



DECLARATION OF CONFORMITY

Device Name: OptiLube [Sachets and Tubes]
Device Description: Water soluble, sterile lubricating jelly
Device Information: **Code:** **Description:** **Units:**
See Appendix 1
Device Classification: Class IIa [sterile], Rule 5
GMDN Code: 60796 – General-body orifice lubricant, sterile

Optimum Medical Solutions Ltd hereby declares, under its sole responsibility, that the abovementioned device(s) meets the provisions of Council Directive 93/42/EEC for Medical Devices as amended by directive 2007/47/EC. The device has been subject to the conformity assessment procedures in accordance with Annex V of the Medical Devices Directive 93/42/EEC; and ISO 13485:2016 Quality Management System.

Legal Manufacturer: Optimum Medical Solutions Ltd, Tennant Hall, Blenheim Grove, Leeds, LS2 9ET, UK
Authorised Representative: MT Promedt Consulting GmbH; Altenhofstrasse 80; 66386 St. Ingbert; Germany

Notified Body: Annex V CE Certificate No. CE 665205, BSI CE 2797 [Revised 12.02.2020, Exp 14.09.2022]
Certificates: ISO 13485:2016 Certificate No. MD 665638, BSI CE 0086 [Revised 04.12.2020, Exp 26.08.2023]

Reference to Standards: BS EN ISO 13485:2016, BS EN ISO 14971:2012, BS EN ISO 11137-1:2015, BS EN ISO 11137-2:2015, BS EN ISO 11137-3:2017, EN ISO 11737-1:2018, EN ISO 11737-2:2009, BS EN ISO 11607-1:2017, BS EN ISO 11607-2:2017, BS EN ISO 14644-1:2015, BS EN ISO 15223-1:2016, BS EN ISO 1041:2008 +A1:2013, USP38<51>, ASTM F1980-16, BS EN ISO 10993-1:2018, BS EN ISO 10993-5:2009, BS EN ISO 10993-10:2010, BS EN 62366-1:2015, MEDDEV 2.4/1, MEDDEV 2.7/1, MEDDEV 2.12/1, MEDDEV 2.12/2.

Technical File Ref & Issue: TF002, Issue 09
Date and Place of Issue: 20th May 2021, Optimum Medical Solutions Ltd

Signature:

Name: Gareth Rimmington
Title: Product Director





APPENDIX 1

Device Family	OptiLube Sachets & Tubes		
Short Name			
Device Models	Description	Units/Box	Units/Case
1119S	OptiLube 20g Sachet – single wrapped	20	200
1119	OptiLube 20g Sachet – double wrapped	20	200
1120	OptiLube 5g Sachet	150	1500
1120EGY	OptiLube 5g Sachet	150	1500
1120US	OptiLube 5g Sachet	150	1500
1123	OptiLube 2.7g Sachet	144	1440
1123TW	OptiLube 2.7g Sachet	144	1440
1123US	OptiLube 2.7g Sachet	144	1440
1129	OptiLube 3g Sachet	144	1440
1129US	OptiLube 3g Sachet	144	1440
1110US	OptiLube 56.5g Tube	12	72
1114	OptiLube 10g Tube	30	300
1121	OptiLube 42g Tube	12	72
1121UK	OptiLube 42g Tube	12	144
1121EGY	OptiLube 42g Tube	12	72
1121NGA	OptiLube 42g Tube	12	72
1121TW	OptiLube 42g Tube	12	72
1122	OptiLube 82g Tube	12	72
1122	OptiLube 82g Tube	12	144
1122DR	OptiLube 82g Tube	12	72
1122EGY	OptiLube 82g Tube	12	72
1122NGA	OptiLube 82g Tube	12	72
1122TW	OptiLube 82g Tube	12	72
1124	OptiLube 5g Tube	48	480





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1127	OptiLube 113g Tube	12	72
1127US	OptiLube 113g Tube	12	72
1140	OptiLube 5g reach Tube	36	360
1141	OptiLube 15g reach Tube	24	240

