

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

schülke wipes

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

Intended Purpose

Risk Class according to Regulation 2017/745 4032651-BSC00000001-CJ

dry wipes to be impregnated with surface disinfectants

annex

VIII

rule

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

ppa.

Schülke & Mayr GmbH **Director Industrial Operations** International Industrial Operations