



SUNOPTIC TECHNOLOGIES, LLC ™  
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		

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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- 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

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

9 - Aug - 2021

Date

## REFERENCE

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	/	/	/

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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Sunoptic Technologies, LLC

9 - Aug - 2021  
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**REFERENCE**

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

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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9-Aug-2021  
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<b>SU-0080</b>	<b>SU-0087</b>	<b>SU-0088</b>	<b>SU-0088-10</b>	<b>SU-0097</b>
<b>SU-2900</b>	<b>SU-2900-WS</b>	<b>SU-HDC2</b>	<b>SL-0080</b>	<b>SL-0088</b>
<b>SL-0097</b>	<b>SL-2900</b>	<b>SU-0089</b>		

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

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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:** 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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<b>SG35-110-VHB</b>	<b>SG-35-110-VHB-B</b>	<b>SG35-110-VHB-EXL</b>	<b>SG35-110-VHB-EXL-B</b>	<b>SG35-110-VSS</b>
<b>SG35-110-VSS-EXL</b>	<b>SG35-140-VHB</b>	<b>SG40-110-VHB-B</b>	<b>SG40-110-VHB-EXL-B</b>	<b>SG35-140-VSS</b>
<b>SG35C-110-VHB</b>	<b>SG35C-110-VHB-EXL</b>	<b>SG35C-110-VSS</b>	<b>SG39-110-VHB</b>	<b>SG40-110-VHB</b>
<b>SL35-110-VHB</b>	<b>SL35-110-VHB-S</b>	<b>SL35-110-VSS</b>	<b>SL40-110-VHB</b>	<b>SSL35C-110-VHB</b>

<b>CNH-80B-SG</b>	<b>DCH-110B</b>	<b>DCH-110S</b>	<b>DRH-110B</b>	<b>DRH-110B-ESG</b>
<b>DRH-110B-LED</b>	<b>DRH-110B-LED-STRT</b>	<b>DRH-110S</b>	<b>SOH-110B-SG</b>	<b>SOH-110S</b>

**END of LIST**



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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:** 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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9-Aug-2021

Date

## REFERENCE

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		

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

9-Aug-2021  
Date

## REFERENCE

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	

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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Robert M. Archie, Director of QA/RA  
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9 - Aug - 2021  
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<b>SSL-5500-KIT</b>	<b>SSL-5500-B-KIT</b>	<b>SSL-5500</b>	<b>SSL-5500-B</b>
<b>SSL-5500-B-K</b>			

<b>LLS-5500-KIT</b>	<b>LLS-5500</b>		

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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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