CERTIFICATES

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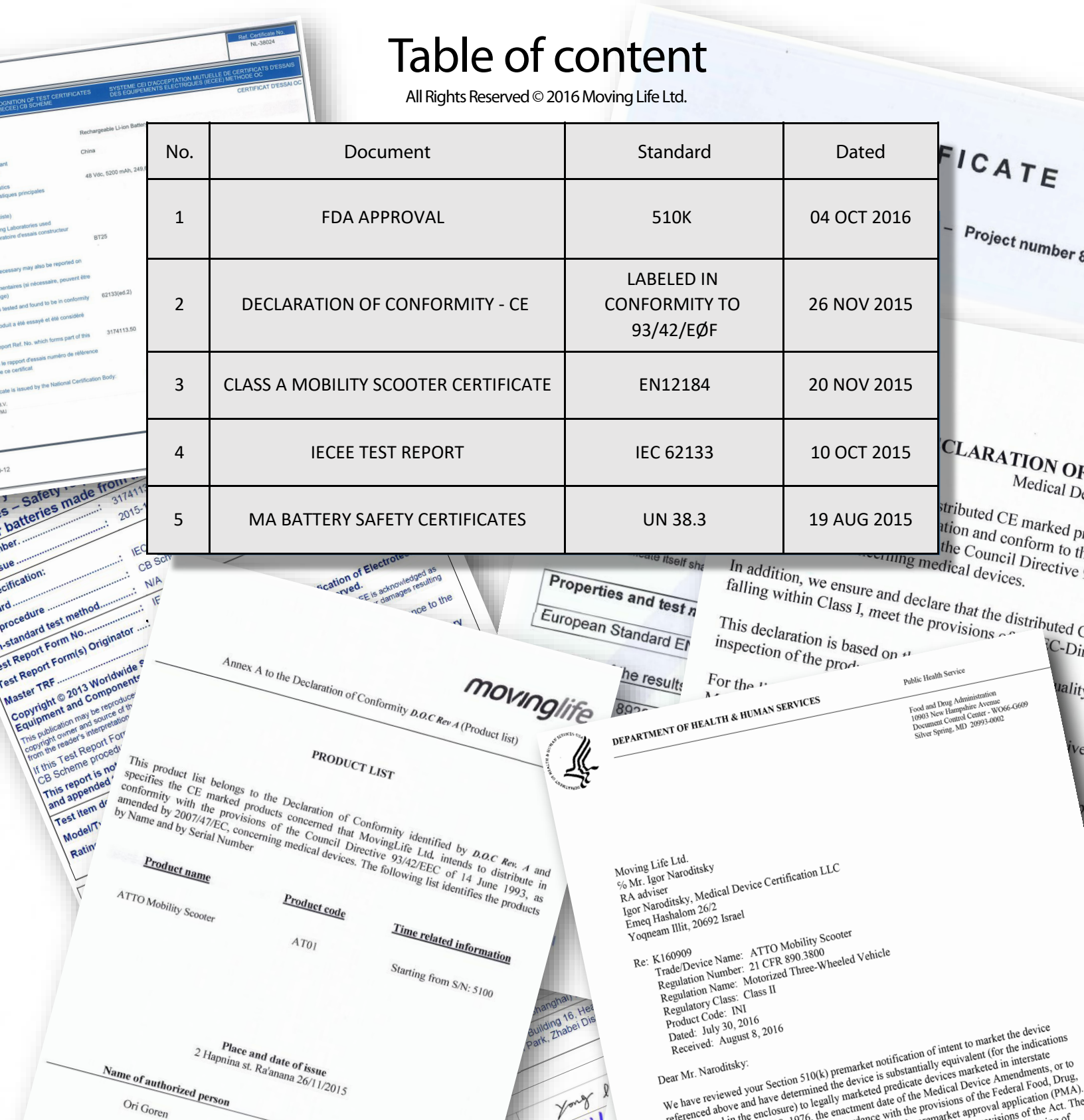

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Moving Life Ltd.
% Mr. Igor Naroditsky
RA adviser
Igor Naroditsky, Medical Device Certification LLC
Emeq Hashalom 26/2
Yoqneam Illit, 20692 Israel

Re: K160909
Trade/Device Name: ATTO Mobility Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: July 30, 2016
Received: August 8, 2016

Dear Mr. Naroditsky:

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 yours,

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

Enclosure

movinglife

DECLARATION OF CONFORMITY

Medical Devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by this declaration and conform to the required technical documentation, in accordance with Annex VII of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EC, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class I, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System for the manufacture and final inspection of the products concerned.

For the list of the applicable standards and other normative documents please refer to the ATTO Mobility Scooter Technical File.

This Declaration of Conformity is issued under the sole responsibility of the MovingLife Ltd. and covers products as specified in the product list Annex A: D.O.C.P.L, belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Manufacturer:
Moving Life ltd. 2 Hapnina st. Ra'anana 43215 Israel

Authorized Representative in the European community
Obelis Group Ltd. Bd Général Wahis, 53, B-1030 Brussels Belgium

Place and date of issue
2 Hapnina st. Ra'anana 26/11/2015

Name of authorized person	Signature
Ori Goren	Moving Life Ltd
CEO	

movinglife

Annex A to the Declaration of Conformity ***D.O.C Rev A*** (Product list)

PRODUCT LIST

This product list belongs to the Declaration of Conformity identified by ***D.O.C Rev. A*** and specifies the CE marked products concerned that MovingLife Ltd. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EC, concerning medical devices. The following list identifies the products by Name and by Serial Number

Product name	Product code	Time related information
ATTO Mobility Scooter	AT01	Starting from S/N: 5100

Place and date of issue
2 Hapnina st. Ra'anana 26/11/2015

Name of authorized person	Signature
Ori Goren	Moving Life Ltd
CEO	

CERTIFICATE

Certificate No.: PL 24079108 01 – Project number 89207808

Valid until November 2016

Holder: Moving Life Ltd
HaPnina 8
Ra'anana
Israël

Product	: Electrically powered scooter
Type	: ATTO - class A, max user weight 100 kg
Identification	: MT15.55780.01
Date of test results	: Week 34 up to week 47, 2015

On basis of the results of the non-recurrent tests specified below, we declare that the above specimen fulfils the requirements of the European Standard EN 12184:2014.

NB: This certificate itself shall not be considered as a type examination certificate.

Properties and test methods	Requirement	Results
European Standard EN 12184:2014	Type test	Pass

Full details of the results can be found in the following report(s):

Reference	Date of issue
TRN Report 89207808	November 20, 2015

Hans Fokkenrood
Author

i/o R.P. van Egmond
a.i. Business Field Manager products

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华南国家计量测试中心
广东省计量科学研究院
SOUTH CHINA NATIONAL CENTER OF METROLOGY
GUANGDONG INSTITUTE OF METROLOGY

ilac-MRA CNAS CNAS L0730

检 测 报 告
TEST REPORT

证书编号 Certificate No. DCW201504028 第 1 页，共 17 页 Page of

委托方 Client

委托方地址 Add. of Client

样品名称 Description 可充电锂离子电池 Rechargeable Li-ion Battery

型号规格 Model/Type BT25

制造厂 Manufacturer

出厂编号 Serial No. 1#~41# 设备编号 Equipment No.

接收日期 Date of Receipt 2015年 08 月 19 日 Y M D

结论 Conclusion 见检测结果页 Shown in the results of test report

检测日期 Date of Test 2015年 08 月 19 日 Y M D

批 准 人 Approved Signatory

核 验 Inspected by

检 测 Tested by

证书专用章 Stamp

本中心地址：中国广州市广园中路松柏东街30号 邮政编码：510405
电话：(8620)86594172 传真：(8620)86590743 投诉电话：(8620)26296063 E-mail: scm@scm.com.cn
Add: No.30, Songbaidong Street, Guangyuanzhong Road, Guangzhou, P. R. China
Post Code: 510405 Tel: (8620)86594172 Fax: (8620)86590743 Complaint Tel: (8620)26296063
证书真伪查询：www.scm.com.cn，www.mtpsp.com Certificate AuthenticityIdentify: www.scm.com.cn，www.mtpsp.com
7150819053 1

IEC IECEE

Test Report issued under the responsibility of:

DEKRA

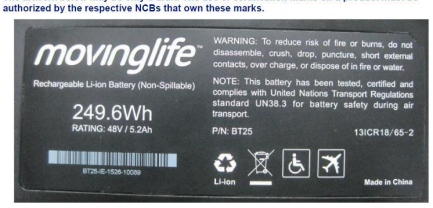
TEST REPORT
IEC 62133
Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

Report Number.	3174113.50
Date of issue	2015-10-10
Test specification:	
Standard	IEC 62133: 2012 (Second Edition)
Test procedure	CB Scheme
Non-standard test method	N/A
Test Report Form No.	IEC62133B
Test Report Form(s) Originator	UL(Demko)
Master TRF	Dated 2013-03

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	Rechargeable Li-ion Battery
Model/Type reference	BT25
Ratings	48 Vdc, 5200 mAh, 249,6 Wh

Copy of marking plate
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Testing procedure and testing location:		
☒ **CB Testing Laboratory:**	DEKRA Testing and Certification (Shanghai) Ltd.	
Testing location/ address	3F, #250 Jiangchangsan Road, Building 16, Headquarter Economy Park Shibei Hi-Tech Park, Zhabei District, Shanghai, 200436, China	
☐ **Associated CB Testing Laboratory:**		
Testing location/ address		
Tested by (name + signature)	Yong Liu	Yong Liu
Approved by (name + signature)	Cliff Lin	Cliff Lin

IEC IECEE CB SCHEME

Ref. Certificate No.
NL-38024

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME
SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE **CERTIFICAT D'ESSAI OC**

Product / Produit	Rechargeable Li-ion Battery
Name and address of the Applicant / Nom et adresse du demandeur	China
Rating and principal characteristics / Valeurs nominales et caractéristiques principales	48 Vdc, 5200 mAh, 249,6 Wh
Trademark (if any) / Marque de fabrique (si elle existe)	
Type of manufacturer's Testing Laboratories used / Type de programme de laboratoire d'essais constructeur	
Model / Type Ref. / Réf. de type	BT25
Additional information (if necessary may also be reported on page 2) / Les informations complémentaires (si nécessaire, peuvent être indiquées sur la 2ème page)	
A sample of product was tested and found to be in conformity with IEC / Un échantillon de ce produit a été essayé et été considéré conforme à la CEI	62133(ed.2)
As shown in the test report Ref. No. which forms part of this certificate / Comme indiqué dans le rapport d'essais numéro de référence qui constitue partie de ce certificat	3174113.50

This CB Test Certificate is issued by the National Certification Body:
DEKRA Certification B.V.
Meander 1051, 6825 MJ
Arnhem
The Netherlands

Ce Certificat d'essai OC est établi par l'Organisme National de Certification

DEKRA

Date: 2015-10-12

Signature: Vicky Zhang

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