SHARPOWER GULF FZE

ONE STOP TOP CLASS SERVICE FOR THE WORLD

SHARPOWER GULF FZE

1 Who we are

2 What we do

3 Certification list

who we are
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PROFILE

Wenzhou Weisiqi Technology Co.,Ltd It is a combo of high-tech enterprise with more than 30 years of domestically medical device design, research and development, manufacturing, branding and sales.

Based on15000 square meters, the factory has a 100000 class purification workshop on 2500 square meters, two imported Spun laced non-woven production lines, dozens of supporting deep processing equipment, with 5000 tons of annual production capability and deep processing for producing various high-end functional Spun laced non-woven fabrics, mainly producing various sanitary cleaning products, personal care sanitary products, baby care products, daily use sanitary products, medical dressings, etc. The company adheres to the business philosophy of "making life more simple", serves customers with high-quality products and returns to the society. In the past 20 years, through unremitting efforts, 70% of its products are exported by itself and sold to the, Japan, South Korea and other countries and regions.

SHARPOWER is our exclusive partner for GCC & Europe Countries, and we aim to provide products with high quality to the customers in order to serve the society.

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WORKSHOP

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WORKSHOP

SHARPOWER GULF FZE

chapter two

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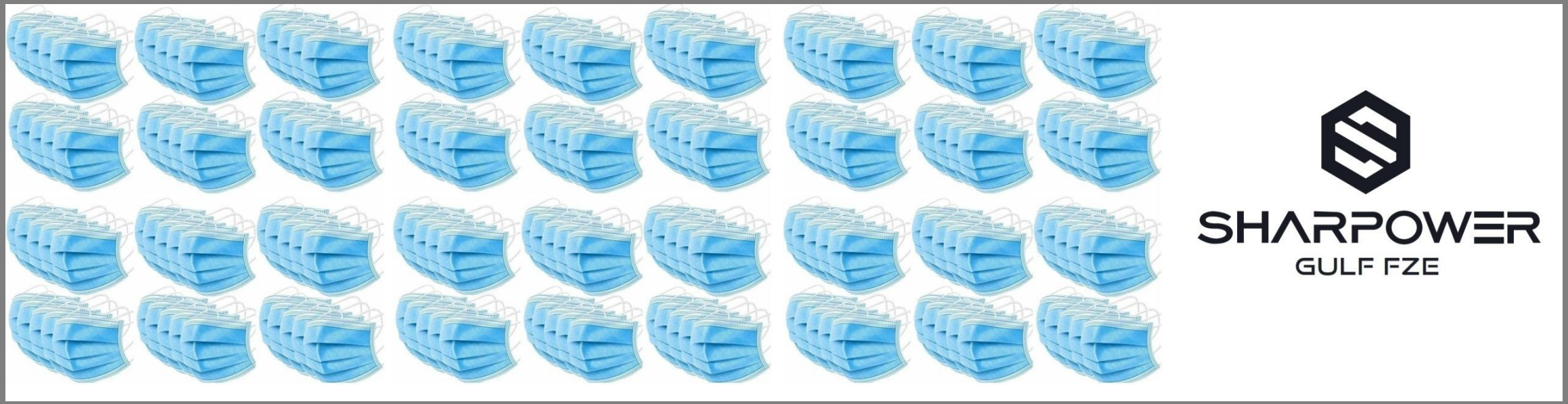
3PLY MASK



PRODUCT DISPLAY

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SHARPOWER GULF FZE

chapter three

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CERTIFICATION

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CE Certification

CE

DECLARATION OF CONFORMITY
ACCORDING TO THE
REGULATION (EU) 2017/745

File. No.: C200416252C

Manufacturer	:	Wenzhou Weisiqi Technology Co.,Ltd. East of the first floor of the industrial plant in block 27, phase 2, China xie du industrial park, Fengmen street, Lucheng district, Wenzhou city, Zhejiang province, China 325000
Product	:	Disposable Face Mask
Model	:	WSQ-001
Classification	:	Class I medical device According to Annex VIII of Regulation (EU) 2017/745
Date of Manufacture	:	Apr 2020
European Authorised Representitive	:	3A Inno UG(haftungsbeschränkt) Eisfelder Str. 12, D-96450 Coburg, Germany Tel: +49 8803 8919981 Email: 3ainnoug@gmail.com
Harmonised Standard which Comply With	:	EN 14683:2019 Medical face masks. Requirements and test methods Type I

The manufacturer declares under his sole responsibility that the above product under normal conditions of use and determined by the manufacturers Conditions is secure and all necessary legal conditions and Requirements fulfilled. The product is a medical device that is unique Use is intended and only corresponds to the manufacturer's instructions.

The manufacturer declares that he has taken all necessary measures to ensure that the Conformity of the products placed on the market with the technical documentation and ensure the basic requirements for this type of product.

Wenzhou Weisiqi Technology Co.,Ltd.

ISSUED DATE: 26 APR 2020
EXPIRED DATE: 25 APR 2021

CERTIFICATION

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CE Registration of Notification

VISHTEC create solutions

REGISTRATION NOTIFICATION

of Competent Authority
According to
Medical Device 93/42/EEC(MDD) and MDR Regulation (EU) 2017/745

Reference number: ERA-DE-20200430013
Issued Date: 30 April, 2020
This certificate will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

This is certified that, According to Medical Device 93/42/EEC (MDD) and MDR Regulation (EU) 2017/745, and the party below accepts the appointment to be the Authorised European Representative for product which listed in attached agreement between below manufacturer and the party below:

Manufacturer: Wenzhou Weisiqi Technology Co.,Ltd.
Address: East of the first floor of the industrial plant in block 27, phase 2, China xie du industrial park, Fengmen street, Lucheng district, Wenzhou city, Zhejiang province, China 325000

Authorised European Representative: 3A Inno UG(haftungsbeschriinkt)
Address: Eisfelder Str. 12, 96450, Coburg, Germany

The Manufacturer declares that Medical Device complies with European Regulations, Rules and Standards including but not limited to

Medical Device 93/42/EEC(MDD) and MDR Regulation (EU) 2017/745

The European Databank on Medical Devices (EUDAMED) is established as of May. 1, 2011, the German Institute of Medical Documentation and Information (DIMDI) is notified of the manufacturer's Medical Devices and has allocated registration numbers shown in:

Disposable Face Mask, UMDN Code: 12-458
Registration number: DE/CA64/00161732

Where the manufacturer affix the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

CE

EA AR European Association of Authorised Representatives

CERTIFICATION

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FDA Certification

Fiscal Year 2020
FDA REGISTRATION CERTIFICATE

Certificate Holder:

WENZHOU WEISIQI TECHNOLOGY CO., LTD

East of the First Floor of the Industrial Plant in Block 27, Phase 2, China Shodu Industrial Park, Fengmen Street, Lucheng District
Wenzhou, Zhejiang, 325000, CHINA

has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration.

Registration Number: N

Owner/Operator Number: 10071062

Device Listing:

Device#	Product Codes	Device Name
D394511	LYU	ACCESSORY, SURGICAL APPAREL (Facemask, Disposable Mask, Disposable face masks for civilian use)

Registration Expiration Date: 2020-12-31

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuit to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICES LLC assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICES LLC is a private registration agent and is not affiliated with the US Food and Drug Administration.

J&F TECHNOLOGY SERVICES LLC.
2424 Morris Ave 818 Union
NEW JERSEY 07083
United States

CERTIFICATION

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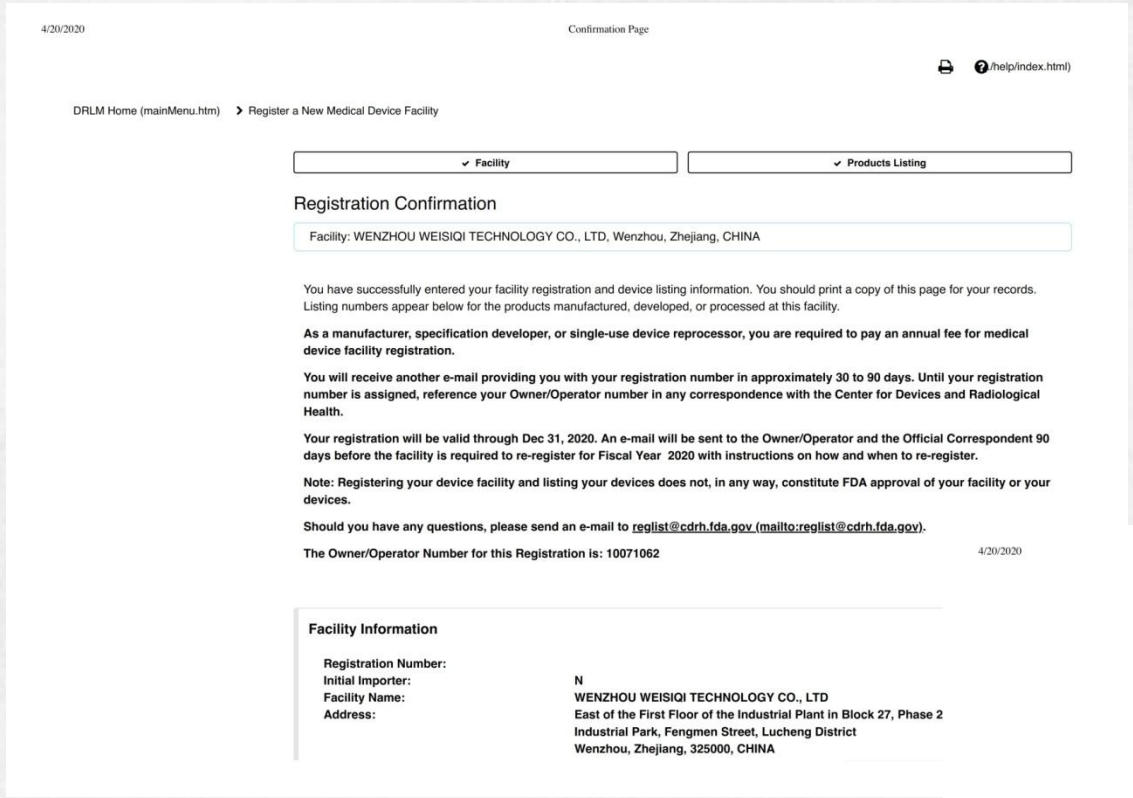
FDA Confirmation



4/20/2020 Confirmation Page

/help/index.html)

DRLM Home (mainMenu.htm) > Register a New Medical Device Facility

✔ Facility ✔ Products Listing

Registration Confirmation

Facility: WENZHOU WEISIQI TECHNOLOGY CO., LTD, Wenzhou, Zhejiang, CHINA

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Your registration will be valid through Dec 31, 2020. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2020 with instructions on how and when to re-register.

Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to reglist@cdrh.fda.gov (mailto:reglist@cdrh.fda.gov).

The Owner/Operator Number for this Registration is: 10071062 4/20/2020

Facility Information

Registration Number:	
Initial Importer:	**N**
Facility Name:	**WENZHOU WEISIQI TECHNOLOGY CO., LTD**
Address:	**East of the First Floor of the Industrial Plant in Block 27, Phase 2 Industrial Park, Fengmen Street, Lucheng District Wenzhou, Zhejiang, 325000, CHINA**

Confirmation Page

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D394511	Exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer Foreign Exporter	

Date of Initial Registration: Mon Apr 20 04:13:16 EDT 2020

TESTING REPORTS

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Testing Report

Testing Report

PONY 谱 尼 测 试
Pony Testing International Group

CMA
160920340809

检 测 报 告
(Test Report)

No. BOY8FVDR897807L1

样品名称 (Sample Description)	Disposable Face Mask
委托单位 (Applicant)	温州卫思齐科技有限公司 Wenzhou Weisiqi Technology Co.,Ltd.

PONY 谱尼测试
Pony Testing International Group
www.ponytest.com

PONY 谱 尼 测 试
Pony Testing International Group

声 明
Statement

1. 本报告无专用章和批准人签章无效。
This report is invalid without the approver's signatures and special seal of inspection.

2. 本报告页面所使用“PONY”、“谱尼”字样为本单位的注册商标，其受《中华人民共和国商标法》保护，任何未经本单位授权的擅自使用和仿冒、伪造、变造“PONY”、“谱尼”商标均为违法侵权行为，本单位将依法追究其法律责任。
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3. 委托单位对报告数据如有异议，请于报告完成之日起十五日内（初级农产品报告请于报告收到之日起五日内）向本单位书面提出复测申请，同时附上报告原件并预付复测费。
If the applicant has any questions about the results, shall provide a written retest application with the original report, and prepay the retest fees to PONY within fifteen days since the approval date (as an exception, it shall be within five days since the date received for the primary agriculture products report).

4. 委托单位办理完毕以上手续后，本单位会尽快安排复测，如果复测结果与异议内容相符，本单位将退还委托单位的复测费。
After the applicant finishes the procedure mentioned above, PONY shall arrange the retest as soon as possible. If the retest result accords with the applicant dissent, PONY shall refund the retest fees.

5. 不可重复性或不能进行复测的实验，不进行复测，委托单位放弃异议权利。
Tests that can not be repeated and tested shall not be carried out again.

6. 委托单位对样品的代表性和资料的真实性负责，否则本单位不承担任何相关责任。
The applicant should undertake the responsibility for the provided samples' representativeness and document authenticity. Otherwise, PONY has not any relevant responsibilities.

7. 本报告仅对所测样品负责，报告数据仅反映对所测样品的评价，对于报告及所载内容的使用，使用所产生的直接或间接损失及一切法律后果，本单位不承担任何经济和法律责任。
This report is only responsible for the provided sample. The test results only represent the evaluation of the tested sample. PONY will not be responsible for any economical or legal liability generated from direct or indirect usage of the test report.

8. 本单位有权在完成报告后处理所测样品。
PONY has the right to dispose the tested sample after approval of the test report.

9. 本单位保证工作的客观公正性，对委托单位的商业信息，技术文件等商业秘密负有保密义务。
PONY assures objectivity and impartiality of the test, and fulfills the obligation of confidentiality for applicant's commercial information, and technique document.

10. 本报告如有转让、盗用、冒用、涂改、未经本单位批准的复制（全文复制除外）或以其它任何形式的篡改均属无效，本单位将对上述行为严究其相应的法律责任。
The report is invalid in case of illegal transfer, embezzlement, imposture, modification or any altering, reproducing except in full, without approval of PONY. PONY shall investigate and affix the applicant's legal liability accordingly.

▲防伪说明(Anti-counterfeiting Description):

(1) 报告编号是唯一的;
The test report has exclusive report code.

(2) 报告采用特制防伪纸张印制，纸张表面带有“PONY”防伪纹路，该防伪纹路不复持复印，即复制件不会带有“PONY”防伪纹路。
The test report is printed by anti-copying paper whose surface shows "PONY" security print with specific anticounterfeiting technique. Security print will disappear after copying. Duplicates are not expected to give "PONY" security print under any circumstances.

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WWW.PONYTEST.COM

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北京实验室：(010) 83055000	武汉实验室：(027) 83997127	哈尔滨实验室：(0451)58627755			
上海实验室：(021) 64851999	长春实验室：(0431)85150908	石家庄实验室：(0311)85376660		温州实验室：(0577)88271060	
青岛实验室：(0532)88706866	大连实验室：(0411)87336618	乌鲁木齐实验室：(0991) 6684186		合肥实验室：(0551)63843474	
深圳实验室：(0755)26050909	郑州实验室：(0371)69350670	呼和浩特实验室：(0471) 3450025		广州实验室：(020) 89224310	
天津实验室：(022) 23607888	西安实验室：(029) 89608785	杭州实验室：(0571)87219096		厦门实验室：(0592)5568048	
苏州实验室：(0512)62997900	太原实验室：(0351) 7555762	宁波实验室：(0574)87736499		成都实验室：(028) 87702708	

TESTING REPORTS

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Testing Report

PONY 谱 尼 测 试
Pony Testing International Group

检 测 结 果
(Test Results)

No. BOY8FVDR897807L1 第 1 页，共 2 页 (page 1 of 2)

样品名称 (Sample Description)	Disposable Face Mask	样品规格 (Sample Specification)	规格 Specification：17.5cm-9.5cm 型号 Model：WSQ-001
委托单位 (Applicant)	温州卫思齐科技有限公司 Wenzhou Weisiqi Technology Co.,Ltd.	商标 (Trade Mark)	——
到样日期 (Received Date)	2020-04-15	生产日期或批号 (Manufacturing Date or Lot No.)	生产日期 Manufacturing Date：2020.04.14 生产批号 Manufacturing Lot No.：LS20200414
检测日期 (Test Date)	2020-04-15~2020-04-27	样品等级 (Sample Grade)	——
样品数量 (Sample Quantity)	80pcs	检测类别 (Test Type)	委托检测 (Commissioning Test)
样品状态 (Sample Status)	正常 Normal	检测环境 (Test Environment)	符合要求 (To meet the requirements)
检测项目 (Test Items)	见下页 See the next page		
检测方法 (Test Methods)	见下页 See the next page		
所用主要仪器 (Main Instruments)	电热恒温培养箱 Electric Heating Constant Temperature Incubator、细菌过滤效率检测仪 Bacterial filtration efficiency detector 等 etc.		
备注 (Note)	限值标准 Limit Standard：EN 14683：2019 生产单位 Production：温州卫思齐科技有限公司 Wenzhou Weisiqi Technology Co.,Ltd. 受检单位 Inspection：温州卫思齐科技有限公司 Wenzhou Weisiqi Technology Co.,Ltd. 以上样品信息由委托单位提供 The information of above sample was provided by the applicant.		
PONY专用章 (Special Stamp of PONY)	编制人 (Edited by)		
	审核人 (Checked by)	郭惠	
	批准人 (Approved by)	戴晴	
	签发日期 (Issued Date)	2020-04-27	

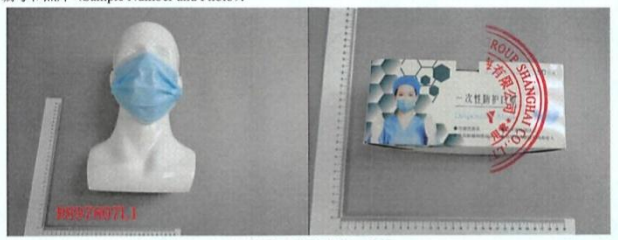
PONY 谱 尼 测 试
Pony Testing International Group

检 测 结 果
(Test Results)

No. BOY8FVDR897807L1 第 2 页，共 2 页 (page 2 of 2)

样品名称和编号 (Sample Description and Number)	检测项目 (Test Items)	限值 II 型 (Limit) Type II	检测结果 (Test Results)		单项结论 (Evaluation)	检测方法 (Test Methods)
R897807L1 Disposable Face Mask	细菌过滤效率 (BFE)，% Bacterial filtration efficiency(BFE)	≥98	No.1	99.9	符合 Conform	EN 14683：2019
			No.2	99.7		
			No.3	99.8		
			No.4	99.7		
			No.5	99.7		
	压力差，Pa/cm² Differential pressure	<40	30.9		符合 Conform	EN 14683：2019
	微生物清洁度，cfu/g Microbial cleanliness	≤30	19		符合 Conform	EN 14683：2019

样品编号和照片（Sample Number and Photo）：



仅对报告照片中的样品负责
Pony authenticate the photo on original report only
——以下空白——
(End of Report)

Overseas Office

SHARPOWER GULF FZE

HUNGARY COMPANY NAME: SHARPOWER INTERNATIONAL KFT

ADDRESS:1027 BUDAPEST BEM JOZSEF UTCA 9.FSZT
ADOSZAM: 27078891-2-41
VAT NUMBER: HU27078891
IBAN NUMBER: HU08
CONTACT: FEHERVARI DENES
PHONE NUMBER:36 2044 93039

THE UAE COMPANY NAME: SHARPOWER GULF FZE

ADDRESS: OFFICE NO LB 09002,JEBEL ALI,FREE ZONE, DUBAI, UAE
CONTACT: SANJU VARGHESE
PHONE NUMBER: 00971 529064039

SHARPOWER GULF FZE

Thank You