DAEJU

Meditech Engineering

Global Leader of Aesthetic Medical Instruments

Contents

1 Company Introduction

1 Company Introduction

- The CEO of Daeju Meditech Engineering Company Ltd (Mr. Charles Kim) has been engaging in the business of Aesthetic Medical devices since 1996 for Korean markets.
- On the bases of these experiences of his what Medical doctors need and want, Daeju Meditech Engineering was founded in 2005 year for pursuing these goals.
- Since its foundation in 2005, all members of Daeju Meditech Engineering Co., Ltd has been striving for the highest standards for the production and development of Aesthetic Medical devices with the economical manufacturing for customers' satisfaction.
- Nowadays we are proud of ourselves for the reputation as one of the best manufacturers in the field of Aesthetic and Medical devices in Korea.
- We are sure that it has been resulted from the continuous efforts for the investment for R&D, promotions for the capable engineering power and good workmanship for manufacturing since the foundation.
- We are not satisfied with this effort, but we will do our best to serve you until your 100% satisfaction without stopping.
- With the slogan of your 100% satisfaction, we are also looking forwards to giving us your unchanged patronage and faith.

2 Company Overview

2 Company Overview

Company Name	Daeju Meditech Engineering Co., Ltd
Business Registration No.	488-87-00220

Name of Representative	Charles KIM
Equity Capital	US$ 300,000
Amount of Annual Sales	US$ 5,500,000
Number of Employee	25 (Office 10, R&D 5, Manufacturing 10)
Year of Establishment	2005

3 Company History

3 Company History

Daeju Meditech Engineering reputation has been established by dealers, doctors and dermatology facilities in the world with the top laser devices since 2005. Your best supplier, Daeju has revolutionized you and your client's business in the aesthetic & medical industries.

2020
-Launched TINEA
-Acquired TGA & GOST

2019
-Launched CLINLUX (Cosmetics)
-Launched ACTIVO (Nd: YAG)
-LaunchedAROMAII (800W)

2017
Acquired the global growth export-oriented company

2016
Acquired patent right for HIPRO-V

2015
Acquired CE for Hipro

2014
Launched Hipro (HIFU)

2011
Acquired CE for Pentagon & Aroma

2010
-Acquired KFDA and FDA for Aroma
-Launched AROMA

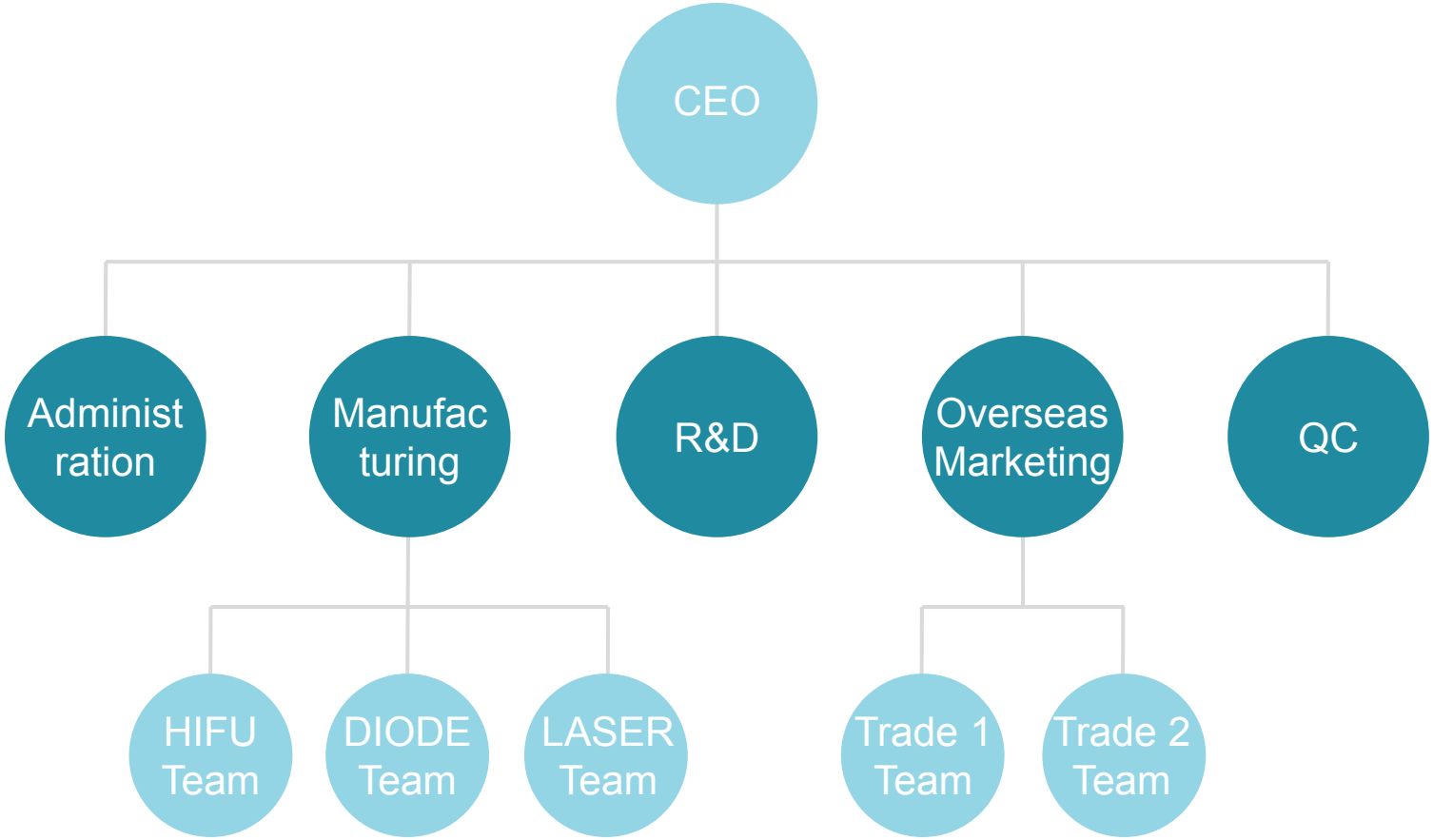
2007
-Acquired KFDA for Pentagon
-Launched Pentagon

2006
-Acquired ISO13485 certification
-Acquired KGMP compliance certificate

2005
Establishment of Company for the medical laser

4 Company Organization

4 Company Organization



5 Product Lines

5 Product Lines

Since 2005 year, we, all of Daeju Meditech people, have been considering how to support the medical doctors, beauticians and therapists from our aesthetic medical devices; robust devices with economical prices.

Also we have been striving for the highest standards for the production and development of medical device system with new concept ideas.

We are not satisfied with the current achievement for exporting our devices to more than 40 countries, but will expand our varieties of products to let our clients satisfied.

Exports more than 40 countries.

6 Product- Devices

6 Product -HIFU

HIPRO STANDARD → HIPRO-S → HIPRO-V → HIPRO-Q

SYSTEM SPECIFICATION

Energy Type	High Intensity Focused Ultrasound
Energy Output	0.1J ~ 2.0[J / ㎠]
Electrical	AC 100-230[V], 50/60[Hz]
Interval	1.0㎜ ~ 2.0㎜
Shot length	30㎜ (full length), 15㎜ (half length)
Cartridge for Face	1.5㎜, 3.0㎜, 4.5㎜ / 10,000 shots
Cartridge for Body	8.0㎜, 13㎜ / 10,000 shots
Energy Emissions	**Continuous shooting with x1, x2, x3, x4, x5 for easy operation**
Display	10.4”
Dimension	450 x 570 x 1,050[㎜], (W x D x H)
Weight	40[kg]

6 Product -HIFU

HIPRO STANDARD | **HIPRO-S** | HIPRO-V | HIPRO-Q

SYSTEM SPECIFICATION

Energy Type	High Intensity Focused Ultrasound
Energy Output	0.1J ~ 2.0[J / ㎠]
Electrical	AC 100-230[V], 50/60[Hz]
Interval	1.0㎜ ~ 2.0㎜
Shot length	30㎜ (full length), 15㎜ (half length)
Cartridge for Face	1.5㎜, 3.0㎜, 4.5㎜ / 10,000 shots
Cartridge for Body	8.0㎜, 13㎜ / 10,000 shots
Energy Emissions	**Continuous shooting with x1, x2, x3, x4, x5 for easy operation**
Display	10.4”
Dimension	350 x 410 x 270[㎜], (W x D x H)
Weight	8[kg]

6 Product –HIFU

HIPRO STANDARD | HIPRO–S | **HIPRO–V** | HIPRO–Q

SYSTEM SPECIFICATION

Energy Type	High Intensity Focused Ultrasound
Energy Output	0.1J ~ 2.0J
Electrical	AC 100–230[V], 50/60[Hz]
Frequency	5 ~ 10[Hz]
Depth for Face	1.5~4.5 Step to 0.5㎜
Depth for Body	6.0~13.0 Step to 1.0㎜
Only handpiece type: Contains 10,000,000 shots (not cartridge used)	
All depths & Energy are adjusted, and controlled by GUI only.	
Warranty	4,000,000shots(200 patients treated for face lifting and tightening with body slimming, 20,000 shots/person) or within 1 year whichever comes earlier, would be expired
Display	10.4”
Dimension	350 x 410 x 290[㎜], (W x D x H)
Weight	10[kg]

6 Product –HIFU

HIPRO STANDARD | HIPRO–S | HIPRO–V | **HIPRO–Q**

SYSTEM SPECIFICATION

Energy Type	High Intensity Focused Ultrasound
Electrical	AC 100–230[V], 50/60[㎐]
Frequency	7[㎐]
Cartridge for Face	3.0[㎜](the collagen to be remodeled for skin tightening) /2,000 minutes
Only one handpiece for 2,000 minutes (not cartridge used)	
Display	5”
Dimension	259 x 309 x 176[㎜], (W x D x H)
Weight	2.0[kg]

6 Product –AROMA

SYSTEM SPECIFICATION

Light Source	DIODE (6 Stacks)
Output Energy	600 [W]
Warranty	10,000,000 shots or within 1 year (whichever comes earlier, would be expired)
Wavelength	808[㎚]
Energy filuence / Intersity	0.2 ~ 100 [J/cm2] / 1 ~ 100 [%]
Pulse Duration	10[㎳] ~ 350[㎳]
Spot Size (Sapphire Size)	14 x 15 [mm] (600 [W])
Repetition Rate	1[㎐] ~ 10[㎐]
Display	10.4”
Dimension	480 x 640 x 1,240[㎜], (W x D x H)
Weight	67[kg]

6 Product –AROMAII

SYSTEM SPECIFICATION

Light Source	DIODE (8 Stacks)
Output Energy	800 [W]
Warranty	10,000,000 shots or within 1 year (whichever comes earlier, would be expired)
Wavelength	808[㎚]
Energy filuence / Intersity	0.2 ~ 100 [J/cm2] / 1 ~ 100 [%]
Pulse Duration	10[㎳] ~ 350[㎳]
Spot Size (Sapphire Size)	14.2 x 18.5 [mm] (800 [W])
Repetition Rate	1[㎐] ~ 10[㎐]
Display	10.4”
Dimension	480 x 640 x 1,240[㎜], (W x D x H)
Weight	67[kg]

6 Product –PENTAGON

SYSTEM SPECIFICATION

Laser Type	ULTRA PULSE CO2 LASER
Power	20W, 30W
Pulse energy	3mJ ~ 300mJ
Ultra Pulse	50 ~ 990 [㎲]
Fractional	3 ~ 300 [mJ]
CW	Laser Spot Size : 0.3mm ~ 0.7mm 1 ~ 20 [W], 1 ~ 30 [W]
Operation Mode / Fractional Mode	Dynamic Mode (Array, Random)
Lesion Depth	All Type 1,500 [㎛]
Spot Density	0.1 ~ 2.0 [mm]
Scan Area Size	3x3[㎜] ~ 20x20[㎜] Adjustable
Scan Area Shape	Square, Circle
Guide Type	Normal (5㎜, 20㎜)
Display	8”
Aiming Beam	Diode Laser Beam 650㎛ (Light Adjustable)
Electrical	200 ~ 240 [VAC], 50/60 [Hz]
Dimension	450 x 510 x 1,150[mm], (W x D x H)
Weight	65[kg]

6 Product –ACTIVO

SYSTEM SPECIFICATION

Laser Type		Q-Switched Nd: YAG	
Wavelength		1064nm / 532nm	
Operation Mode		Q-switched & Spectra Mode (Quasi-long Pulse)	
Beam Profile		Top Hat Mode	
Pulse Energy	1064 mode (Q-Switched mode)	Max. 2,700mJ	
	532 mode (Q-Switched mode)	Max. 900mJ	
Type of Pulse		Single Pulse	One whole pulse
		Double Pulses	Photoacoustic Twin pulses
		Triple Pulses	Photoacoustic Triple pulses
Auto-calibration & Self-restoration			
Pulse Width		5 – 10 [ns] (Q-switched Mode) / 500 ㎲ (FR mode)	
Spot Size	1064nm (Q-Switched mode)	2 – 10 [㎜]	
	532nm (Q-Switched mode)	2 – 10 [㎜]	
Pulse Rate	1064, 532, FR mode	Max. 10 [Hz]	
Memory		5 User Programmable Memory	
Optical Delivery		Articulated Arm	
Aiming Beam		Diode 650nm (Red), Adjustable Brightness	
Display		10.4"	
Cooling		Closed Circuit Water to Air	
Input Power		Single phase, 220[VAC], (Fuse 250V / 20A), 50/60[Hz], Power consumption : 3kVA	
Dimension		315 x 825 x 1,022[mm], (W x D x H)	
Weight		90[kg]	

6 Product –TINEA

SYSTEM SPECIFICATION

Laser Type		DIODE
Wavelength		405nm / 635nm
Emitting Area		140mm x 1.2mm(W x D)
Operation Time (CW Mode)	MODE 1	Max 12 minutes
	MODE 2	Max 15 minutes
	MODE 3	Max 20 minutes
Operation Power	405nm	20mW
	635nm	50mW
Electrical		100-240[VAC], 50/60[Hz]
Power Consumption		20VA
Dimension		406 x 382 x 351[mm], (W x D x H)
Weight		14.5[kg]

7 Product- Cosmetics

7 Product –CLINLUX After Laser Care R-Concentrate

SYSTEM SPECIFICATION

After the laser care, the skin needs intensively hydrating & nutrients to regenerate and maintain.
Nourish your skin with 'Clinlux After Laser Care R-Concentrate'.
Help skin radiant, firmer and healthier-looking.

Product name	Clinlux After Laser Care R-Concentrate
Volume	50g
Key Ingredients	Oligopeptide - scar relief Adenosine - tightening Niacinamide - brightening Centella asiatica extract - hydrating, calming Galactomyces Ferment Filtrate - vitalizing, lifting
Features	✓ Intensively hydrating, daily moisturizing. ✓ Strengthens skin's natural defenses to support natural repair systems. ✓ Protects against skin dulling pollutants to form an invisible skin shield. ✓ Helps reduce the number, depth and size of wrinkles for visibly renewed smoothness. ✓ Helps release redness, itching and tingling.
How to use	1. Apply adequate amounts to face evenly. 2. Avoid applying directly onto the eyes. 3. Allow to fully absorb into the skin.

7 Product –CLINLUX After Laser Care R–Cream

SYSTEM SPECIFICATION

By the thermal reaction of the laser, the skin becomes very dry.
Moisturize your skin with a moisturizing and calming,
'Clinlux after laser care R–cream'.
Leaves skin soft, supple and perfectly conditioned.

Product name	Clinlux After Laser Care R-Cream
Volume	50g
Key Ingredients	 Centella asiatica extract - hydrating, calming  Phellinus linteus Extract – derma immunization  Tocopherol - antiaging  Snail secretion filtrate -firming, new layer
Features	✓ Provides long-lasting hydration and helps restore skin's moisture balance ✓ Helps release redness, itching and tingling ✓ Diminishes the appearance of fine lines and wrinkles ✓ Helps replace what skin has lost overtime
How to use	1. Apply adequate amounts to face evenly. 2. Avoid applying directly onto the eyes. 3. Allow to fully absorb into the skin.

7 Product –CLINLUX After Laser Care SUN SHIELD

SYSTEM SPECIFICATION

By the laser care, the skin is weakened and UV rays causes pigmentation.
Shield your skin with non-irritating,well-absorbed,
'Clinlux After Laser Care Sun Shield SPF50+ PA+++'.
Maintain hydrated and soft skin even in the most heavily polluted cities.

Product name	Clinlux After Laser Care SUN SHIELD (SPF 50+ PA+++)
Volume	50g
Key Ingredients	Propolis Extract – disinfecting Anemarrhena Asphodeloides Root Extract - hydrating Centella asiatica extract – hydrating, calming Morinda Citrifolia Extract – antioxidant Collagen Extract – wrinkle relief Paeonia Suffruticosa Root Extract – anti-aging
Features	✓ Strengthens skin's natural defenses to support natural repair systems. ✓ Protects against skin pollutants to form an invisible skin shield. ✓ Defends against 98% of harmful UVB rays with SPF 50 formula containing 100% micronized titanium dioxide and zinc oxide. ✓ Quickly and smoothly infuse your skin.
How to use	1. Apply adequate amounts to face evenly. 2. Avoid applying directly onto the eyes.

8 Company Certification

8 CompanyCertification – TGA& GOST

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

InMed Aesthetics Pty Ltd

for approval to supply

InMed Aesthetics Pty Ltd - HIPRO - Ultrasonic skin contouring system

ARTG Identifier	327939
ARTG Start date	19/12/2019
Product Category	Medical Device Included Class IIb
GMDN	62436
GMDN Term	Ultrasonic skin contouring system
Intended Purpose	High Intensity Focused Ultrasonic device used for cosmetic and aesthetic procedures

Manufacturer Details	Address	Certificate number(s)
Daeju Meditech Engineering Co Ltd	2F 3F 487 Mangu-ro Jungnang-gu , Seoul, Korea - Republic of	DV-2019-MC-17125-1

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. HIPRO - Ultrasonic skin contouring system

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 327939
ARTG Start Date: 19/12/2019

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 06 ноября 2020 года № РЗН 2020/12410

На медицинское изделие
Аппарат медицинский лазерный диодный AROMA GRAND

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Медитек" (ООО "Медитек"), Россия, 105062, Москва, Подсосенский пер., д. 23, стр. 6, офис 4, пом. 1

Производитель
"ДЭДЖУ МЕДИТЕК ИНЖИНИРИНГ КО., ЛТД.", Корея, DAEJU MEDITECH ENGINEERING CO., LTD., 2F, 487 Mangu-ro, Jungnang-gu, Seoul, Republic of Korea

Место производства медицинского изделия
DAEJU MEDITECH ENGINEERING CO., LTD., 2F, 3F, 487 Mangu-ro, Jungnang-gu, Seoul, Republic of Korea

Номер регистрационного досье **№ РД-32186/20961 от 01.04.2020**

Класс потенциального риска применения медицинского изделия **2б**

Код Общероссийского классификатора продукции по видам экономической деятельности **26.60.13.170**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 06 ноября 2020 года № 10238
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы по надзору в сфере здравоохранения **А.В. Самойлова**

0049786

8 CompanyCertification – CE

Certificate

kiwa
Partner for progress

EC Certificate
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-16-405

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:
DAEJU MEDITECH ENGINEERING CO., LTD.
2F, 3F,487, Mangu-ro, Jungnang-gu, Seoul, Korea

Product: High Intensity Focused Ultrasonic Equipment
Model: HIPRO

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa Meyer for details.

Report Number: M.4540.01
Valid until : 13 October 2021

Kiwa Meyer Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number : 1984

14 October 2016, Istanbul, Turkey — Head of Notified Body

Kiwa Meyer Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

* Certificates without seal are not valid.

ITC

Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE
No. 13 0555 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the medical devices of Class IIb:

ULTRA PULSE CO2 FRACTIONAL LASER
Model: GRAND CELL

manufactured by company

DAE-JU Meditech Engineering
134-22, Mangwoo-Dong, Joongrang-ku, Seoul, Korea

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3 and 5 of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601942/2013, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 17th June 2018 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlin, on 18th June 2013

INSTITUTE FOR TESTING AND CERTIFICATION ITC 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

8 CompanyCertification – CE, ISO13485

NOTIFIED BODY No. 1023
Institute for Testing and Certification, Inc., Zlin, Czech Republic

EC CERTIFICATE

No. 11 0476 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the medical devices of Class IIb:

Diode Laser
Model: AROMA (Cheveux)

manufactured by company

DAE-JU Meditech Engineering Co., Ltd.
134-22, Mangwoo-Dong, Joongrang-ku, Seoul, Korea

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3 and 5 of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601196/2011, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 6th June 2016 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlin, on 7th June 2011

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

CERTIFICATE

No. 820252

LL-C Certification

This is to certify that the Quality Management System of Medical Devices of

DAEJU MEDITECH ENGINEERING CO., LTD.
2F, 3F, 487 Mangu-ro,
Jungnang-gu, Seoul,
Republic of Korea

has been assessed and found to be in compliance with the standard

EN ISO 13485:2016

applicable to

Design and Development, Production, sales and service for Laser Equipment, High Intensity Focused Ultrasonic Equipment and Liposuction System

The certificate has been issued under No. **820252** for the registration period from 10th June 2018 to 9th June 2021. The first certificate date of issue is 9th June 2017.

Approved by

Printed by

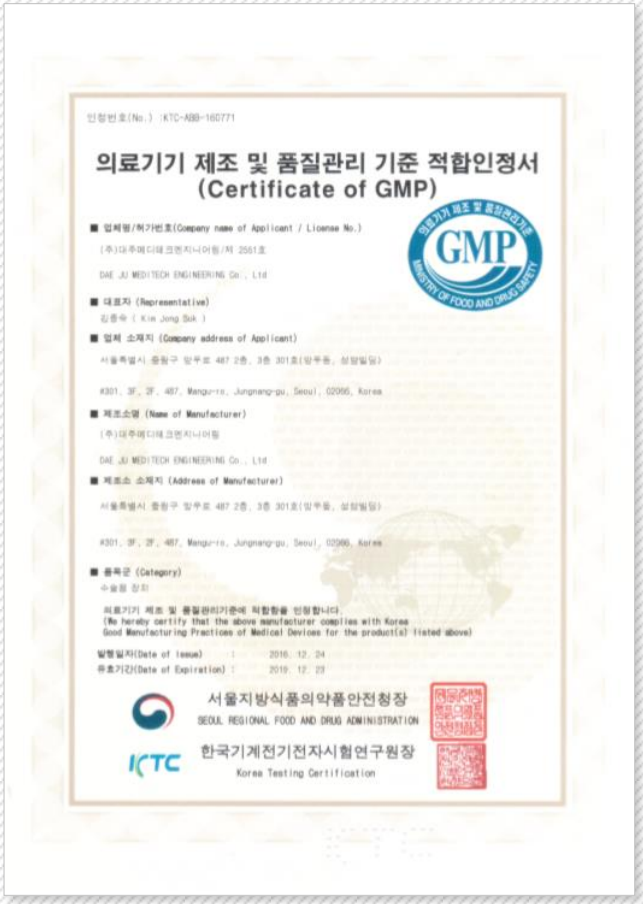
S 3137

validity codes **FD7EC696-F12**
Check the validity of this certificate using this code at www.ll-c.info

www.ll-c.net

LL-C (Certification) Czech Republic s.r.o. | Pobřežní 620/3, 186 00 Praha 8

8 CompanyCertification – GMP, FDA



인정번호(No.) :KTC-ABB-160771

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)

(주)대주메디테크엔지니어링/제 2561호

DAE JU MEDITECH ENGINEERING Co., Ltd

■ 대표자 (Representative)

김종숙 (Kim Jong Suk)

■ 업체 소재지 (Company address of Applicant)

서울특별시 중랑구 망우로 487 2층, 3층 301호(망우동, 삼정빌딩)

#301, 3F, 2F, 487, Mangu-ro, Jungnang-gu, Seoul, 02095, Korea

■ 제조소명 (Name of Manufacturer)

(주)대주메디테크엔지니어링

DAE JU MEDITECH ENGINEERING Co., Ltd

■ 제조소 소재지 (Address of Manufacturer)

서울특별시 중랑구 망우로 487 2층, 3층 301호(망우동, 삼정빌딩)

#301, 3F, 2F, 487, Mangu-ro, Jungnang-gu, Seoul, 02095, Korea

■ 품목군 (Category)

수술용 장치

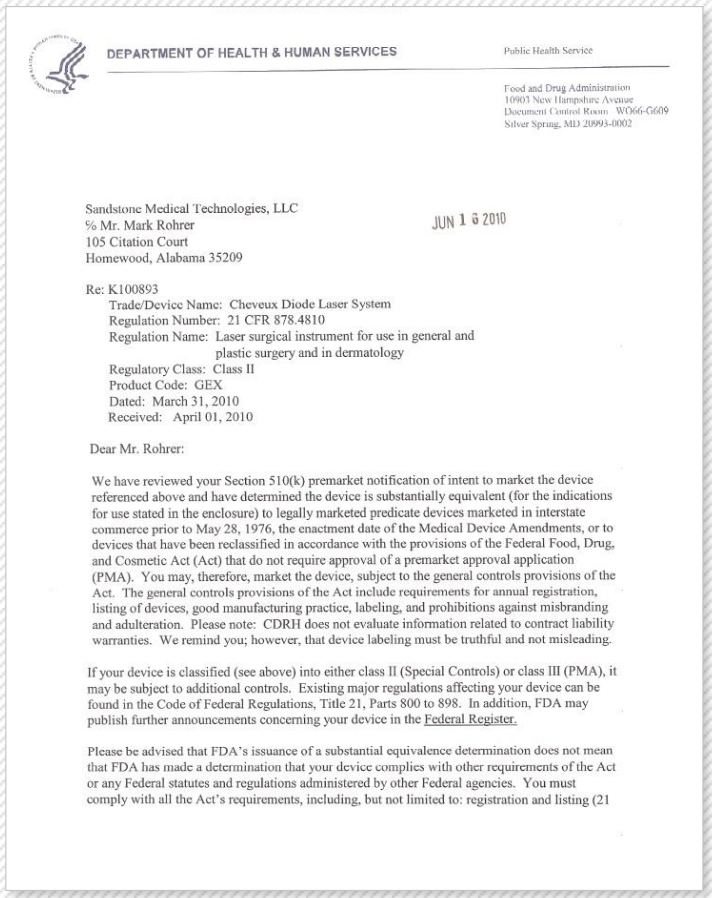
의료기기 제조 및 품질관리기준에 적합함을 인정합니다
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product(s) listed above)

발행일자(Date of Issue) : 2016. 12. 24

유효기간(Date of Expiration) : 2019. 12. 23

서울지방식품의약품안전청장
SEOUL REGIONAL FOOD AND DRUG ADMINISTRATION

KTC 한국기계전기전자시험연구원장
Korea Testing Certification



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Sandstone Medical Technologies, LLC
% Mr. Mark Rohrer
105 Citation Court
Homewood, Alabama 35209

JUN 16 2010

Re: K100893
Trade/Device Name: Cheveux Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 31, 2010
Received: April 01, 2010

Dear Mr. Rohrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

8 Company Certification – PATENT, INNO-BIZ

특허증
CERTIFICATE OF PATENT

특허 Patent Number 제 10-1687569 호

출원번호 Application Number 제 10-2016-0039128 호

출원일 Filing Date 2016년 03월 31일

등록일 Registration Date 2016년 12월 13일

발명의 명칭 Title of the Invention
일체형 핸드피스를 구비한 초음파 시술장치

특허권자 Patentee
등록사항란에 기재

발명자 Inventor
등록사항란에 기재

위의 발명은 「특허법」에 따라 특허등록원부에 등록되었음을 증명합니다.
This is to certify that, in accordance with the Patent Act, a patent for the invention has been registered at the Korean Intellectual Property Office.

2016년 12월 13일

특허청장
COMMISSIONER,
KOREAN INTELLECTUAL PROPERTY OFFICE
최 동 규

제 160105 - 00700 호

기술혁신형 중소기업(INNO-BIZ) 확인서

업 체 명 : (주)대주에디테크엔지니어링
대 표 자 : 김종숙
주 소 : 서울 중랑구 망우로 499 (망우동) 2층
등 급 : A
유효기간 : 2016. 7. 11 ~ 2019. 7. 10

위 업체는 기술혁신형 중소기업 발굴 육성사업에 의해 선정된 기술혁신형 중소기업(INNO-BIZ)임을 확인합니다.

2016년 7월 12일

중 소 기 업 청 장

8 CompanyCertification

제 2018114779 호

기업부설연구소 인정서

1. 연 구 소 명: (주)대주메디테크엔지니어링 기업부설연구소
   [소속기업명: (주)대주메디테크엔지니어링]
2. 소 재 지: 서울특별시 중랑구 망우로 499
   2층 (망우동)
3. 신고 연월일: 2018년 10월 02일

과학기술정보통신부

「기초연구진흥 및 기술개발지원에 관한 법률」 제14조의 2제1항 및 같은 법 시행령 제27조제1항에 따라 위와 같이 기업부설연구소로 인정합니다.

2018년 10월 11일

한국산업기술진흥협회장

수출의 탑 수상확인증

(Award Certificate for Outstanding Export Performance)

무역업고유번호 (Trade Business Code) : 30683095

회 사 명 (Company Name) : (주)대주메디테크엔지니어링 DAEJU MEDITECH ENGINEERING CO., LTD.

상기의 회사가 아래와 같이 수출의 탑을 수상하였음을 확인함.
It is hereby certified that the company mentioned above was awarded for outstanding export performance as stated below.

	수상연도 Awarded year	수상종류 Export volumn	비고 Remarks
1	2016 53th Trade Day	1백만불탑/무역의날 $1-Million Export Tower	

KITA

2017 년 Year 01 월 Month 19 일 Day

사단법인 한국무역협회 회장

Chairman & CEO
Korea International Trade Association

Document Number:1432-8894-2684-6407

Osong Health Technology Administration Complex,187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea, 363-700Tel: +82-43-719-1010, Fax: +82-43-719-1000

No. of Certificate : 20150092140 Date : 2015/05/29

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea

Importing(requesting) country : Not Determined

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is/are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. 2551)

DEJU MEDITECH ENGINEERING

Sirugae bldg, 402L, 467, Wausan-ro, Mapo-gu, Seoul

Product-License No.	Classification
10-70	Laser surgical unit, diode

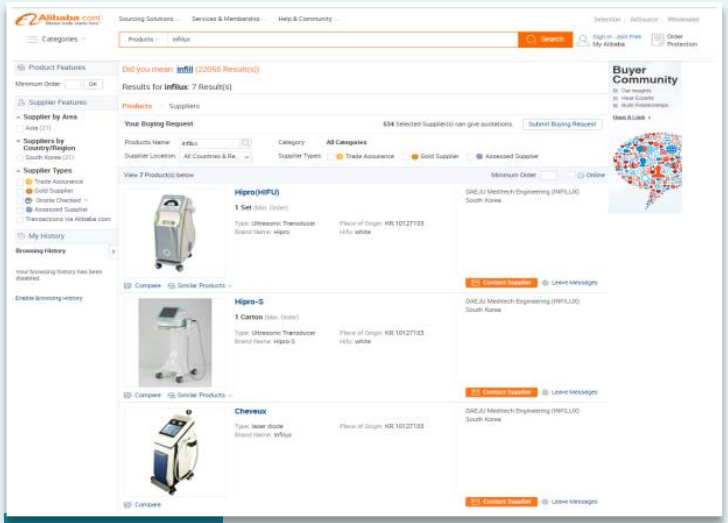
※ Attached : List of Product Classification and Model

Director of High-Tech Medical Devices DivisionDepartment of Medical Device EvaluationNational Institute of Food and Drug Safety EvaluationMinistry of Food and Drug Safety

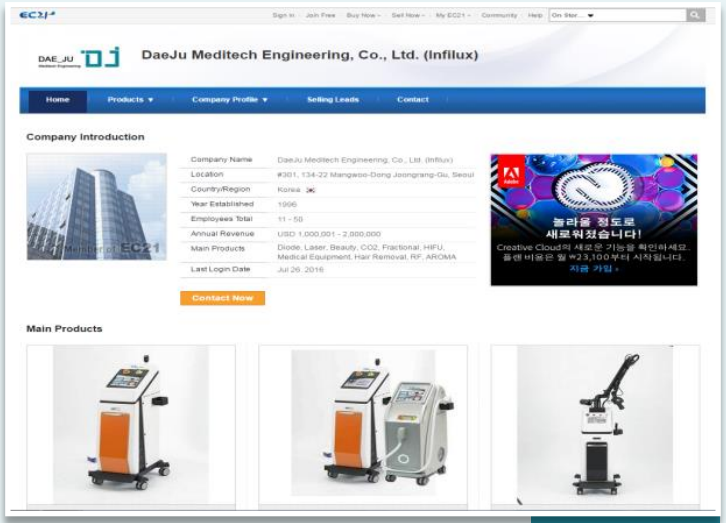
1 / 2

9 Marketing Activities

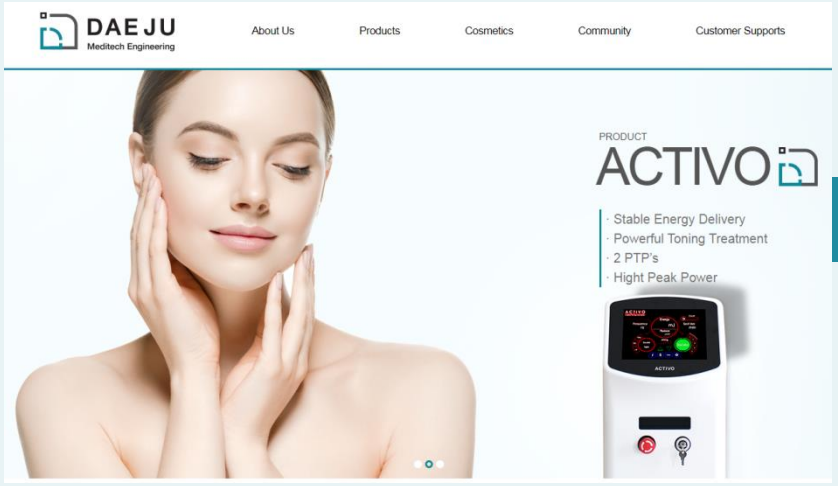
9 Marketing Activities –Online



Alibaba



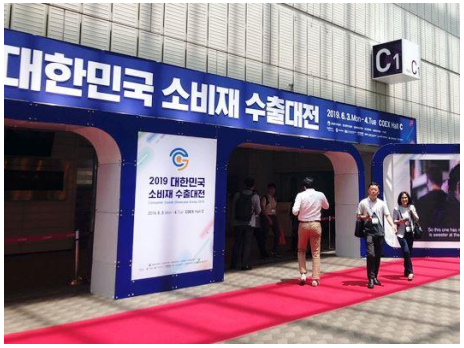
EC 21



Our Website

9 Marketing Activities –Exhibition

Acquisition of overseas marketing information



Exporting companies More than 40 countries

Participation in domestic and overseas exhibitions more than 5 times in a year

Brand awareness raising

Establishing dermatology and plastic surgery network

Self-development and production

THANK YOU

We will be your successful Business Partner!!!