-DI
Code acc. to Art. 26 2017/745
Intended Purpose

4032651-BSC00000002-CM
V9099
cleaning agent for suction units

Risk Class
according to Regulation 2017/745

I
annex VIII
rule 1

Standards applied

EN ISO 13485
additional standards see technical documentation
Schülke & Mayr GmbH

Conformity Assessment Procedure
according to Regulation 2017/745

annex II / III

Certificate

EN ISO 13485

004567 MP2016

Version

3-0

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

15.08.2024
ppa.

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ppa.


Dr. Rainer Wolber
Schülke & Mayr GmbH
Director Innovation & Regulatory
Affairs


Lars Lemke
Schülke & Mayr GmbH
Chief Operating Officer