

## 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**

pump for 500ml /1I

basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose # 180303, 180803 4032651-BSC00000008-D7 V9099

Risk Class

dispensing pump

according to Regulation 2017/745

annex VIII

Standards applied

EN ISO 13485

additional standards see technical documentation

Schülke & Mayr GmbH

Conformity Assessment Procedure according to Regulation 2017/745

annex IV / V

certificate

EN ISO 13485

004567 MP2016

Version

2-0

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

09. Nov. 2021

ppa.

Dr. Uwe Berlekamp Schülke & Mayr GmbH Director Business Line Healthcare рра.

/ Jörn Ahlsdorff
Schülke & Mayr GmbH
Director Industrial Operations
International Industrial Operations