EU Declaration of Conformity (DoC)

This Declaration of Conformity is issued under the sole responsibility of the Diversey Europe Operations B.V.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Diversey Europe Operations B.V.	Maarssenbroeksedijk 2 3542 DN Utrecht, The Netherlands	NL-MF-000006623

Intended use: Suma Med family products are a broad spectrum cleaners used on invasive and non-invasive medical devices.

PRODUCT IDENTIFICATION			
Product Name	**Reference number /SKU**	**GMDN**	**Basic UDI-DI**
Suma Med Alu L10	• 100854033 Suma Med Alu L10 200L • 100854034 Suma Med Alu L10 2x5L	63385	8720938285Suma Med7W
Suma Med Super LpH	• 7517688 Suma Med Super LpH 20L • 7517689 Suma Med Super LpH 2x5L • 7517690 Suma Med Super LpH 200L • 101104762 Summox Suma Med Super LpH 2x5L		
Suma Med Super Plus	• 7517685 Suma Med Super Plus 10L		

	• 7517686 Suma Med Super Plus 2x5L • 101101206 Suma Med Super Plus 5L		
Suma Med Enzyme	• 7511762 - Suma Med Enzyme 2x5L • 7512082 - Suma Med Enzyme 200L		
Suma Med Rinse	• 7511765 - Suma Med Rinse 2x5L • 100966521 - Suma Med Rinse 200L	58061	8720938285Suma RinseAE
Suma Med Rinse Plus	• 7511767 - Suma Med Rinse Plus 2x5L		

CONFORMITY ASSESSMENT		
Device Family	**Conformity assessment procedure description**	**CE certificate number**
Suma Med	Conformity of the products are according to the Regulation MDR 2017/745: Annex IX Chapters I and III	Not applicable

Device Classification: Class I, rule 1 according to Annex VIII of MDR

List of standards applicable: See appendix 1

EU Notified body: Not applicable. self certified

Notified body ID : Not applicable

Person Responsible for Regulatory Compliance:

Name	**Edwin Baars**
Function	Executive Director GTS & Regulatory Europe & Person Responsible for Regulatory Compliance
Place and Date	Utrecht, 22-04-2024
Signature	

Appendix 1: List of applicable standards
Device family: Suma Med

1. **Applicable regulations**

Regulations	
Regulation (EU) 2017/745	The European Parliament and the Council of 5 April 2017 - on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
UK MDR 2002	Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
Detergents Regulation (EC) No 648/2004	Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, pp. 1–35) and UK Detergents Regulation
CLP Regulation (EC) No 1272/2008 -- Classification, labelling and packaging of substances and mixtures **GB CLP**	Regulation (EC) No 1272/2008 Of The European Parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 and GB CLP
REACH Regulation **UK REACH**	(EC) No 1907/2006 (including mandatory referral to Personal Protective Equipment 89/686/EEC) and UK-REACH

ADR	European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)

2. Applicable standards

Standards	
EN ISO 13485:2016/A11:2021	Medical Devices Quality Management systems for regulatory purposes
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 14971:2019 + A11 2021	Application of Risk Management System for Medical Devices
EN ISO 10993-1:2020	Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within risk management process
EN ISO 10993-5: 2009	Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
EN ISO 10993-18: 2020	Biological evaluation of medical devices part 18- Chemical characterization of medical device materials within a risk management process
EN ISO 20417:2021	Medical Devices- Information to be supplied by the manufacturer
EN IEC 62366-1:2015+A1:2020	Medical Devices – part 1: Application of usability engineering to medical devices

3. **Applicable guidance documents**

Guidance documents	
ISO/TR 15499:2016	Biological evaluation of medical devices – Guidance on the conduct of biological evaluation within a risk management process
ISO/TR 20416:2020	Medical Devices – Post-market surveillance for manufacturers
ISO/TR 24971:2020	Medical Devices – Guidance on the application of ISO 14971
MEDDEV 2.7/1, Rev 04:06/2016	Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12/1, Rev 08:01/2013	Guidelines on a medical devices vigilance system
MDCG 2021-24:October 2021	Guidance on classification of medical devices
MDCG 2018-1 Rev 4: April 2021	Guidance on Basic UDI-DI and changes to UDI-DI

4. **Common Specifications (CS)-** Not applicable