



America

CERTIFICATE

No. QS6 003984 0001 Rev. 00

Certificate Holder: PEMF Systems, Inc.
14556 Weddington Street
Sherman Oaks CA 91411-4036
USA

Certification Mark:



Scope of Certificate: Design, Manufacture, Distribution and Service of Pulsed Electromagnetic Frequency Generators and Treatment Coils for Treatment of Non-Union Bone Fractures; Temporary Alleviation of Pain; Temporary Increase in Mobility; Temporary Reduction in Inflammation

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Health Canada, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 83-070-0816

Effective Date: 2019-09-25

Expiry Date: 2022-09-24

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Date of Issue: 2019-09-25

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



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Regulatory Requirements: **Audit/Certification Criteria**

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Facility(ies):

PEMF Systems, Inc.
14556 Weddington Street, Sherman Oaks CA 91411-4036,
USA

Facility Scopes:

Design, Manufacture, Distribution and Service of Pulsed
Electromagnetic Frequency Generators and Treatment Coils
for Treatment of Non-Union Bone Fractures; Temporary
Alleviation of Pain; Temporary Increase in Mobility; Temporary
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Test Report issued under the responsibility of:



**IEC 60601-1
Medical electrical equipment**

Part 1: General requirements for basic safety and essential performance

Report Reference No.....: 102273635LAX-001

Date of issue.....: 2017-12-20

Total number of pages.....: 125

CB Testing Laboratory.....: Intertek Testing Services N.A., Inc.

Address.....: 25800 Commercentre Drive
Lake Forest, CA 92630 USA

Applicant's name: PEMF Systems, Inc.

Address.....: 422 Kirkstone Way
Las Vegas, NV 89123, USA

Test specification:

Standard: IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)

Test procedure: CB Scheme

Non-standard test method.....: N/A

Test Report Form No.....: IEC60601_1G

Test Report Form Originator.....: Underwriters Laboratories Inc.

Master TRF.....: Dated 2011-11

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This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description.....: Pulsed Electro Magnetic Fields (PEMF) stimulation and healing

Trade Mark: N/A

Manufacturer.....: PEMF Systems, Inc.

Model/Type reference.....: High Power, Medium Power, Low Power

Ratings.....: High Power: 120-230VAC, 50-60 Hz, 1.5A Max.

Medium Power: 120-230VAC, 50-60 Hz, 1.2A Max.

Low Power: 120-230VAC, 50-60 Hz, 0.7A Max.