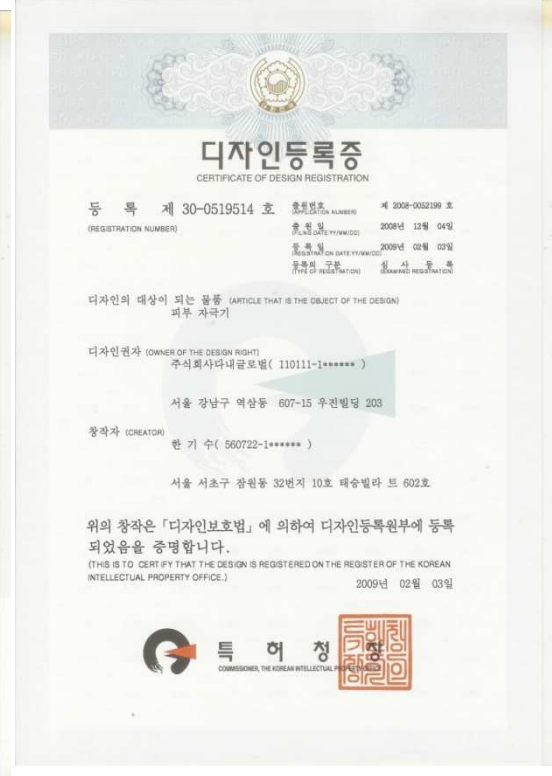
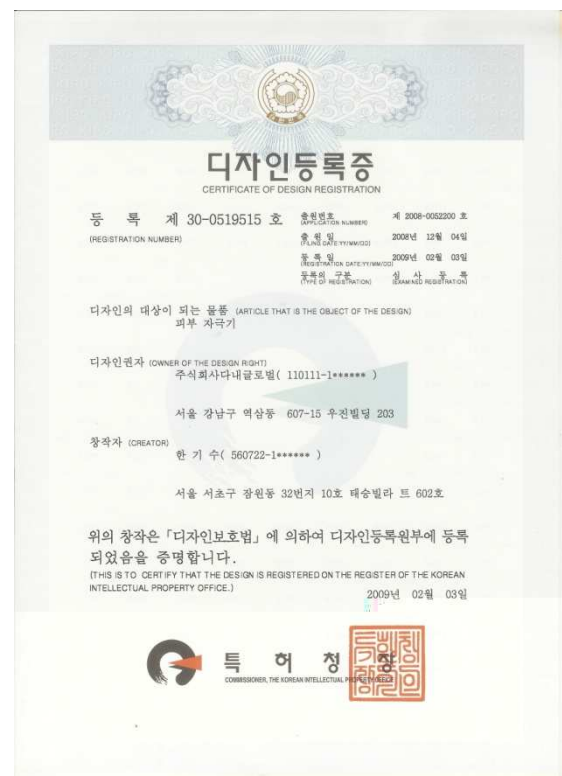


# Proprietà Intellettuale



Brevetti	Data	Numero applicazione.	Nome dell' applicazione	Status
Brevetto	2008. 12.01	10-0885732	The skin stimulus system (Core technology)	Registered
Brevetto	2008. 12. 01	10-0917430	Disk of skin-stimulation apparatus, composed of needle-stick having inclined planes(Shape of needle)	Registered
Brevetto	2008. 12. 01	10-0917431	The skin stimulus system (For protection)	Registered
Brevetto	2008. 12. 15	10-0917429	The skin stimulus system (Cartridge)	Registered
Design	2008. 12. 04	30-0519514	The skin stimulus system (Inserted Disk Design)	Registered
Design	2008. 12. 04	30-0519515	The skin stimulus system-vibrator roller design(Vibrator Design)	Registered
Marchio	2008. 12. 04	41-0190844	"DTS"	Registered

# Certificato di proprietà intellettuale



# Certificato di Approvazione KFDA, GMP

**KFDA**  
문서확인번호 0242-2679-8746-7865

제허 09-374 호

## 의료기기 제조품목 허가증

업허가구분 : 제2664 호  
구분 : 제조

제품명(품목명 및 형명)	측정 및 유도용 기구(Medi025SW외 15건)	분류번호(등급)	A64000(2)
형상 및 구조	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
원자재	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
제조방법	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
사용목적	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
사용방법	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
사용시 주의사항	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		

분류번호	별첨
지정방법 및 유효기간	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조
시험규격	별첨(알괄경도)
제조원(수입의 경우)	별첨
허가조건	별첨
비고	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조

의료기기법 제6조 및 동법시행규칙 제5조 제2항의 규정에 따라 위와 같이 허가합니다.

2009년 05월 13일

식품의약품안전청

본 증명서는 인터넷으로 발급되었으며 식품의약품안전청(<http://emed.kfda.go.kr/>) 홈페이지에서 확인할 수 있습니다.

KEMTI-AC-090113 1176

## 의료기기 제조 및 품질관리기준 적합인정서 (Certificate of GMP)

**GMP**  
Korea Food & Drug Administration

- 업 소 명 (Name of Manufacture)  
(주)지에스 스탠다드 이엔지  
GS STANDARD ENG CO., LTD.
- 소 재 지 (Address of Manufacture)  
서울특별시 금천구 가산동 481-10 벽산경인지지빌리2차 1006호,1007호  
#1006, #1007, Byucksan Gyeongin Digital 2-cha Valley, 481-10,  
Gasan-dong, Geumcheon-gu, Seoul, Korea.
- 대 표 자 명 (Representative of Manufacture)  
김 성 남 ( Seong Nam, Kim, )
- 품 목 군 : 품 목 명 (붙임 참조)  
(Name of Category : Name of Classification) (See attached list)

의료기기제조및품질관리기준에 적합함을 인정합니다.  
We hereby certify that the above manufacture complies with Korea Good Manufacturing Practices for the product(s) listed above.

발행일자 (the Date of Issue) : 2009. 06. 23  
유효기한 (the Date of Expiration) : 2011. 05. 18

**KFDA** 식품의약품안전청  
Korea Food & Drug Administration

**KEMTI** 한국생활환경시험연구원  
Korea Environment & Merchandise Testing Institute

# Certificato di approvazione CE 0120

Certificate KR11/01726


The management system of  
**DTS MG Co., Ltd.**  
#401, 402 14 Yeonmujaeng 17-gil, Seongdong-gu, Seoul, Korea

has been assessed and certified as meeting the requirements of  
**ISO 13485:2003**  
**EN ISO 13485:2012**

For the following activities  
**Design and manufacture of sterile micro needle roller for treatment of acne scarring**

This certificate is valid from 10 November 2014 until 10 February 2015 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 31 October 2015  
Issue 4. Certified since 9 November 2011





Authorised by



SGS United Kingdom Ltd. Systems & Services Certification  
Rosemore Business Park, Ellesmere Port, Cheshire CH83 3EN UK  
t +44 (0)151 350-6565 f +44 (0)151 350-6500 www.sgs.com

SGS 13485-2.0714

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This document is issued by the Company subject to its General Conditions of Certification (revision accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm)). Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authority of this document may be verified at <http://www.sgs.com/en/Our-Company/Certified-Clients/Directions/Certified-Clients-Directions.aspx>. Any unauthorised alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

EC Certificate Full Quality Assurance System: Certificate KR11/01727

The management system of  
**DTS MG Co., Ltd.**  
#401,402 Daegun IndusTown, 275-29, Seongsu-Dong 2-ga, Seongdong-gu, Seoul, Korea

has been assessed and certified as meeting the requirements of  
**Directive 93/42/EEC**  
on medical devices, Annex II (excluding Section 4)


For the following products  
**Sterile micro needle roller for treatment of acne scarring**

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 23 May 2012 until 9 November 2016 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 31 October 2014  
Issue 2. Certified since 9 November 2011

Certification is based on reports numbered KR/SEL Y-PC/11279



Authorised by



SGS United Kingdom Ltd, Notified Body 0120  
2028 Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0311

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# Registrazione FDA & KFDA



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville, Maryland 20850

Certificate No. 5220-7-2006

## 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)

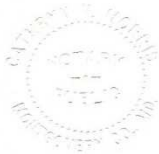
Name of Manufacturer/Distributor Address

See attached list  
(1 page)

Clinical Resolution Laboratory  
14401 Chambers Road  
Tustin, CA 92780

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.



*Theresa McDonald*

Theresa McDonald  
Chief, Regulatory Policy and Systems Branch  
Division of Risk Management Operations  
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY  
STATE OF MARYLAND

Subscribed and sworn to before me this 18 day of July month 2006 year.

*Cathryn N. Morris*

CATHRYN N. MORRIS  
NOTARY PUBLIC STATE OF MARYLAND  
County of Montgomery  
My Commission Expires January 1, 2009



문서 확인번호 0171-5339-8375-4149



수허 07-162 호

## 의료기기 수입품목 허가증

업허가구분 : 제1134 호

구분 : 수입

제품명(품목명 및 형태)	속칭 및 유도용 기구(Microneedle Therapy System Dermalroller CR5의 5건)	분류번호(등급)	A640000
항상 및 구조	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
원자재	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
제조방법	제조원의 제조방법에 따른다.		
사용목적	피부를 자극하여 의약품 등의 흡수를 도와주는 기구		
사용방법	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
사용시 주의사항	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
포장단위	표장단위		
지정방법 및 유효기간	건냉하고 환기가 잘되는 곳 보관하며, 높은 압력은 피할 것., 180일		
시험규격	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		
제조원(수입의 경우)	Clinical Resolution Laboratory, 미국, 14401 Chambers Road Tustin, CA 92780, USA		
비고	<a href="http://emed.kfda.go.kr">http://emed.kfda.go.kr</a> 참조		

의료기기법 제14조 및 동법시행규칙 제18조 제3항의 규정에 따라 위와 같이 허가합니다.

2007년 02월 15일

식품의약품안전청



본 증명서는 인터넷으로 발급되었으며 식품의약품안전청(<http://emed.kfda.go.kr>) 홈페이지에서 확인할 수 있습니다.