

## 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
<b>Product Name</b>	<b>rotasept®</b>
Basic UDI-DI Code acc. to Art. 26 2017/745 Intended Purpose	4032651BSC00000029AJ Z12011385 cleaning and disinfection of rotary dental instruments
Risk Class according to Regulation 2017/745	II b Annex VIII rule 16
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany No.: 0297
Conformity Assessment Procedure according to Regulation 2017/745	Annex IX Chapter I, II section 4 and III
Certificates	Annex IX 004567 MDR2017Q 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 05.11.2024  
ppa.

05.11.2024  
ppa.

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

  
 Lars Lemke  
 Schülke & Mayr GmbH  
 Chief Operating Officer