CE & FDA Certificate

Legal Entity: Global-Standard Testing Service Co., Ltd.
Room 1911-1914 , Noble Plaza, Qian Jin 1st Road,
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Global-Standard Testing

Certificate of Conformity

Certification No.	:	S00.08.0320E
Applicant	:	Guangzhou Ekai Electronic Technology Co., Ltd.
Address	:	Third Floor, Building A, No.81, Zijing Road, Liwan District, Guangzhou, Guangdong, China.
Manufacturer	:	Guangzhou Ekai Electronic Technology Co., Ltd.
Address	:	Third Floor, Building A, No.81, Zijing Road, Liwan District, Guangzhou, Guangdong, China.
Certification Marking	:	CE-EMC
Product Description	:	Micro-needle system
Model	:	V8, V6, V3, V2, A6, A1, M5, M7, N2, DNS192, MNS192, Dr.roller192, Dr.roller540, Dr.roller64, ZGTS192, ZGTS540, DRS540, DRS192, DRS600, DRS1200, DRS180, DRS1080, DRS40, DRS200, DRS400, Derma vib, DRS360, DRS3 in 1, DRS4 in 1, MYM, DNS REVO, DNS SE, DRS140, HN20, A7, V9, V7, M8, X5, HN64, Hydra pen
Trademark	:	

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards	:	EN 60601-1-2:2007 EN 61000-3-2:2014 EN 61000-3-3:2013

When tested as specified, the submitted sample complies with EMC Directive 2014/30/EU and MDD Directive 93/42/EEC.

The certificate is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test laboratory logo.

CE

Authorized Signer:
Tim Su, Manager
August 19, 2015

Global-Standard Testing Service Co., Ltd. APPROVED

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書

Fiscal Year 2018
CERTIFICATION OF REGISTRATION

This certifies that:

Guangzhou Ekai Electronic Technology Co., Ltd.
3/F Building A, No. 81 Zijing Road, Liwan District, Guangzhou, Guangdong, China

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: US.FDA@sungogroup.com

Owner/Operator Number: 10057206
Device Listing#: See annex

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Sungo FDA

Executive Director
Issued: Mar. 07 2018
Cert. No.: 2006US604518
Expiration Date: Dec. 31 2018

SUNGO CHINA OFFICE Tel: 021-58597193 Email:Shage2008@126.com Website: www.sungogroup.com
Add: 17th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書

Fiscal Year 2018
CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2006US604518

Listing No	Code	Device Name
D317130	KNM	DEVICE, PRESSURE APPLYING (DRS/ZGTS/DNS/MNS Derma Roller, Dr.roller; Hydra-Needle; Derma Vib; Dr.pen/MyM Derma Pen; Artmex Permanent Makeup Machine; Disposable Needle Cartridge; Hydra Roller)
D317131	GED	BRUSH, DERMABRASION, MANUAL (DRS/ZGTS/DNS/MNS Derma Roller, Dr.roller; Hydra-Needle; Derma Vib; Dr.pen/MyM Derma Pen; BIO Galvanic Machine; Face Cleaning Machine; Skin Lifting Machine; Artmex Permanent Makeup Machine; Disposable Needle Cartridge; Derma Stamp)

END OF THE ANNEX