IYASOCARE®

FOCUS
RESEARCH
DEVELOPMENT
PRODUCTION

Chongqing Iyasocare Medical Co.,Ltd.
Free Trade Tower, Xiyong street. Chongqing, China
iyaso@iyasocare.com
0086-136 1835 0425

www.iyasocare.com
iyasocare.en.alibaba.com

CHONGQING IYASOCARE MEDICAL CO.,LTD.

PRODUCT CATALOG BROCHURE

COMPANY INTRODUCTION

Chongqing IYASOCARE MEDICAL CO.,LTD. was established in 2006 and is headquartered in the beautiful mountain city of Chongqing in China. It is an integrated industry and trade company specializing in medical device R&D, production, sales and consulting services, with business all over the world. The company' s main products include wheelchairs, hospital beds, electric scooters, walkers,commode chair, etc.; the company is committed to providing customers with reasonable, complete, reliable, and high-quality medical procurement programs; since the company was founded, it has served the United States, the United Kingdom, and Australia , France, Saudi Arabia, Egypt, Pakistan, Japan, South Korea and other global customers; and has obtained medical device registration certificate, medical device production license, medical device business license, ISO13485, CE, TUV, MDR, CFS and other qualifications Certificate; is a supplier of continuous strategic cooperation with China Medical Device Association.

AUTHENTICATION CERTIFICATE

ISO 13485

Medical Management System Certification

Award

CHONGQING IYASOCARE MEDICAL CO.,LTD.

The Medical management system of the above organizations has been reviewed and complied with

ISO 13485:2016

Requirements of applicable clauses of Medical management system standards

This system is valid for the Production and sales of Medical equipment,Wheelchair, Manual wheelchair, Electric wheelchair, Scooter, Electric handcycle, Manual bed, Electric Bed, Medical bed products

Spain European Certified organization Limited

WWW.CCE-ISO.COM

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: Chongqing Iyasocare Medical Co., Ltd
Address: 406, 4 / F, Software Park Phase 2, 8 Xiyuan North Street (Free Trade Tower)
SRN: /

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971:2019
EN ISO 13223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 12184:2014
EN 60601-1:2006/A2:2021
EN 60601-1-2:2015/A1:2021
EN 62366-1:2015

Remark
The declaration of conformity is valid in connection with the release technical document CG/MDR-Y122127-01.
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: ELECTRIC WHEELCHAIR
Model: see annex
EMDN: Y122127
Basic UDI: /
Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date:2023.12.26
Position: GM Place: Chongqing/China

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: Chongqing Iyasocare Medical Co., Ltd
Address: 406, 4 / F, Software Park Phase 2, 8 Xiyuan North Street (Free Trade Tower)
SRN: /

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971:2019
EN ISO 13223-1:2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 12184:2014
EN 60601-1:2006/A2:2021
EN 60601-1-2:2015+A1:2021
EN 62366-1:2015

Remark
The declaration of conformity is valid in connection with the release technical document CG/MDR-Y122124-02
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: Electric scooter
Model: see annex
EMDN: Y122124
Basic UDI: /
Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date:2023.12.28
Position: GM Place: Chongqing/China

Certificate of Conformity

Certificate No. :ECT2021P0905389R-1
Applicant :CHONGQING IYASOCARE MEDICAL CO.,LTD.
:Room 201-269,115 Longan Avenue,Tuzhu Town,Shapingba District,Chongqing Province, China
Product Name :Wheelchair,Manual wheelchair, Electric wheelchair, Scooter, Electric handcycle, Commode chair,Walking aids, Transfer wheelchair
Trade Name :N/A
Model :(see the following annex)
Classification :Class I (accordingly to the Manufacturer's declaration)
Review goal :Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation (EU) 2017/745

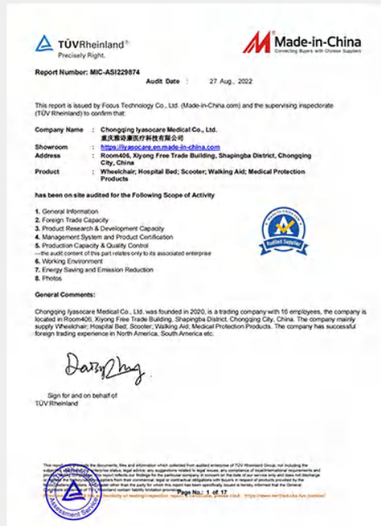
This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices Regulation.

The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECT Voluntary Mark for the certification of products.

Date : Sep.18.2021

The results in this report are applicable only to the equipment tested. This report shall not be re-produced except in full without the written approval of Shenzhen ECT Testing Technology Co., Ltd.

Shenzhen ECT Testing Technology Co., Ltd.
3th Floor, Guohaitong Business Center, Building A, No. 36 Gonghe Industrial Road, Bacon District,Shenzhen City, China
Tel: +86-755-87167493 Fax: +86-755-87167493 http://www.ect-lab.com



TÜVRheinland® Precisely Right.

Made-in-China Connecting Buyers with Global Suppliers

Report Number: MIC-ASI229874

Audit Date : 27 Aug., 2022

This report is issued by Focus Technology Co., Ltd. (Made-in-China.com) and the supervising inspectorate (TÜV Rheinland) to confirm that:

Company Name : Chongqing Iyasocare Medical Co., Ltd.
重庆原谷医疗科技有限公司
Showroom : https://iyasocare.en.made-in-china.com
Address : Room406, Xiyong Free Trade Building, Shapingba District, Chongqing City, China
Product : Wheelchair; Hospital Bed; Scooter; Walking Aid; Medical Protection Products

has been on site audited for the Following Scope of Activity:

1. General Information
2. Foreign Trade Capacity
3. Product Research & Development Capacity
4. Management System and Product Certification
5. Production Capacity & Quality Control
—the audit content of this part relates only to its associated enterprise
6. Working Environment
7. Energy Saving and Emission Reduction
8. Photos

General Comments:

Chongqing Iyasocare Medical Co., Ltd. was founded in 2020, is a trading company with 10 employees, the company is located in Room406, Xiyong Free Trade Building, Shapingba District, Chongqing City, China. The company mainly supply Wheelchair; Hospital Bed; Scooter; Walking Aid; Medical Protection Products. The company has successful foreign trading experience in North America, South America etc.

Sign for and on behalf of TÜV Rheinland

Page No.: 1 of 17

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Fascinatio Boulevard 522 (Unit 1.7)
2909 VA Capelle aan den IJssel

Farmatec
Bezoekadres:
Hofplein
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20240044

Bijlagen

Uw aanvraag
5 januari 2024

Correspondentie uitsluitend richten aan het rotsoordres met vermelding van de datum en het kenmerk van deze brief.

Datum: 16 februari 2024
Betreft: notificatie medische hulpmiddelen klasse I

Geachte heer Luo,

Hierbij bevestig ik de ontvangst op 5 januari 2024 van de notificatie van de medische hulpmiddelen klasse I, die bedrijf Chongqing Iyasocare Medical Co., Ltd., met Europees gemachtigde SUNGO Europe B.V., als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
De producten zijn onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over een of meer van deze producten het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Electric scooter
(geen merknaam) (NL-CA002-2024-78196)
Electric wheelchair
(geen merknaam) (NL-CA002-2024-78195)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelenindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw producten overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaande hulpmiddelen te registreren in Eudamed.[3]

[1] O.g.v. art. 29 MDR.
[2] O.g.v. art. 31 MDR.
[3] www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. Zie vraag en antwoord nummer 26.

Pagina 1 van 2

Electric Stair Climbing Wheelchair

YSE201

FEATURES:

1.Universal controller
2.High quality stair climber stair climbing chair for disabled and elderly people
3.Climbing lock: slow down and reverse lock
4.Flat ground and stair climbing dual use

PARAMETERS:

Driving Range:15KM
Max Speed:8KM/h
Battery: 20Ah lithium
Cushion: Artificial leather
Climb speed: 15 stair steps/Min
Climbing ability: 500 stairs steps
Stair width required: ＞700mm
Stair depth required: ＞1100mm
Stair slope required:＜45°

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
95KG/108KG	150KG	100CM	65CM	120CM	44CM	45CM	8 inches	12 inches	53CM	50CM	98*65*50CM	112*75*79CM

YSE202

FEATURES:

Battery: 24V 13Ah lithium
Cushion: Artificial leather
Climb speed: 30 stair steps/Min
Climbing ability: 500 stairs steps
Stair width required: ＞650mm
Staircase corner width and depth required: ＞1200mm
Stair slope required:＜50°

PARAMETERS:

1. Aluminum alloy material, light weight, can be folded
2. Wide range of applications, can load most of the manual wheelchairs on the market
3. Convenient operation, stable climbing, no high threshold for use
4. small size, suitable for most residential stairs

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
33KG/42KG	100KG	160CM	77CM	70CM	/	/	2.5 inches	5 inches	/	/	105*50*23 CM	130*56*18CM

YSE203

FEATURES:

1.Universal controller
2.Multifunctional height adjustable folding wheelchair for stair climbing
3.Textile breathable sponge cushion, pillow adjustable
4.Electric driving and electric climbing dual use

PARAMETERS:

Driving Range:15KM
Max Speed:8KM/h
Battery: 20Ah lithium
Driving motor: 24V 250W*2
Climbing motor: 24V 250W
Cushion: Artificial leather
Climb speed: 15 stair steps/Min
Climbing ability: 500 stairs steps
Stair width required: ＞700mm
Stair depth required: ＞1100mm
Stair slope required:＜45°

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
60/69kg	150KG	102CM	70CM	110CM	44CM	44CM	7.5 inches	12 inches	78CM	44CM	70*58*93CM	112*75*79CM

YSE204

FEATURES:

1.Lightweight multifunctional height adjustable folding wheelchair for stair climbing
2.3 gears climbing speed
3.New large wheel, easy to deal with various road conditions
4.Four-season dual-use seat cushion

PARAMETERS:

Battery: 13 Ah lithium
Cushion: Artificial leather
Climb speed: 15 stair steps/Min
Climbing ability: 500 stairs steps
Stair width required: ＞650mm
Stair depth required: ＞1100mm
Stair slope required:＜45°

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
28KG/31KG	150KG	108CM	50CM	151CM	45CM	45CM	4 inches	12 inches	50CM	50CM	50*29*103CM	104*54*30CM

Electric Stair Climbing Wheelchair

YSE205

FEATURES:

1.Universal controller
2.High quality stair climber stair climbing chair for disabled and elderly people
3.Climbing lock: slow down and reverse lock
4.Flat ground and stair climbing dual use
5.Reclining chair

PARAMETERS:

Driving Range:15KM
Max Speed:8KM/h
Motor:24V DC 370W
Battery:20Ah(lithium battery)
Parking brake:manual brake and electromagnetic brake
Cushion:Artificial leather
Minimum depth of stairs: 1.3m
Climbed Number: 500
Stair width: ⩾0.7m
Stair slope:<45°
Climb speed: 15 stair steps/Min

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
93/100KG	150KG	108CM	68CM	130CM	48CM	43CM	8 inches	12 inches	/	44CM	68*77*88CM	/

YSE207

FEATURES:

1.Universal controller
2.High quality stair climber stair climbing chair for disabled and elderly people
3.Climbing lock: slow down and reverse lock
4.Flat ground and stair climbing dual use
5.Backup camera
6.Climb the stairs independently
7.Large comfortable seat

PARAMETERS:

Driving Range:15KM
Battery: 20Ah lithium
Cushion: Artificial leather
Climb speed: 15 stair steps/Min
Climbing ability: 500 stairs steps
Stair width required: ＞850mm
Stair depth required: ＞1500mm
Stair slope required:＜45°

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
130KG	150KG	128CM	76CM	140CM	50CM	50CM	8 inches	12 inches	/	63CM	114*76*120CM	78*126*125CM

YSE208

FEATURES:

1.Universal controller
2.Multifunctional height adjustable folding wheelchair for stair climbing
3.Electric driving and electric climbing dual use

PARAMETERS:

Driving Range:15KM
Battery: 13Ah lithium
Cushion: Artificial leather
Climb speed: 15 stair steps/Min
Climbing ability: 500 stairs steps
Stair width required: ＞700mm
Stair depth required: ＞1100mm
Stair slope required:＜45°

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
38KG/43KG	150KG	98CM	65CM	125CM	43CM	45CM	8 inches	12 inches	/	44CM	110*65*35CM	123*60*71CM

YSE209

FEATURES:

Battery: 10Ah lithium
Cushion: Artificial leather
Climb speed: 15 stair steps/Min
Climbing ability: 500 stairs steps
Stair width required: ＞700mm
Staircase corner width and depth required: ＞1100mm
Stair slope required:＜45°

PARAMETERS:

1.Electrical stair climbing
2.Textile breathable sponge cushion
3.Manual drive and electrical stair climbing dual use

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
27KG/31KG	100KG	81CM	57CM	145CM	41CM	35CM	4 inches	5 inches	41CM	/	102*57*34CM	104*58*35CM

Electric Stair Climbing Wheelchair

YSE-F1

FEATURES:

1. Simple operation, can be quickly learned to use.
2. It can be docked with manual wheelchairs of different types, with wide versatility.

PARAMETERS:

Battery: 12Ah
Climb speed: 15 stair steps/Min
Climbing ability: 900 stairs steps (1 hour)
Stair width required: ＞700mm
Stair depth required: ＞1300mm
Stair slope required:＜45°

MAIN PARAMETERS

N/G	Load	overall length	overall width	overall height	seat width	seat depth	front wheel	rear wheel	backrest height	seat height	folding size	DIM
80KG/98KG	130KG	102CM	45CM	29CM	/	/	/	/	/	44CM	98*65*50CM	112*75*79CM

IYASOCARE®