Mandatory and Voluntary Standards Applied for the FA100 SCCD:

Quality Management System
EN ISO 13485:2012

Medical Electrical Equipment, Safety
EC/EN 60601-1: 2012, 3.1 Ed.
IEC/EN 60601-1-2:2007
IEC 60601-2-10:2012
IEC 60601-1-11:2010

Medical Device Software
IEC 62304:2006
IEEE 1028-1997

Risk Management & Usability
EN ISO 14971:2012
ISO 62366 -1:2015
IEC 60601-1-6:2006

Labeling & Symbols
ISO 15223-1:2012
EN 1041:2008

Biological Evaluation
ISO 10993-1: 2009
ISO 10993-5:2007
ISO 10993-10:2002

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 647082**

Issued To: **Flowaid Medical Technologies Corp.**
44 Wall St
2nd Floor
New York
New York
10005
USA

In respect of:

Design, development and manufacture of electrical muscle stimulators for enhancement of peripheral circulation.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **07 July 2016** Date: **07 July 2016** Expiry Date: **06 July 2021**

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Flowaid Medical Technologies Corp.
44 Wall Street
2nd Floor
New York
New York
10005
USA

Holds Certificate No: **FM 647147**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Design, development and manufacture of electrical muscle stimulators for the enhancement of peripheral circulation.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 04/11/2016 Effective Date: 07/08/2016 Expiry Date: 02/28/2019

CMDCAS Recognized Registrar

SCC Accredited CB-MS OCSM Accrédité CCN

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Santé Canada Health Canada

LN/NH: 97539

Therapeutic Products Directorate
Medical Devices Bureau
Direction des produits thérapeutiques
Bureau des matériels médicaux

Medical Device Licence

Homologation d'un instrument médical

Licence Number: 97539 **No d'homologation:**

First Issue Date: 2016/08/18 **Première date de délivrance:**

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

FA100 SEQUENTIAL CONTRACTION COMPRESSION DEVICE

Licence Type/Type d'homologation:

System / Système

Manufacturer Name & Address/Nom du fabricant & adresse

FLOWAID MEDICAL TECHNOLOGIES CORP.
44 WALL STREET
2ND FLOOR
NEW YORK, NEW YORK
UNITED STATES
10005

Carey Agnew, A/Director, Medical Devices Bureau/Directrice intérimaire, Bureau des matériels médicaux

Application Number:
Numéro de la demande: 256666

Manufacturer ID:
Identificateur du fabricant: 135135

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

FA100 SCCD CIRCULATORY ENHANCEMENT DEVICE

Device ID/No de l'instrument: 818732

Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):

9FA10000

FA100 SCCD ELECTRODES SET

Device ID/No de l'instrument: 818733

Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):

8FA10000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 14, 2017

FlowAid Medical Technologies, Corp.
Mr. Jacob Brezel
CEO
44 Wall Street
New York, New York 10005

Re: K162987
Trade/Device Name: FA100 SCCD (Sequential Continuous Contraction Device)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: January 4, 2017
Received: January 5, 2017

Dear Mr. Brezel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure