MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD 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**


**Date of Issue:** 2019-09-25

Dawn Tibodeau

( 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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# CERTIFICATE

## No. QS6 003984 0001 Rev. 00

**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 Reduction in Inflammation
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Test Report issued under the responsibility of:

intertek
Total Quality. Assured.

# 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<br>Lake Forest, CA 92630 USA |
| Applicant's name .....: | PEMF Systems, Inc. |
| Address.....: | 422 Kirkstone Way<br>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 |



| | |
|---|---|
| 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.<br>Medium Power: 120-230VAC, 50-60 Hz, 1.2A Max.<br>Low Power: 120-230VAC, 50-60 Hz, 0.7A Max. |