

BẢN SAO



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 11070-6-2017

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
See Attached List (Three Pages)	See Attached List (One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Robin W. Newman
 Robin W. Newman MSN EdD CPNP
 Director
 Office of Compliance
 Center for Devices and Radiological Health
 U.S. Food and Drug Administration, DHHS

CHỨNG THỰC BẢN SAO ĐÚNG VỚI BẢN CHÍNH

This certificate is valid from June 27, 2017 to June 26, 2019.
 Ngày: 24-05-2018

Số chứng thực: 1295 01 Quyền số: SCT/BS



CÔNG CHỨNG VIÊN
Chu Cảnh Hưng





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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

DKK DAI-ICHI SHOMEI CO, LTD
32-26, SAKASHITA 1-CHOME
ITABASHI-KU, Tokyo JAPAN 174-0043

Name of Distributor

Skytron, LLC
5085 Corporate Exchange Blvd SE
Grand Rapids, MI USA 49512

---END OF MANUFACTURER/DISTRIBUTOR LIST---





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VCALFSAUA7

VCALFSAUA5

VCALFSAUA75

VCALFSAUA55

LFSVCAAUA7

LFSVCAAUA5

LFSVCAAUA75

LFSVCAAUA55

Surgical Lights

Stellar XL Series

LFSSTX55

LFSLSSTX5

LFSLSSTX55

LFSSTX5

LFSSTX555

STX-EH-555

STX5-1090

STX5-1090B

STX5-1285

STX5-1285B

STX5-895

STX5-895B

STX5-EA-1500

STX5-EA-2000

STX5-EH-1090

STX5-EH-1285

STX5-EH-1500

STX5-EH-2000

STX5-EH-895

STX5-HY-1090

STX5-HY-1285

STX5-HY-1500

STX5-HY-895

STX55-1090/895

STX55-1090/895B

STX55-1285/1090

STX55-1285/1090B

STX55-895/700

STX55-895/700B

STX55-EA-1500/1300

STX55-EA-2000/1500

STX55-EH-1090/895

STX55-EH-1285/1090

STX55-EH-1500/1300

STX55-EH-2000/1500

STX55-EH-895/700

STX555

STX5S

Exam Lights

SPECTRA Series

AUT1C

AUT1W

AUT1S

Exam Lights

Lucina 4 Series

LCN4-PKG1

LCN4-PKG2

LCN4-PKG3



PH
NG
NG
NG
PH



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LCN4-PKG4
Exam Lights
Aurora Astro Series
AUA3-1090
AUA3-1090B
AUA3-1285
AUA3-1285B
AUA3-895
AUA3-895B
AUA3-EA-1500
AUA3-EA-2000
AUA3-EH-1090
AUA3-EH-1285
AUA3-EH-1500
AUA3-EH-2000
AUA3-EH-895
AUA3-HY-1090
AUA3-HY-1285
AUA3-HY-1500
AUA3-HY-895
AUA33-1090/895
AUA33-1090/895B
AUA33-1285/1090
AUA33-1285/1090B
AUA33-895/700
AUA33-895/700B
AUA33-EA-1500/1300
AUA33-EA-2000/1500
AUA33-EH-1090/895
AUA33-EH-1285/1090
AUA33-EH-1500/1300
AUA33-EH-2000/1500
AUA33-EH-895/700
AUA3S
LFSUA3
LFSUA33
LFSLFSUA3
LFSLFSUA33

-----END OF PRODUCT LIST-----

