

1. Information about the company, scope, general

The company Hi-Fortune Health Products Co., Ltd. located in No. 301, Qinhe Road, Zhangpu Town, Kunshan City, Jiangsu Province, P.R, China, provided the following CE technical documentation to TÜV SÜD China, Shanghai Branch in May, 2016:

- CE technical documentation for Electronic Lift, document no. HF/CE01, Rev A/1, date 2016-04-11

The following model is covered in the CE technical documentation:

HY101-01A

The Electronic Lift is designed for short-distance transfer for patient in domestic area, hospital or sanatorium. According to Directive 93/42/EEC, the classification is class I.

According to the manufacturer's application, TÜV SÜD China, Shanghai Branch has reviewed the CE documentation and drafted this report on a voluntary basis. This report is only valid in combination with a valid ISO13485 certificate issued by TÜV SÜD.

The EC Representative is KINGSMEAD SERVICE LIMITED, located in 145-157 St John Street, London, EC1V 4PY (UK).

2. Purpose of the review

Review for completeness of Technical Documentation on a voluntary basis based on Annex VII, section 3 of the Council Directive 93/42/EEC on Medical Devices.

3. Content of the review

The CE technical documentation has been reviewed by Yanan Liu who is authorized by the certification body of TÜV SÜD Product Service for Medical Device Lead Auditor. The technical file review included the following parts:

- Section 1, Declaration of conformity (No. FH/CE02-01)

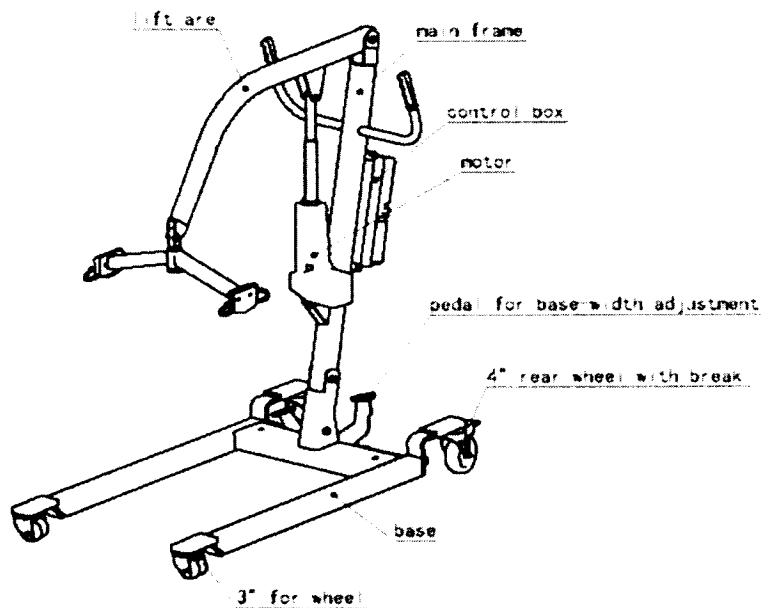
Declaration of conformity was issued by Mr. G.M in 2015-03-20.

- Section 2, Intended use described in product description

The Electronic Lift is designed for short-distance transfer for patient in domestic area, hospital or sanatorium.

- Section 3, Product description (No. FH/CE01-06)

The device is made of Leather, stainless steel materials.



Technical Specification:

Size: L 1200mm x W 620mm x H 1225mm

Max Base Width: 800mm

Lifting range: 755mm—1700mm

Lifting speed: 3.8mm/s

Power supplier: 220V 50Hz

Motor: 24V/8000N

Load: 180KG

Net weight: 45KG

Noise: 65dB (A)

Stability: no tip or turnover by pull strength 120N.

- Section 4, essential requirements checklist

Following harmonized standards are listed in the ER checklist #FH/CE01-04 and listed in the applied standards form # FH/CE01-03: EN ISO 14971:2012, EN 60601-1:2005+A1:2013, EN 60601-1-2:2007+AC:2010, EN 62366:2008, EN ISO 10993-1:2009, ISO 10535:2006.

Test reports #TRS14120001 R/C 31496 according to EN 60601-1:2006/A1:2013, #TRE14110124 R/C 60773 according to EN 60601-1-2:2007/AC: 2010 were compiled by Shenzhen Huatongwei. # FH/CE01-04 according EN62366:2008 compiled by the manufacturer, No.18/2015 according to ISO10535:2006 conducted by National quality supervision& Test Center for rehabilitation Technical Aids are spot-checked.

- Section 5, risk management report

Risk management report #FH/RS-LY-2014 issued in 2015-04-20, include risk

management plan, the product description, responsibility of analysis stuff, risk acceptance criteria, risk analysis summary, conclusion, etc. After taken risk reduction activity, all risk is acceptable level.

- Section 6, clinical data

Literature search is selected as the clinical evaluation route, and the evaluation is conducted according to MEDDEV2.7.1.

Clinical evaluation report #FH/CE01-12 is issued in 2016-04-20 by Mr. Fan Jianjiang.

- Section 7, information supplied by the manufacturer

Instruction for use #IFU-EL, A/1 for HY101-01A Electronic Lift.

Nameplate as below

Electronic Lift

Model: HY101-01A

Power supplier: 230Vac 2A 50Hz Motor: 24V/8000m

Load: 180KG Net weight: 45KG

Lifting range: 755mm— 1700mm Lifting speed: 3.8mm/s

Max Base Width: 800mm

Size: L 1200mm x W 620mm x H 1225mm

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 Hi-Fortune Health Products Co.,Ltd.

No. 331 Qinheroad, Zhangpu town, Kunshan, Jiangsu Province, China

 **KINGSMEAD SERVICE LIMITED**

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- Section 8, biocompatibility

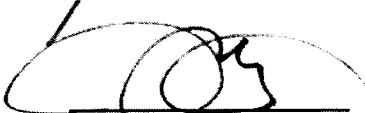
In vitro Cytotoxicity test report # SDWH-M201401669, # SDWH-M201401675 according ISO10993-5:2009, Skin Sensitization test report #SDWH-M201401670, #SDWH-M201401670 according ISO 10993-10:2010, Skin Irritation test report # SDWH-M201401677 according ISO 10993-10:2010 for article supplied by the manufacturer conducted by Sanitation & Environment Technology Institute, Soochow University.

The CE technical file except risk management report is in English.

4. Summary of Review

With regard to the reviewed documents, TÜV SÜD China, Shanghai Branch was able to verify that the CE technical documentation is complete according to the requirements of Directive 93/42/EEC Annex VII. The objectives of this review are met:

- Hi-Fortune Health Products Co., Ltd. located in No. 301, Qinhe Road, Zhangpu Town, Kunshan City, Jiangsu Province, P.R, China has established a CE technical documentation for Electronic Lift.
- The content of CE technical documentation is complete with respect of the requirements of Annex VII section 3 of the Council Directive 93/42/EEC on Medical Devices

	Name	Signature	Date
Reviewed by	Yanan Liu		2016-05-28
Approved by	Irene Chen		2016-05-28