EU Declaration of Conformity

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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	**thermodent® alka clean**
basic UDI-DI	4032651-BSC00000004-CT
Code acc. to Art. 26 2017/745	V0799
Intended Purpose	cleaning agent for automated 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 II / III
Certificate	EN ISO 13485 004567 MP2016
Version	3-0

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 15.08.2024
ppa.

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

15.08.2024
ppa.

Lars Lemke
Schülke & Mayr GmbH
Chief Operating Officer

This Declaration is valid until an updated version has been issued, but not longer than 19.07.2027