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EU Declaration of Conformity

Device Name:	**OptiLube**	
Description:	Sterile non-medicated lubricating jelly	
Intended Purpose:	A water-soluble, sterile lubricating jelly intended for the smooth insertion of medical devices, and examinations, reducing the risk of trauma during procedures, including: insertion of catheters, endoscopy, gynaecological examinations, rectal examinations and cystoscopy.	
SRN Number:	GB-MF-000005194	
Basic UDI-DI:	506022247OPTILUBES&TZU	
Risk Classification:	Class IIb, sterile	
Risk Rule:	Annex VIII, Rule 5 and 21. Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body.	
GMDN:	60796	General-body orifice lubricant, sterile
EMDN:	V9007	Sterile instrument lubricants

Optimum Medical Solutions Ltd hereby declares, that the Declaration of Conformity is issued under its sole responsibility and that the device(s) listed meet(s) the provisions of the Medical Device Regulation (EU) 2017/745 of the European Parliament and of the council of 5th April 2017 on medical devices. The device has been subject to the conformity assessment procedure in accordance with Annex IX Chapter I and III of the Medical Device Regulation (EU) 2017/745; and EN 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, Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
QMS Certification:	Certificate No. MD 665638, BSI Assurance UK Ltd (0086), revised 23.08.2023, expires 26.08.2026
Approved Body:	Certificate No. MDR 757549 R000, BSI The Netherlands (CE 2797), issued 19.09.2022, expires 18.09.2027.

Reference to Standards:

BS EN ISO 13485:2016+A11:2021, BS EN ISO 14971:2019+A11:2021, BS EN ISO 11137-1:2015+A2:2019, BS EN ISO 11137-2:2015, BS EN ISO 11137-3:2017, EN ISO 11737-1:2018+A1:2021, EN ISO 11737-2:2020, BS EN ISO 11607-1:2020+A11:2023, BS EN ISO 14644-1:2015, BS EN ISO 15223-1:2021, BS EN ISO 20417:2021, BS EN ISO 10993-1:2020, BS EN ISO 10993-5:2009, BS EN ISO 10993-10:2021, BS EN 62366-1:2015+A1:2020, BS EN 868-5:2018, BS EN ISO/IEC 17050-1:2010, USP38 <51>, ASTM F1980-21, ASTM F1886 / F1886M-16, ASTM F1929-15, ASTM F2054/F2054M-13, ASTM F88M-21, ISTA 3A 2018, ISTA 2A 2012, MEDDEV 2.7/1 REV 4 2010, MEDDEV 2.12/1 REV 8 2019, MEDDEV 2.12/2 REV 2 2012, MDCG 2020-5, MDCG 2020-6, MDCG 2020-7, MDCG 2020-8, MDCG 2020-13, MDCG 2021-24.

Technical File Ref & Issue:	TF002, Issue 03
Date and Place of Issue:	15/11/2023, Optimum Medical Solutions Limited
Signature:	
Name:	Nadine Turner
Title:	Quality and Regulatory Director

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List of Devices

Device Name	Code	Description	Units/Box	Units/Case
OptiLube	1119S	OptiLube 20g Sachet – single wrapped	20	200
OptiLube	1119	OptiLube 20g Sachet – double wrapped	20	200
OptiLube	1120	OptiLube 5g Sachet	150	1500
OptiLube	1120UK	OptiLube 5g Sachet – UK	150	1500
OptiLube	5469000	OptiLube 5g Sachet – Intersurgical	150	1500
OptiLube	1123	OptiLube 2.7g Sachet	144	1440
OptiLube	11233	OptiLube 2.7g Sachet – bulk packaging	720	1440
OptiLube	1114	OptiLube 10g Tube	30	300
OptiLube	1121	OptiLube 42g Tube	12	72
OptiLube	1121UK	OptiLube 42g Tube – UK	12	72
OptiLube	1122	OptiLube 82g Tube	12	72
OptiLube	1122UK	OptiLube 82g Tube – UK	12	72
OptiLube	1122E	OptiLube 82g Tube – Egypt	12	72
OptiLube	1122DR	OptiLube 82g Tube – Dominican Republic	12	72
OptiLube	1124	OptiLube 5g Tube	48	480
OptiLube	1127	OptiLube 113g Tube	12	72
OptiLube	1140	OptiLube 5g reach Tube	36	360
OptiLube	1141	OptiLube 15g reach Tube	24	240

Optimum Medical is a trading name of Optimum Medical Solutions Ltd
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