19060711-1

# United States of America



### **DEPARTMENT OF STATE**

### To all to whom these presents shall come, Greetings:

I Certify That the document hereunto annexed is under the Seal of the Department of Health and Human Services, United States of America, and that such Seal is entitled to full faith and credit.\*

\*For the contents of the annexed document, the Department assumes no responsibility This certificate is not valid if it is removed or altered in any way whatsoever

> In testimony whereof, I, Michael R. Pompeo, Secretary of State, have hereunto caused the seal of the Department of State to be affixed and my name subscribed by the Assistant Authentication Officer, of the said Department, at the city of Washington, in the District of Columbia, this seventeenth day of September, 2019.

*Issued pursuant to CHXIV. State of Sept.* 15, 1789, 1 Stat. 68-69; 22 *USC* 2657; 22*USC* 2651a; 5 *USC* 301; 28 *USC* 1733 et. seq.; 8 *USC* 1443(f); RULE 44 Federal Rules of *Civil Procedure.* 

By\_ Rep Mr. Secretary of State

Assistant Authentication Officer, Department of State



U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov

Certificate No. 11138-6-2019

#### 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:

#### Name of Product(s)

See Attached List

(One Page)

#### Name of Manufacturer/Distributor, Address

Name of Manufacturer

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.

Sincerely,

a

CDR Cesar A. Perez, PhD, Director DRP2: Division of Establishment Support Office of Regulatory Programs Office of Product Evaluation and Quality Center for Devices and Radiological Health U.S. Food and Drug Administration, DHHS

This certificate is valid from June 25, 2019 to June 24, 2021.



E03798047



U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov

Certificate No. 11138-6-2019 Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1 Name of Manufacturer LIGER MEDICAL LLC

#### Name of Product(s)

TC Thermocoagulator HTU-110 HTU-110A HTU-110B HTU-110C HTU-16F HTU-19F HTU-19F Electrosurgical Generator Unit ESU-110 Electrocautery Unit ECU-110 ------END OF PRODUCT LIST------



E03798048



3300 North Running Creek Way Building G, Basement Suite G20 Lehi, Utah 84043 United States of America 801-256-6576 www.ligermedical.com

## **FDA CFG Listed Countries**

## Purpose

This document lists all the countries listed with Liger Medical's US FDA issued Certificate to Foreign Government (Certificate No. 11138-6-2019). This certificate expires on June 24, 2021.

## Scope

The following is a list of all countries listed with the FDA when this certificate was filed.

AFGHANISTAN	BAHRAIN
ALAND ISLANDS	BANGLADESH
ALBANIA	BARBADOS
ALGERIA	BELARUS
AMERICAN SAMOA	BELGIUM
ANDORRA	BELIZE
ANGOLA	BENIN
ANGUILLA	BERMUDA
ANTARCTICA	BHUTAN
ANTIGUA AND BARBUDA	BOLIVIA, PLURINATIONAL STATE
ARGENTINA	OF
ARMENIA	BOSNIA AND HERZEGOVINA
ARUBA	BOTSWANA
AUSTRALIA	BOUVET ISLAND
AUSTRIA	BRAZIL
	BRITISH INDIAN OCEAN
AZERBAIJAN	TERRITORY
BAHAMAS	BRUNEI DARUSSALAM



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## **FDA CFG Listed Countries**

BULGARIA	CURACAO
BURKINA FASO	CYPRUS
BURUNDI	CZECH REPUBLIC
CAMBODIA	DENMARK
CAMEROON	DJIBOUTI
CANADA	DOMINICA
CAPE VERDE	DOMINICAN REPUBLIC
CAYMAN ISLANDS	ECUADOR
CENTRAL AFRICAN REPUBLIC	EGYPT
CHAD	EL SALVADOR
CHILE	EQUATORIAL GUINEA
CHINA	ERITREA
CHRISTMAS ISLAND	ESTONIA
COCOS (KEELING) ISLANDS	ETHIOPIA
COLOMBIA	FALKLAND ISLANDS (MALVINAS)
COMOROS	FAROE ISLANDS
CONGO	FIJI
CONGO, THE DEMOCRATIC	FINLAND
REPUBLIC OF THE	FRANCE
COOK ISLANDS	FRENCH GUIANA
COSTA RICA	FRENCH POLYNESIA
COTE D'IVOIRE	FRENCH SOUTHERN
CROATIA	TERRITORIES
CUBA	GABON



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GAMBIA	INDIA
GEORGIA	INDONESIA
GERMANY	IRAN, ISLAMIC REPUBLIC OF
GHANA	IRAQ
GIBRALTAR	IRELAND
GREECE	ISLE OF MAN
GREENLAND	ISRAEL
GRENADA	ITALY
GUADELOUPE	JAMAICA
GUAM	JAPAN
GUATEMALA	JERSEY
GUERNSEY	JORDAN
GUINEA	KAZAKHSTAN
GUINEA-BISSAU	KENYA
GUYANA	KIRIBATI
HAITI	KOREA, DEMOCRATIC PEOPLE'S
HEARD ISLAND AND	REPUBLIC OF
MCDONALD	KOREA, REPUBLIC OF
	KOSOVO
HOLY SEE (VATICAN CITY STATE)	KUWAIT
HONDURAS	KYRGYZSTAN
HONG KONG SAR	LAO PEOPLE'S DEMOCRATIC
HUNGARY	REPUBLIC
ICELAND	LATVIA



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LEBANON	PARAGUAY
MOROCCO	PERU
MOZAMBIQUE	PHILIPPINES
MYANMAR	PITCAIRN
NAMIBIA	POLAND
NAURU	PORTUGAL
NEPAL	PUERTO RICO
NETHERLANDS	QATAR
NEW CALEDONIA	REUNION
NEW ZEALAND	ROMANIA
NICARAGUA	RUSSIAN FEDERATION
NIGER	RWANDA
NIGERIA	SAINT HELENA, ASCENSION AND
NIUE	TRISTAN
NORFOLK ISLAND NORTHERN MARIANA ISLANDS NORWAY	DA CUNHA
	SAINT KITTS AND NEVIS
	SAINT LUCIA
OMAN	SAINT MARTIN
PAKISTAN	SAINT PIERRE AND MIQUELON
PALAU	SAINT VINCENT AND THE GRENADINES
PALESTINIAN TERRITORY,	SAMOA
OCCUPIED	SAN MARINO
PANAMA	SAO TOME AND PRINCIPE
PAPUA NEW GUINEA	SAUDI ARABIA



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SENEGAL	TAIWAN
SERBIA	TAJIKISTAN
SEYCHELLES	TANZANIA, UNITED REPUBLIC
SIERRA LEONE	OF
SINGAPORE	THAILAND
SINT MAARTEN	TIMOR-LESTE
SLOVAKIA	TOGO
SLOVENIA	TOKELAU
SOLOMON ISLANDS	TONGA
SOMALIA	TRINIDAD AND TOBAGO
SOUTH AFRICA	TUNISIA
SOUTH AFRICA	TURKEY
SOUTH	TURKMENISTAN
SANDWICH ISLANDS	TURKS AND CAICOS ISLANDS
SOUTH SUDAN	TUVALU
SPAIN	UGANDA
SRI LANKA	UKRAINE
SUDAN	UNITED ARAB EMIRATES
SURINAME	UNITED KINGDOM
SVALBARD AND JAN MAYEN	UNITED STATES MINOR
SWAZILAND	OUTLYING ISLANDS
SWEDEN	URUGUAY
SWITZERLAND	UZBEKISTAN
SYRIAN ARAB REPUBLIC	VANUATU



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VENEZUELA, BOLIVARIAN REPUBLIC OF VIET NAM VIRGIN ISLANDS, BRITISH VIRGIN ISLANDS, U.S.

WALLIS AND FUTUNA WESTERN SAHARA YEMEN ZAMBIA ZIMBABWE