


EC 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	not issued so far
Product name	edisonite® classic
basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose	4032651-BSC00000003-CQ V07 cleaning agent for manual reprocessing of medical devices
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 IV / V
Certificate	EN ISO 13485 004567 MP2016
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 15.02.2021
ppa.


 Dr. Uwe Berlekamp
 Schülke & Mayr GmbH
 Director Business Lines, Research &
 Regulatory Affairs

ppa. 
 Dr. Thorsten August
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