

	Document Number: RW-FRM-004-02	Date: 2026/02/12
	Revision: 1.6	
	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 lubrication 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	60365
Basic UDI	871869240RW-GLPT2
Classification	Class I, Rule 5
Conformity assessment procedure	N/A
Notified body	N/A
Notified body's ID	N/A
EC Certificate(s) #	N/A

We declare under our sole responsibility that the product(s) specified above meet(s) the provisions of the European Regulation 93/42/EC on medical devices.

Relevant standards	EN ISO 13485:2016+A11:2021: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes EN ISO 10993-1:2020: Biological evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process EN ISO 14971:2019+A11:2021: Medical Devices - Application of risk management to medical devices EN ISO 15223-1:2021: Medical devices - Symbols to be used with Medical Device labels, labelling and information to be supplied - Part 1: General requirements EN ISO 20417:2021 Medical devices - Information to be provided by the manufacturer EN ISO 10993-1: 2020 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process EN 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
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Place Raamsdonksveer Date of issue: 12-feb-2026
The Netherlands

Signature 

Full name: Ron BRUIJNS
Managing Director
On behalf of Rushwood b.v.



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Appendix 1: Product list

Product	Variant	Packaging	REF number	UDI-DI	Language code*
Group	Original	8 ml Stick pack	8718692401372	8718692403833	1
				8718692403932	4
				8718692404410	8
				8718692404502	11
				8718692405455	13
		75 ml tube	8718692401426	8718692401495	1
				8718692401525	2
				8718692401556	3
				8718692401617	5
				8718692401648	6
				8718692401679	8
				8718692402300	10
				8718692402324	12
				8718692402348	11
				8718692404694	13
		150 ml tube	8718692401419	8718692402003	1
				8718692402034	2
				8718692402065	3
				8718692402096	4
				8718692402126	5
				8718692402157	6
				8718692402188	8
				8718692402201	7
				8718692402249	12
				8718692402263	11
				8718692402461	10
		8718692404052	13		
		500 ml bottle	8718692401174	8718692401174	1
				8718692401235	2
				8718692401266	3
				8718692401143	4
				8718692401112	5
				8718692401204	6
				8718692401464	7
				8718692401310	8
				8718692402386	10
8718692402409	11				
8718692402423	12				
8718692402720	4				
8718692404632	13				
8718692405882	17				



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Product	Variant	Packaging	REF number	UDI-DI	Language code*
Gloup	Forte	8 ml Stick pack	8718692402805	8718692403994	1
				8718692404199	4
				8718692404441	8
				8718692404571	11
				8718692405486	13
		500 ml bottle	8718692401334	8718692401334	1
			8718692402959	8718692402959	2
			8718692402980	8718692402980	4
			8718692403017	8718692403017	5
			8718692403130	8718692403130	6
			8718692403161	8718692403161	7
			8718692403079	8718692403079	8
			8718692403109	8718692403109	12
			8718692403581	8718692403581	3
			8718692403789	8718692403789	11
			8718692405387	8718692405387	13
			8718692405790	8718692405790	17
			8718692405851	8718692405851	10



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Product	Variant	Packaging	REF number	UDI-DI	Language code*	
Gloup	Zero	8 ml Stick pack	8718692402362	8718692403963	1	
				8718692404137	5	
				8718692404168	4	
				8718692404380	8	
				8718692404533	11	
				8718692405295	6	
		8718692405424	13			
		75 ml tube	8718692401792		8718692402751	1
					8718692403314	2
					8718692403635	3
					8718692403666	10
					8718692403697	11
					8718692404298	8
					8718692404663	13
					8718692405264	14
					8718692405325	15
					8718692405516	12
		150 ml tube	8718692402379		8718692402287	1
					8718692403253	4
					8718692403284	3
					8718692403345	2
					8718692403468	5
					8718692403529	10
					8718692403727	11
					8718692404328	8
					8718692405264	14
					8718692405325	6
					8718692405394	13
					8718692405516	12
					8718692405943	18
					500 ml bottle	8718692402928
		8718692403376	2			
		8718692403192	4			
		8718692403437	5			
		8718692403499	10			
		8718692403550	3			
8718692404359	8					
8718692403758	11					
8718692404601	13					
8718692405233	14					
8718692405547	12					
8718692405769	17					
8718692405820	6					
8718692405912	18					



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Product	Variant	Packaging	REF number	UDI-DI	Language code*
Gloup	Forte Lemon	500 ml bottle	8718692404496	8718692404496	1

Product	Variant	Packaging	REF number	UDI-DI	Language code*
Gloup	FEES	500 ml bottle	8718692405608	8718692405608	0

Product	Variant	Packaging	REF number	UDI-DI	Language code*
Gloup	Kids	150 ml Tube	8718692404564	8718692404786	1
				8718692404816	2
				8718692404847	3
				8718692404908	5
				8718692404939	6
				8718692404960	7
				8718692404991	8
				8718692405028	9
				8718692405059	10
				8718692405080	11
				8718692405110	12
				8718692405141	13
				8718692405172	14
				8718692405202	15

Product	Variant	Packaging	REF number	UDI-DI	Language code*
Gloup	Family	500 ml bottle	8718692401419	8718692401419	0