

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

4032651BSC00000069AW

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

A13

Risk Class according to Regulation 2017/745

dispensing pump

1

annex rule

VIII

Standards applied

EN ISO 13485

additional standards see technical documentation

Schülke & Mayr GmbH

Conformity Assessment Procedure according to Regulation 2017/745

annex

 $\parallel / \parallel \parallel$

Certificate

EN ISO 13485

004567 MP2016

Version

4-0

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

03.02.2025

рра.

03.02.2025

ppa.

Dr. Rainer Wolber

Schülke & Mayr GmbH Director Innovation & Regulatory

Affairs

Lars Lemke Schülke & Mayr GmbH Chief Operating Officer