RUSHWOOD PRACTICAL HEALTHCARE SOLUTIONS	Document Number: RW-FRM-004-01	Date: **2025/04/16**
	Revision: **1.2**	
	Owner: **RAQA**	
Document Title	***Declaration of Conformity***	

Manufacturer's name	Rushwood b.v.
Manufacturer's address	Ottergeerde, 30 4941 VM Raamsdonksveer The Netherlands
Manufacturer SRN	NL-MF-000005745
Product type	Oral lubrification gel
Product	Gloup, Oral lubrication gel
Model # and name	See Appendix 1 for a full list of reference numbers and UDI-DI codes
GMDN / EMDN	
Classification	Class I (rule 5)
Conformity assessment procedure	Annexes I, II & III of the (EU) MDR 2017/745
Notified body	NA
Notified body's ID	NA
EC Certificate(s) #	NA

We declare under our sole responsibility that the product(s) specified above meet(s) the provisions of the European Regulation 2017/745 on medical devices, Annexes I, II and III.

Relevant standards	ISO 13485:2016: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes ISO 10993-1:2018: Biological evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process ISO 14971:2019: Medical Devices - Application of risk management to medical devices ISO 15986:2011: Symbol for use in the labelling of Medical Devices - Requirements for labelling of Medical Devices containing phthalates ISO 15223-1:2021: Medical devices - Symbols to be used with Medical Device labels, labelling and information to be supplied - Part 1: General requirements

Place	Raamsdonksveer The Netherlands	Date of issue	2025-04-16
		Valid till	**2027-12-12**
Signature			
Full name:	Ron BRUIJNS Managing Director		

Appendix 1: Product list

Product	Variant	Packaging	REF number	UDI-DI
Gloup	Original	8 ml Stick pack	8718692401372	8718692403833 8718692403932 8718692404410 8718692404502 8718692405455
		75 ml tube	8718692401426	8718692401495 8718692402300 8718692402324 8718692403864 8718692404021 8718692404694
		150 ml tube	8718692401419	8718692402003 8718692402034 8718692402065 8718692402096 8718692402126 8718692402157 8718692402188 8718692402201 8718692402225 8718692402249 8718692402263 8718692402461 8718692402812 8718692404229
		500 ml bottle	8718692401174 8718692401235 8718692401266 8718692401143 8718692401112 8718692401204 8718692401464 8718692401310 8718692402386 8718692402409 8718692402423 8718692404632	8718692401174 8718692401235 8718692401266 8718692401143 8718692401112 8718692401204 8718692401464 8718692401310 8718692402386 8718692402409 8718692402423 8718692404632

Product	Variant	Packaging	REF number	UDI-DI
Gloup	Forte	8 ml Stick pack	8718692402805	8718692403994 8718692404199 8718692404441 8718692404571 8718692405486
		500 ml bottle	8718692401334 8718692402959 8718692402980 8718692403017 8718692403130 8718692403161 8718692403116 8718692403079 8718692403109 8718692401747 8718692403581 8718692403789	8718692401334 8718692402959 8718692402980 8718692403017 8718692403130 8718692403161 8718692403116 8718692403079 8718692403109 8718692401747 8718692403581 8718692403789

Product	Variant	Packaging	REF number	UDI-DI
Gloup	Zero	8 ml Stick pack	8718692402362	8718692403963 8718692404137 8718692404168 8718692404380 8718692404533 8718692405295 8718692405424
		75 ml tube	8718692401792	8718692402751 8718692403314 8718692403635 8718692403666 8718692403697 8718692404298 8718692404663 8718692405264 8718692405325 8718692405516
		150 ml tube	8718692402379	8718692402287 8718692403253 8718692403284 8718692403345 8718692403468 8718692403529 8718692403727 8718692404328 8718692405516 8718692405592
		500 ml bottle	8718692402928 8718692403376 8718692403192 8718692403222 8718692403437 8718692403499 8718692404359 8718692403758 8718692404601	8718692402928 8718692403376 8718692403192 8718692403222 8718692403437 8718692403499 8718692404359 8718692403758 8718692404601

Product	Variant	Packaging	REF number	UDI-DI
Gloup	Forte Lemon	500 ml bottle	8718692404496	8718692404496

Product	Variant	Packaging	REF number	UDI-DI
Gloup	FEES	500 ml bottle	8718692405608	8718692405608

Product	Variant	Packaging	REF number	UDI-DI
Gloup	Kids	150 ml tube	8718692404564	8718692404786 8718692404816 8718692404847 8718692404908 8718692404939 8718692405080 8718692405141

Product	Variant	Packaging	REF number	UDI-DI
Gloup	Family	500 ml bottle	8718692401419	8718692404878