



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
Breite Straße 3
40213 Düsseldorf, Germany
Telephone: +49 211 54059 6030
- 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: 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

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: 5/20/2022

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

5-20-2022

Date

Expiration Date: This declaration of conformity expires three (3) years from the signature date limited by the issuance of a new declaration of conformity after the addition of a new product or a change in the product(s) listed.

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	TITANX400ST-A	TITANX400ST-K
TITANX400ST-A	TITANX400ST-C	TITANX400ST-D	TITANX400ST-AU	TITANX400ST-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	400CX-K	400CX-A
400CX-C	400CX-D	400CX-AU	400CX-J	

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: DPLS-01
Reference: See Attached
Product Description: Xenon Light Source, General Purpose
Basic UDI-DI: ++M678DPLS300W0KJ
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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Sunoptic Technologies, LLC

5-20-2022

Date

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REFERENCE

SSL-P300ST-K	SSL-P300ST-A	SSL-P300ST-AU	SSL-P300ST-C	SSL-P300ST-D
SSL-P300ST-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 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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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	SSL-4500T-SC-A	SSL-4500T-SC-C	SSL-4500T-SC-D
SSL-4500T-SC-J	SSL-4500T-SC-K	SSL-4500T-SC-AU		

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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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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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: LLS-050
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

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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	/	/

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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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REFERENCE

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

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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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: 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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REFERENCE

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		

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

END of LIST



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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: N/A
Reference #: See Attached
Product Description: Fiberoptic Cable and Accessories
Basic UDI-DI: ++M678FOCYV
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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REFERENCE

EQ-BLU30U072	EQ-BLU30U090	EQ-BLU30U108	EQ-BLU40U072	EQ-BLU40U090
EQ-BLU40U108	EQ-BLU50U072	EQ-BLU50U090	EQ-BLU50U108	EQ-BLU50U090-CR
EQ-GYW50-W108	EQ-GYA50W108	EQ-GYS48P090	EQ-GYO50W108	EQ-BLS50F108
EQ-BLAO50S090	EQ-GYA50S108	EQ-GTAO40S090	AQ4CLO50S108	

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: LHD-30
Reference #: See Attached
Product Description: Wireless Video Camera System
Basic UDI-DI: ++M678WCS3H
Intended Use:
To record, display and playback video of surgical procedures.
- VI. **RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. **UMDNS CODE:** 10559

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REFERENCE

SSL-LHD-30	LLS-LHD-30	SSL-LHD-CAM	SSL-LHD-30-A
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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: HDC-300, HDC-100
Reference #: See Attached
Product Description: Video Camera System and Accessories (acc)
Basic UDI-DI: ++M678CSFT
Intended Use:
To record, display and playback video of surgical procedures.
- VI. RISK CLASSIFICATION**
Class I per Section 6, Rule 13 of Annex VIII
- VII. UMDNS CODE:** 10559

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REFERENCE

HDC-300	HDC-300-DEMO	HDC-HC	HDC-100-CONSOLE
HDC-HC	HDC-100	HDC-100-DEMO	
HDC-FS1 (acc)	HDC-VM1 (acc)	HDC-VC2 (acc)	

CSC-300	CSC-300-DEMO	CSC-300-CONSOLE	CSC-HC
CSC-100	CSC-100-CONSOLE		
CSC-FS1 (acc)	CSC-VC2 (acc)	CSC-VM1 (acc)	

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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

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: 5/20/2022

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

5-20-2022

Date

Expiration Date: This declaration of conformity expires three (3) years from the signature date limited by the issuance of a new declaration of conformity after the addition of a new product or a change in the product(s) listed.

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	

END of LIST



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
Breite Straße 3
40213 Düsseldorf, Germany
Telephone: +49 211 54059 6030
- 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-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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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: 5/20/2022

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

5-20-2022

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REFERENCE

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

LLS-5500-KIT	LLS-5500		

END of LIST