Wiemspro Revolution Pro: technical specifications and regulatory documentation

Study	EMS-PL HF STUDY
Trial registration	DRKS00040045 (registered 24 April 2026)
Principal Investigator	Damian Sendrowski, Pomeranian University in Słupsk
Equipment	Wiemspro Revolution Pro (Wiemspro, Spain)
Reporting guideline	TREND statement

Contents

Purpose and scope

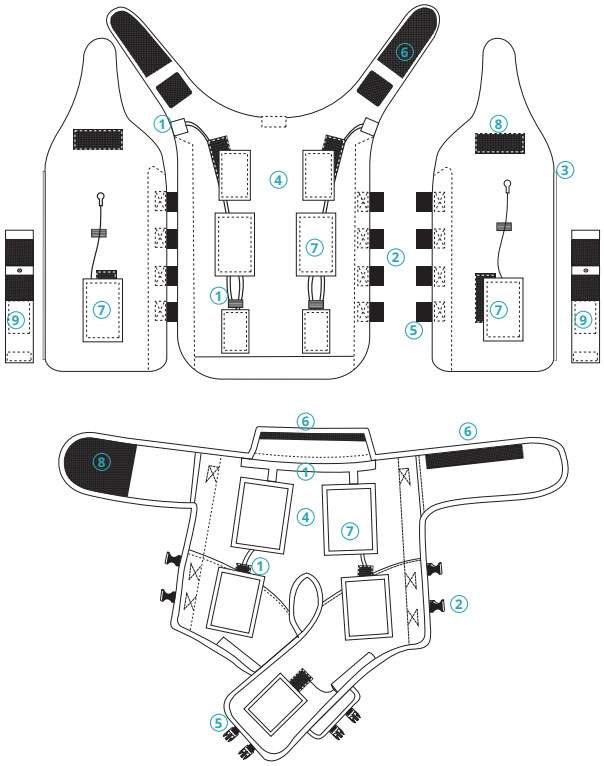
This supplementary file consolidates the manufacturer's technical specifications and the principal regulatory and conformity documentation for the Wiemspro Revolution Pro whole-body electrical muscle stimulation (WB-EMS) system used in EMS-PL HF STUDY. The device addresses ten major muscle groups through a wearable suit (quadriceps, hamstrings, gluteals, lumbar paraspinals, latissimus dorsi, trapezius, abdominal muscles, pectorals, biceps brachii and triceps brachii) and is operated wirelessly by a trained supervisor. Active-arm sessions use an 85 Hz biphasic current at 50–60% of each participant's maximally tolerated intensity; sham-arm sessions use a 100 Hz "massage" pattern at a minimally perceivable intensity that does not elicit training-level contractions. All documents reproduced here are issued by the manufacturer or by independent regulatory bodies and are provided unaltered for editorial and reviewer reference.

SIZES: XXS | XS | S | M | L | XL | XXL

Product description

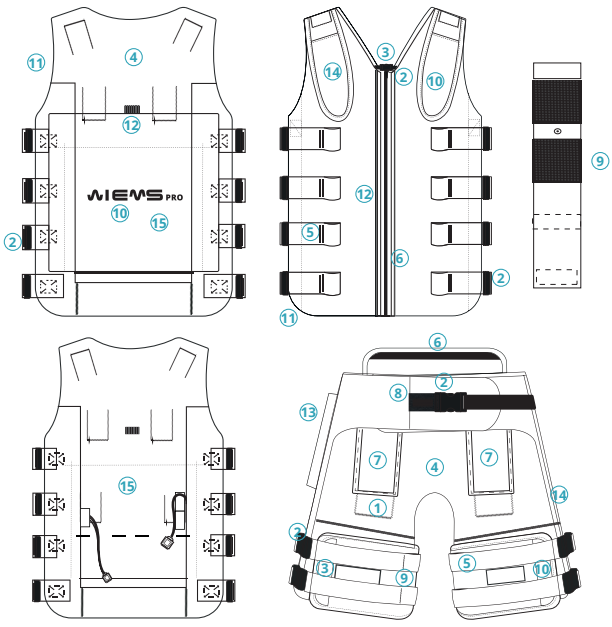
Electrostimulation suit that allows the athlete to develop high intensity training with the greatest resistance and comfort. Composed of intelligent fabric that maintains the user's ideal conditions for maximum comfort through movement.

Its use is indicated to be used by several clients, after cleaning and disinfection by the training professional.



1. Waist guide or guides
2. Plastic closure
3. Zipper
4. Lycra
5. Straps
6. Velcro ultra
7. Electrode
8. Velcro
9. Arm band

Washing Recommendations



1. Waist guide or guides
2. Pastic closure
3. Zipper
4. Lycra
5. Straps
6. Velcro ultra
7. Electrode
8. Velcro
9. Arm band
10. Logo
11. Sewing
12. Reflective stitching
13. Pocket
14. Carbonium
15. Connection pocket

MUSCLE	ZONE	Nº
QUADRICEPS	LEFT	3
QUADRICEPS	RIGHT	4
ARM	LEFT	5
ARM	RIGHT	6
LUMBAR	LEFT	7
LUMBAR	RIGHT	8
TRAPEZE	LEFT	9
TRAPEZE	RIGHT	10
DORSAL	LEFT	11
DORSAL	RIGHT	12
GLUTEUS	LEFT	15
GLUTEUS	RIGHT	16
ABDOMINAL	RIGHT	18
CHEST	RIGHT	20
ABDOMINAL	LEFT	17
CHEST	LEFT	19
HAMSTRING	LEFT	21
HAMSTRING	RIGHT	21
EXTRA	LEFT	23
EXTRA	RIGHT	24

Main materials

EXTERIOR: 100% Polyester

WEIGHT: 1,70 - 2 kg

COVER : 92% Cotton | 8% Elastane

CONDUCTIVE FABRIC : 70% Polyester | 20% Silver | 10% Elastane

MEASURES : **

NAME	XXS	XS	S	M	L	XL	XXL
REV.PRO WIDE JACKET	29 cm	32 cm	37 cm	40 cm	43 cm	48 cm	50 cm
REV.PRO LONG JACKET	45 cm	48 cm	52 cm	55 cm	61 cm	65 cm	68 cm
REV.PRO PERIMETER JACKET	72-90 cm	76-100 cm	82-105 cm	92-110cm	98-120cm	108-130 cm	112-135 cm
REV.PRO PANTS WAIST PERIMETER	92-115 cm	105-125 cm	110-114 cm	120-146 cm	130-150 cm	140-165 cm	148-170 cm
REV. PANTS PRO LONG	35 cm	35 cm	36 cm	37 cm	37 cm	38 cm	39 cm
REV.PRO PANTS THIGH PERIMETER	45-55 cm	47-59 cm	50-64 cm	53-69 cm	54-72 cm	57-77 cm	58-80 cm

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

Fabricante del producto: Medical Cables SL
Product manufacturer: *Medical Cables SL*

Dirección: Duque de la Victoria, 6 29015 Málaga (España)
Address: *Duque de la Victoria, 6 29015 Málaga (Spain)*

DECLARAN BAJO SU RESPONSABILIDAD QUE EL PRODUCTO:
DECLARE UNDER THEIR RESPONSIBILITY THAT THE PRODUCT:

PRODUCTO: Dispositivo inalámbrico de electroestimulación para Fitness – Wiemspro.
PRODUCT: *Wireless Electro Muscle Stimulation device for Fitness – Wiemspro.*

CUMPLE CON LA SIGUIENTE
COMPLY WITH THE FOLLOWING

NORMATIVA APLICADA:
APPLIED STANDARDS:

EN 60601-1-2:2007 CORR:2010. Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1 +A1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

IEC 60601-2-10:2012: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

ROHS 2011/65/UE: Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

EN 60335: Household and similar electrical appliances. Safety. General requirements.

Lugar y fecha: Málaga, 2 de junio de 2017
Location & date: *Málaga, Jun 2nd. 2017*

Nombre y Firma: José Fuertes Peña
Name & signature: *José Fuertes Peña*

2020

CERTIFICATE OF REGISTRATION

This certifies that:

WIEMSPRO S.L
Jacinto Verdaguer, 11
Malaga Malaga, SPAIN 29002

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3015781781**
DUNS No.:	**46-715-2206**
Device Classification Name:	**STIMULATOR, MUSCLE, POWERED, FOR MUSCLE CONDITIONING**
Product Code:	**NGX**
Regulation Number:	**890.5850**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp 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. Registrar Corp 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. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp

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Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: December 16, 2019

República de Colombia
Ministerio de Salud y Protección Social
Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA

RESOLUCIÓN No. 2018042199 DE 1 de Octubre de 2018
Por la cual se concede un Registro Sanitario

El Director técnico de Dispositivos Médicos y otras Tecnologías del Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, en ejercicio de las facultades Legales conferidas en el Decreto 2078 de 2012, decreto Reglamentario 4725 de 2005, ley 1437 de 2011 y ley 962 de 2005

CONSIDERANDO

QUE ANTE ESTE INSTITUTO SE HA SOLICITADO LA CONCESIÓN DE UN REGISTRO SANITARIO AUTOMATICO CON BASE EN LA VERIFICACIÓN DE LA DOCUMENTACIÓN TÉCNICO LEGAL ALLEGADA ANTE LA DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS, EMITIENDO CONCEPTO FAVORABLE PARA LA EXPEDICIÓN DE ESTE REGISTRO SANITARIO.
EN CONSECUENCIA A LO ANTERIOR, DE CONFORMIDAD CON EL ARTICULO 57 DE LA LEY 962 DE 2005 EL INVIMA REALIZARA EL CONTROL POSTERIOR DENTRO DE LOS QUINCE (15) DIAS SIGUIENTES A SU EXPEDICIÓN.

RESUELVE

ARTICULO PRIMERO.- CONCEDER REGISTRO SANITARIO POR EL TÉRMINO DE DIEZ (10) AÑOS A

PRODUCTO:	DISPOSITIVO INALAMBRICO DE ESTIMULACION ELECTROMUSCULAR
MARCA:	MEDICAL CABLES S.L.
REGISTRO SANITARIO NO.:	INVIMA 2018DM-0018686
TIPO DE REGISTRO:	IMPORTAR Y VENDER
TITULAR(ES):	STARK INDUSTRIES & SERVICES S.A.S. CON DOMICILIO EN BOGOTA - D.C.
FABRICANTE(S):	MEDICAL CABLES, S.L. CON DOMICILIO EN ESPAÑA
IMPORTADOR(ES):	DISTRIBUCIONES AUDIOLOGICAS S.A.S CON DOMICILIO EN BOGOTA - D.C.
ACONDICIONADOR(ES):	DISTRIBUCIONES AUDIOLOGICAS S.A.S CON DOMICILIO EN BOGOTA - D.C.
EQUIPO BIOMÉDICO:	EQUIPO DE APOYO TERAPEUTICO
RIESGO:	IIA
SISTEMAS:	ELECTRÓNICOS
SUBSISTEMAS:	CHALECO, ADAPTADOR, CABLES DE MEDICIÓN, ADAPTADOR, SISTEMA ESTIMULADOR CON BATERIA, APLICACIÓN DE CONTROL Y ALMACENAMIENTO DE DATOS
USOS:	ES UN SISTEMA QUE PERMITE EJERCITAR LOS MÚSCULOS USANDO IMPULSOS ELÉCTRICOS LOCALES, TAMBIÉN CONOCIDA EN EL SECTOR DEL FITNESS COMO EMS (ELECTRICAL MUSCLE STIMULATION). LOS IMPULSOS SON GENERADOS DESDE DISPOSITIVOS Y TRANSMITIDOS POR MEDIO DE ELECTRODOS LOCALIZADOS SOBRE LOS MÚSCULOS QUE SE QUIEREN ESTIMULAR. LOS IMPULSOS IMITAN EL POTENCIAL DE ACCIÓN QUE PROVIENE DEL SISTEMA NERVIOSO CENTRAL, CAUSANDO LA CONTRACCIÓN MUSCULAR.
PRESENTACIÓN COMERCIAL:	UNIDAD Y ACCESORIOS
OBSERVACIONES:	EL PRESENTE REGISTRO SANITARIO AMPARA LOS SIGUIENTES MODELOS ACCESORIOS Y REPUESTOS EXCLUSIVOS DEL EQUIPO: WIEMSPRO
VIDA ÚTIL:	15 AÑOS
EXPEDIENTE NO.:	20151646
RADICACIÓN NO.:	20181194753
FECHA DE RADICACIÓN:	24 09 2018

ARTICULO SEGUNDO.- CONTRA LA PRESENTE RESOLUCIÓN PROCEDE ÚNICAMENTE EL RECURSO DE REPOSICIÓN, QUE DEBERÁ INTERPONERSE ANTE EL DIRECTOR DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS, DENTRO DE LOS DIEZ (10) DÍAS SIGUIENTES A SU NOTIFICACIÓN, EN LOS TÉRMINOS SEÑALADOS EN EL CÓDIGO DE PROCEDIMIENTO ADMINISTRATIVO Y DE LO CONTENCIOSO ADMINISTRATIVO.

ARTICULO TERCERO.- LA PRESENTE RESOLUCIÓN RIGE A PARTIR DE LA FECHA DE SU EXPEDICIÓN.

ARTICULO CUARTO.- LOS DERECHOS QUE SE DERIVEN DE ESTA RESOLUCIÓN QUEDARAN SUJETAS AL CONTROL POSTERIOR QUE DEBE REALIZAR EL INSTITUTO NACIONAL DE VIGILANCIA DE MEDICAMENTOS Y ALIMENTOS INVIMA DE CONFORMIDAD CON LO PREVISTO POR EL ARTICULO 22 DEL DECRETO 4725 DE 2005.

COMUNIQUESE, NOTIFIQUESE Y CUMPLASE

DADA EN BOGOTÁ D.C. A LOS 1 DE OCTUBRE DE 2018
ESTE ESPACIO, HASTA LA FIRMA SE CONSIDERA EN BLANCO.

ELKIN HERNAN OTALVARO CIFUENTES
DIRECTOR TECNICO DE DISPOSITIVOS MEDICOS Y OTRAS TECNOLOGIAS
Proyecto: Legal: salbam, Técnico: msandovalc, Revisó: cordina_varios

Instituto Nacional de Vigilancia de Medicamentos y Alimentos - Invima
Bogotá
Principal: Cra 10 N° 64 - 28
Administrativo: Cra 10 N° 64 - 60
(1) 2948700
www.invima.gov.co

Certificate ES13/13628

The management system of

Medical Cables, S.L.

C/ Ferrocarril del Puerto, 18 - Oficina 3-4
29002 Málaga, Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture and supply of: SPO2 sensors, SPO2 extension cables, ECG cables and lead wires, non invasive blood pressure (nibp cuff), extension tubes for nibp cuffs, fiber optic cables, temperature probes for electromedical devices.

Diseño, fabricación y venta de: Sensores de SPO2, cables de extensión de sensores de SPO2, cables y latiguillos de ECG, manguitos de medida de la tensión arterial, tubos de extension para manguitos de medida de la tensión arterial, cables de fibra óptica y sondas de temperatura para equipos electromédicos.

This certificate is valid from 18 February 2019 until 17 February 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 05 February 2022
Issue 9. Certified since 18 February 2013

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

STATUS LETTER:

TO WHOM IT MAY CONCERN

The firm / company:

Att. José Fuertes Peña

MEDICAL CABLES

C/ Duque de la Victoria, 6 1º

29015 Málaga

The equipment Wiemspro has been tested according to the following Standards:

- IEC 60601-1-2:2007
- IEC 60601-1 + A1:2012
- IEC 60601-2-10:2012

From the results of the inspection and tests on the submitted sample, we conclude that it complies with the requirements of the Standards.

The results of the different tests and conclusions are included in the following Test Reports:

EMC Test Report No. 2416/0674

Safety Test Report No. 2116/0674

For any question do not hesitate to contact with us.

Best regards,

SGS Tecnos, S.A.
Número: 0556
Fecha: 02/06/2017
SALIDA | LABORATORIO

SGS Tecnos, S.A.

Fernando Montes Claver
Technical Manager of E&E Laboratory Spain.

Contract Number: 800091

Certificate: SGSNA/17/TEC/00006
Test Report Number: 2116/0674/1

Certified Product:	**Wireless stimulator**
Trademark (if any):	-
Model(s):	WIEMSpro
Technical Data:	183 V; 125 mA; 1200 Ohm; 5 Vdc (Internally powered); IPX0; Type BF
Name and Address of Applicant:	Medical Cables, S.L. Calle Duque de la Victoria 6, 1ª Planta, 29015, Malaga, Spain
Name and Address of Manufacturer:	Medical Cables, S.L. Calle Duque de la Victoria 6, 1ª Planta, 29015, Malaga, Spain
Name and Address of Factory:	Medical Cables, S.L. Calle Duque de la Victoria 6, 1ª Planta, 29015, Malaga, Spain

This certificate supercedes previous certificates issued with the same certificate number. Certification is valid when products are indicated on the SGS directory of certified products at www.sgs.com. The product is certified according to ISO/IEC Guide 17067, *Conformity assessment - Fundamentals of product certification, System 3*, and in accordance with

ANSI/AAMI ES60601-1:2005 +C1:2009 +A2:2010
CAN/CSA C22.2 No. 60601-1:08
-

Authorized by

Paul Krauss
Certifier

Effective date: 11 October 2017

Consumer and Retail Services, a division of SGS North America Inc.
620 Old Peachtree Road, Ste. 100, Suwanee, GA 30024, USA
t +1 770 570 1800 f +1 770 277 1240 www.sgs.com

Contract Number: 800151

Certificate: SGSNA/17/TEC/00007
Test Report Number: 2116/0674/1

Certified Product:	**Wireless stimulator**
Trademark (if any):	-
Model(s):	WIEMSpro
Technical Data:	183 V; 125 mA; 1200 Ohm; 5 Vdc (Internally powered); IPX0; Type BF
Name and Address of Applicant:	Luva3 LLC 7702 SW 84th PL., 33143, Miami, Florida, United States of America
Name and Address of Manufacturer:	Medical Cables, S.L. Calle Duque de la Victoria 6, 1ª Planta, 29015, Malaga, Spain
Name and Address of Factory:	Medical Cables, S.L. Calle Duque de la Victoria 6, 1ª Planta, 29015, Malaga, Spain

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medicalcables
Innovation & Compatibility for Health

PRODUCT DATA SHEET

ELECTROMIOESTIMULATION CABLE (EMS CABLE)

- Reference: COPEMS6
- Compatible Suits: Revolution, Comfort Fit y Lithe.
- Connector:
    - Brand and model: 3M TS-0669 – 10126-3000
    - Number of pins: 26
    - Conductive Material: Copper alloy.
    - Isolation: 80 µ" [2.0 µm] of Nickel.
    - Exterior insulation material: Reinforced poilyester.
- Wiring:
    - Conductive material: Copper.
    - Insulating Material: PVC.
    - Length: between 35cm y 125cm.
    - Exterior insulation: 43/0.1TC. Spiral
    - Exterior diameter: 1.8mm±0.1mm.
- Bananas:
    - Interior Material: Beryllium copper.
    - Exterior Material: PVC.
    - Male banana : 2.0mm*14.6mm.
    - Female banana : 2.0mm*14.6mm.
- Latex free.
- Presentation: Individual anti-static bag.