

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	octenisept® wound gel		
basic UDI-DI	4032651BSC00000032A7		
Code acc. to Art. 26 2017/745	Z12019003		
Intended Purpose	wound treatment: supports a fast wound healing of acute wounds and slight burns		
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