MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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 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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US-Letter / 07.17

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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 Reduction in Inflammation
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