

**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>octenilin<sup>®</sup> wound irrigation solution</b>		
basic UDI-DI	4032651BSC00000030A3		
Code acc. to Art. 26 2017/745	Z12019003		
Intended Purpose	wound treatment: cleansing and moistening encrusted, contaminated and chronic skin wounds.		
Risk Class according to Regulation 2017/745	II b		
	annex	VIII	
	rule	4	
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, III and section 4
certificate	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 10.02.2025  
ppa.

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

10.02.2025  
ppa.

  
Lars Lemke  
Schülke & Mayr GmbH  
Chief Operating Officer