

# Technical File - Section 1 (Declaration of Conformity)



## MANUFACTURER'S DECLARATION OF CONFORMITY Medical Devices Directive

DermLite LLC declares that the devices listed on the attached product schedule conform to the relevant sections of The Medical Devices Directive 93/42/EEC.

**Manufacturer's Name:** DermLite LLC

**Business Address:** 21 Argonaut, Unit A, Aliso Viejo, CA 92656, USA

**SRN (Single Registration Number)** (US-MF-000005170)

**Basic UDI-DI:** 0855997006DL180218J

**Medical Device(s):** See Attached Product Schedule

**Classification:** Class I

**Conformity Assessment Route:** Annex IV

**GMDN Code and Term:** 18021 – Dermatoscope, Optical

**Scope of Application:** All devices to which the Declaration of Conformity Procedure has been applied

The medical devices in the attached product schedule comply with the applicable provisions of the essential principles and the classification rules before being supplied.

These devices and their manufacturing processes do not incorporate any animal substances, nor do the devices incorporate medicinal substances.

**Notified Body:** N/A

**CE Mark Certificate number:** N/A

**Expiry date of CE Mark Certificate:** N/A

**Standards Applied:** EN 13485; EN 14971; EN 20417; EN 15223-1, EN 60601-1 & EN 60601-1-2

**Registrations:** MHRA

**Responsible Person:** Responsible Person Ltd. Summit House, 4-5 Mitchell Street, Edinburgh, United Kingdom, EH6 7BD

**Authorised Signatory:**

  
John Bottjer (May 18, 2023 17:03 EDT)

Name: John Bottjer, President, DermLite LLC

May 18, 2023

Date

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Product Code	Device Name	Class	Family	Use Single / Reusable	Sterile or non-sterile	Method of Sterilisation ETO; Gamma; etc	Custom Made or Procedure Pack/Kit	GMDN Code	GMDN Term
DL200HY	DermLite DL200 Hybrid Gold	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL100	DermLite DL100	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
LUM	DermLite Lumio	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DLU2	DermLite Lumio 2	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DLC	DermLite Carbon	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL1	DermLite DL1	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DLUS	DermLite Lumio S	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL3N	DermLite 3 DL3N	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DLF2P	DermLite Foto II Pro	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
LUM UV	DermLite Lumio UV	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL1	DermLite 1	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL1B	DermLite DL1 Basic	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
HÜD	DermLite HUD	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL200HY	DermLite DL200 Hybrid	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL200HR	DermLite DL200 HR	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL4	DermLite DL4	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL4W	DermLite DL4W	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DLGL	DermLite GL	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL200HYG	DermLite DL200 Hybrid	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DLFX	DermLite Foto X	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
FFH2	DermLite handyscope	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
NL1	DermLite Nailio	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
V900L	DermLite Syris V900L	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
HÜD2	DermLite HÜD2 Home Skin Monitor	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical
DL5	DermLite DL5	I	DermLite	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical

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ICDL200-100	Accessory to DL200, Non-sterile Single Use Covers, 100-pack	I	DermLite (Accessory)	Single Use	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
ICDL200-25	Accessory to DL200, Non-sterile Single Use Covers, 25-pack	I	DermLite (Accessory)	Single Use	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
ICDL4-100	Accessory to DL4 & Foto X, Non-sterile Single Use Covers, 100-pack	I	DermLite (Accessory)	Single Use	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
ICDL4-25	Accessory to DL4 & Foto X, Non-sterile Single Use Covers, 25-pack	I	DermLite (Accessory)	Single Use	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
ICFFH2-25	Accessory to FFH2 Handyscope Non-sterile Single Use Covers, 25-pack	I	DermLite (Accessory)	Single Use	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
ICNL1-50	Accessory to NL1 Nailio Non-sterile Single Use Covers, 50-pack	I	DermLite (Accessory)	Single Use	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
DL200SCP	Accessory to DL200, Small Area Contact Plate	I	DermLite (Accessory)	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
DL4SCP	Accessory to DL4, Small Area Contact Plate	I	DermLite (Accessory)	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
DL5-IC25	Accessory to DL5, Non-sterile Single Use Covers, 25- Pack	I	DermLite (Accessory)	Single Use	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
DL5-CPG	Accessory to DL5, Contact Plate – Grid	I	DermLite (Accessory)	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)
DL5-SCP	Accessory to DL5, Small Contact Plate	I	DermLite (Accessory)	Reusable	Non-sterile	N/A	No	18021	Dermatoscope, Optical (Accessory)







# MDOCUK-0001 Rev E Final

Final Audit Report

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