



SUNOPTIC TECHNOLOGIES, LLC TM
6018 BOWDENDALE AVENUE
JACKSONVILLE, FLORIDA 32216 USA
PHONE: 904-737-7611 · FAX: 904-733-4832

DECLARATION OF CONFORMITY

- I. **MANUFACTURER**
Sunoptic Technologies®, LLC
6018 Bowdendale Avenue, Jacksonville, FL 32216
SRN: US-MF-000006235
- II. **AUTHORIZED REPRESENTATIVE**
AJW Technology Consulting GmbH
Königsallee 106
40215 Düsseldorf, Germany
- III. **NOTIFIED BODY**
DQS Medizinprodukte GmbH (0297)
August-Schanz-Straße 21
D-60433 Frankfurt am Main
Phone: +49 69 95427-388
- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: LED 050, 1000, 2000
Reference: See Attached
Product Description: LED Light Source
Basic UDI-DI: ++M678LED509P
Intended Use:
To provide light for illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. **UMDNS CODE:** 12340

This Declaration of Conformity has been issued under the sole responsibility of Sunoptic Technologies, LLC, located at 6018 Bowdendale Ave., Jacksonville, FL 32216 located in the USA.

I, Robert M. Archie, Director of QA/RA and Management Representative, hereby declare, on behalf of Sunoptic Technologies, LLC, that the medical devices, as listed within this Declaration, conform to Annex IX of the MDR Directive 2017/745, on this day of: 8/9/2021

Robert M. Archie, Director of QA/RA
Sunoptic Technologies, LLC

9-Aug-2021
Date

REFERENCE

| | | | | |
|-------------|-------------|--------------|-------------|----------|
| SSL-2000T-C | SSL-2000T-D | SSL-2000T-AU | SSL-2000T-J | SSL-4LPA |
| SSL-2000T-K | SSL-2000T-A | SSL-4LAW | | |

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|-------------|-------------|--------------|-------------|----------|
| LLS-2000T-C | LLS-2000T-D | LLS-2000T-AU | LLS-2000T-J | LLS-4LPA |
| LLS-2000T-K | LLS-2000T-A | LLS-4LAW | | |

END of LIST



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D-60433 Frankfurt am Main
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- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: LED 4000
Reference: See Attached
Product Description: LED Light Source
Basic UDI-DI: ++M678LED4000X5
Intended Use:
To provide light for illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. **UMDNS CODE:** 12340

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I, Robert M. Archie, Director of QA/RA and Management Representative, hereby declare, on behalf of Sunoptic Technologies, LLC, that the medical devices, as listed within this Declaration, conform to Annex IX of the MDR Directive 2017/745, on this day of: 8/9/2021

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Sunoptic Technologies, LLC

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|-----------------|----------------|----------------|----------------|-----------------|
| SSL-4000T-SC-K | SSL-4000T-SC-A | SSL-4000T-SC-C | SSL-4000T-SC-D | SSL-4000T-SC-AU |
| SSL-4000T-SC-J | SSL-4000T-HC-K | SSL-4000T-HC-A | SSL-4000T-HC-C | SSL-4000T-HC-D |
| SSL-4000T-HC-AU | SSL-4000T-HC-J | / | / | / |

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|-----------------|----------------|----------------|----------------|-----------------|
| LLS-4000T-SC-K | LLS-4000T-SC-A | LLS-4000T-SC-C | LLS-4000T-SC-D | LLS-4000T-SC-AU |
| LLS-4000T-SC-J | LLS-4000T-HC-K | LLS-4000T-HC-A | LLS-4000T-HC-C | LLS-4000T-HC-D |
| LLS-4000T-HC-AU | LLS-4000T-HC-J | / | / | / |

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- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: LED 3000
Reference: See Attached
Product Description: LED Light Source
Basic UDI-DI: ++M678LED3000WW
Intended Use:
To provide light for illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. **UMDNS CODE:** 12340

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|-------------|--------------|-------------|-------------|-------------|
| SSL-3000T-D | SSL-3000T-AU | SSL-3000T-J | SSL-3000T-K | SSL-3000T-A |
| SSL-3000T-C | | | | |

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|-------------|-------------|-------------|-------------|--------------|
| LLS-3000T-K | LLS-3000T-A | LLS-3000T-C | LLS-3000T-D | LLS-3000T-AU |
| LLS-3000T-J | | | | |

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- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: N/A
Reference #: See attached
Product Description: Headlight Fiberoptic Cable, Bifurcated and Accessories
Basic UDI-DI: ++M678HLCYW
Intended Use:
To provide the transmission of light for the illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 4, Rule 1 of Annex VIII
- VII. **UMDNS CODE:** 15308

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I, Robert M. Archie, Director of QA/RA, and Management Representative, hereby declare, on behalf of Sunoptic Technologies, LLC, that the medical devices, as listed within this Declaration, conform to Annex IX of the MDR Directive 2017/745, on this day of: 8/9/2021

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|----------------|-------------------|----------------|-------------------|----------------|
| SU-0080 | SU-0087 | SU-0088 | SU-0088-10 | SU-0097 |
| SU-2900 | SU-2900-WS | SU-HDC2 | SL-0080 | SL-0088 |
| SL-0097 | SL-2900 | SU-0089 | | |

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|--------------|--------------|--------------|----------------|--------------|
| C0100 | C0101 | C0102 | C0103 | C0104 |
| C0105 | C0106 | C0107 | C0200 | C0201 |
| C0202 | C0203 | C0204 | C0205 | C0206 |
| C0225 | C026 | WPB1 | EX-0203 | |

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- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: Surgical Headlight
Part Number(s): See Attached
Product Description: Surgical Headlight
Basic UDI-DI: ++M678HLFU
Intended Use:
To provide light for illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 4, Rule 1 of Annex VIII
- VII. **UMDNS CODE:** 12345

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|-------------------------|--------------------------|-------------------------|---------------------------|-----------------------|
| SG35-110-VHB | SG-35-110-VHB-B | SG35-110-VHB-EXL | SG35-110-VHB-EXL-B | SG35-110-VSS |
| SG35-110-VSS-EXL | SG35-140-VHB | SG40-110-VHB-B | SG40-110-VHB-EXL-B | SG35-140-VSS |
| SG35C-110-VHB | SG35C-110-VHB-EXL | SG35C-110-VSS | SG39-110-VHB | SG40-110-VHB |
| SL35-110-VHB | SL35-110-VHB-S | SL35-110-VSS | SL40-110-VHB | SSL35C-110-VHB |

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|---------------------|--------------------------|-----------------|--------------------|---------------------|
| CNH-80B-SG | DCH-110B | DCH-110S | DRH-110B | DRH-110B-ESG |
| DRH-110B-LED | DRH-110B-LED-STRT | DRH-110S | SOH-110B-SG | SOH-110S |

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- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: Tx450D, Tx350D, Tx350A
Reference: See Attached
Product Description: Xenon Light Source, Tx Series
Basic UDI-DI: ++M678TXHQ
Intended Use:
To provide light for illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. **UMDNS CODE:** 12345

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|----------------|----------------|---------------|---------------|----------------|
| TITANX450ST-K | TITANX450ST-A | TITANX450ST-C | TITANX450ST-D | TITANX450ST-AU |
| TITANX450ST-J | TITANX350ST-K | TITANX350ST-A | TITANX350ST-C | TITANX350ST-D |
| TITANX350ST-AU | TITANX350ST-J | TITANX300ST-K | TITANX300ST-A | TITANX300ST-C |
| TITANX300ST-D | TITANX300ST-AU | TITANX300ST-J | | |

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|-------------|--------------|-------------|-------------|-------------|
| EX-400T-K | EX-400T-A | EX-400T-C | EX-400T-D | EX-400T-AU |
| EX-400T-J | EX-300T-K | EX-300T-A | EX-300T-C | EX-300T-D |
| EX-300T-AU | EX-300T-J | ELITE1000-K | ELITE1000-A | ELITE1000-C |
| ELITE1000-D | ELITE1000-AU | ELITE1000-J | | |

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D-60433 Frankfurt am Main
Phone: +49 69 95427-388
- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: LED-9000
Part Number(s): See Attached
Product Description: LED Headlight, Battery Operated
Basic UDI-DI: ++M678LED9000Y5
Intended Use:
To provide light for illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. **UMDNS CODE:** 11963

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|-----------------|-----------------|-----------------|------------------|------------------|
| SSL-9500-K | SSL-9500-A | SSL-9500-C | SSL-9500-D | SSL-9500-AU |
| SSL-9500-J | SSL-9500-B-K | SSL-9500-B-A | SSL-9500-B-C | SSL-9500-B-D |
| SSL-9500-B-AU | SSL-9500-B-J | SSL-9500-SB-K | SSL-9500-SB-A | SSL-9500-SB-C |
| SSL-9500-SB-D | SSL-9500-SB-AU | SSL-9500-SB-J | SSL-9500-DB-K | SSL-9500-DB-A |
| SSL-9500-DB-C | SSL-9500-DB-D | SSL-9500-DB-AU | SSL-9500-DB-J | SSL-9500-DB-B-K |
| SSL-9500-DB-B-A | SSL-9500-DB-B-C | SSL-9500-DB-B-D | SSL-9500-DB-B-AU | SSL-9500-DB-B-J |
| SSL-9500-SBDB-K | SSL-9500-SBDB-A | SSL-9500-SBDB-C | SSL-9500-SBDB-D | SSL-9500-SBDB-AU |
| SSL-9500-SBDB-J | SSL-LX2-C | SSL-LX2-J | SSL-LX2-K | SSL-LX2-A |
| SSL-LX2-D | SSL-LX2-AU | SSL-LX2-CH-AU | SSL-LX2-CH-J | SSL-LX2-CH-K |
| SSL-LX2-CH-A | SSL-LX2-CH-C | SSL-LX2-CH-D | SSL-LX2-SB-J | SSL-LX2-SB-AU |
| SSL-LX2-SB-K | SSL-LX2-SB-A | SSL-LX2-SB-C | SSL-LX2-SB-D | |

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|-----------------|-----------------|-----------------|------------------|------------------|
| LLS-9500-K | LLS-9500-A | LLS-9500-C | LLS-9500-D | LLS-9500-AU |
| LLS-9500-J | LLS-9500-B-K | LLS-9500-B-A | LLS-9500-B-C | LLS-9500-B-D |
| LLS-9500-B-AU | LLS-9500-B-J | LLS-9500-SB-K | LLS-9500-SB-A | LLS-9500-SB-C |
| LLS-9500-SB-D | LLS-9500-SB-AU | LLS-9500-SB-J | LLS-9500-DB-K | LLS-9500-DB-A |
| LLS-9500-DB-C | LLS-9500-DB-D | LLS-9500-DB-AU | LLS-9500-DB-J | LLS-9500-DB-B-K |
| LLS-9500-DB-B-A | LLS-9500-DB-B-C | LLS-9500-DB-B-D | LLS-9500-DB-B-AU | LLS-9500-DB-B-J |
| LLS-9500-SBDB-K | LLS-9500-SBDB-A | LLS-9500-SBDB-C | LLS-9500-SBDB-D | LLS-9500-SBDB-AU |
| LLS-9500-SBDB-J | LLS-LLX-C | LLS-LLX-J | LLS-LLX-K | LLS-LLX-A |
| LLS-LLX-D | LLS-LLX-AU | LLS-LLX-CH-AU | LLS-LLX-CH-J | LLS-LLX-CH-K |
| LLS-LLX-CH-A | LLS-LLX-CH-C | LLS-LLX-CH-D | LLS-LLX-SB-J | LLS-LLX-SB-AU |
| LLS-LLX-SB-K | LLS-LLX-SB-A | LLS-LLX-SB-C | LLS-LLX-SB-D | |

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- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: LED-5500
Part Number(s): See Attached
Product Description: LED Headlight, Battery Operated
Basic UDI-DI: ++M678LED5500Y5
Intended Use:
To provide light for illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. **UMDNS CODE:** 11963

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|---------------------|-----------------------|-----------------|-------------------|
| SSL-5500-KIT | SSL-5500-B-KIT | SSL-5500 | SSL-5500-B |
| SSL-5500-B-K | | | |

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| LLS-5500-KIT | LLS-5500 | | |
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- IV. **QUALITY SYSTEM**
DIN EN ISO 13485:2016 + AC:2017-07
EN ISO 13485:2016 + AC:2016
ISO 13485:2016
- V. **PRODUCT INFORMATION**
NB Conformity Assessment: N/A
Model Number: ROVER
Reference: SSL-4LPA, SSL-4LPW
Product Description: LED Light Source, Rover Series
Basic UDI-DI: ++M678ROVERL8
Intended Use:
To provide light for illumination of a surgical site / field.
- VI. **RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. **UMDNS CODE: 12276**

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