



## DECLARATION OF CONFORMITY

REVISION: 20  
EFFECTIVE DATE: 2021-05-28  
EXPIRY DATE: 2023-05-28  
AUTHOR: A. Bruijns  
PAGE: 1 of 4

<b>Identification of the Legal Manufacturer:</b>	 <p>Rushwood b.v. Ottergeerde 30 4941 VM Raamsdonksveer The Netherlands</p>
This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.	
<b>Single Registration Number (SRN):</b>	APP000007544
<b>Identification of the device(s) concerned:</b>	“Gloop” / Oral lubrication gel. See Appendix I for a full list of reference numbers / UDI-DI codes.
<b>Risk Classification:</b>	Class I rule 5 as non-sterile and non-measuring function device
We hereby declare that the above mentioned devices comply with the European Medical Devices Regulation 2017/745 Appendix I to III are fulfilled in the Technical File available for competent authorities.	
<b>Relevant Harmonized Standards</b>	ISO 10993-1:2009 ISO 14971:2012 EN 15986:2011 EN 2366:2008 EN 15223
<b>Name and address of Notified Body:</b>	Not relevant
<b>Applicable CE Certificate(s):</b>	Not relevant
<b>First date of CE-marking</b>	2013-04-01
<b>Identification of the person authorized to sign on behalf of Legal Manufacturer:</b>	Name: A.A.A. Bruijns Signature:  Title: Managing Director Place of Issue: Raamsdonksveer Date: May 31 <sup>th</sup> , 2021



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## APPENDIX I: List of Devices

Device name	Reference number / UDI-DI
"Gloup" / Oral lubrication gel	8718692400504
	8718692401402
	8718692400825
	8718692400856
	8718692400887
	8718692401082
	8718692400948
	8718692400979
	8718692401440
	8718692401297
	8718692401914
	8718692401938
	8718692401952
8718692401976	
8718692401730	
"Gloup Original" / Oral Lubrication gel	8718692401426
	8718692401419
	8718692401174
	8718692401235
	8718692401266
	8718692401143
	8718692401112
	8718692401204
	8718692401464
	8718692401310
	8718692402362
	8718692402386
	8718692402409
8718692402423	
8718692401747	
8718692401372	



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Device name	Reference number / UDI-DI
"Gloup Forte"/ Oral Lubrication gel	8718692401334 8718692402959 8718692402980 8718692403017 8718692403130 8718692403161 8718692403116 8718692403079 8718692403109 8718692401747 8718692402805 8718692403581
"Gloup Zero"/Oral Lubrication gel	8718692403413 8718692402362 8718692402379 8718692402928 8718692403376 8718692403192 8718692403222 8718692401792 8718692403437 8718692403499 8718692403550



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### APPENDIX II: Revision History

<i>Rev</i>	<i>Date</i>	<i>DCN</i>	<i>What changed?</i>	<i>Why did it change?</i>	<i>Author</i>
A	2016-10-07	8	New Layout DoC	New Layout DoC	A. Bruijns
B	2016-10-07	9	Addition of expiry date DoC	Request German authorities	A. Bruijns
C	2017-14-04	10	Adding Reference numbers	Completing list products	B. Luykx
D	2017-21-06	11	Adding Reference numbers	New number bottles	B. Luykx
E	2017-13-09	12	Adding Reference number	New number bottles	B. Luykx
F	2017-27-09	13	Adding text to Risk Classification		A. Bruijns
G	2017-11-08	14	Adding new product	Forte	B. Luykx
H	2018-19-09	15	Adding new product	Zero	B. Luykx
I	2018-05-11	16	Adding stick packs	Original, Forte, Zero	B. Luykx
J	2018-11-27	17	Adding reference number	Zero	B. Luykx
K	2020-01-21	18	Adding reference number	Zero and Forte	B. Luykx
L	2021-05-17	19	Revision to MDR	MDR Complince	A. Bruijns
M	2021-05-31	20	Addition SRN number		A. Bruijns