樂齡科技產品的機電安全考量及注意事項

2025年3月28日

樂齡科技產品的安全考量

1. 用家

- 活動能力 – 適合長時間使用、機械風險防護
- 認知能力 – 故障保護、減低誤用而導致意外的風險
- 心理健康 – 容易使用

2. 環境

- 安老院舍、殘疾人士院舍等 – 受訓練人士協助下使用

3. 護理需求

- 長期護理 – 為重複使用而設計，適當地減低其材料老化/疲勞等帶來的風險、減少交叉感染風險

4. 原擬用途

- 與用家直接接觸 – 生物相容性 (刺激性 / 引發免疫/過敏反應)、 超溫防護

安全標準

1. 基本安全標準 – 醫用電氣設備

e.g. 電動躺可傾斜/可調教高度的便椅/淋浴椅 Electric tilt-in-space/ height adjustable commode / shower chair

- IEC 60601-1 醫用電氣設備 第1部分: 基本安全性和基本性能的通用要求

2. 特定安全標準

e.g. 醫療護理床 Smart Hospital Bed

- IEC 60601-2-52 醫用電氣設備 第2-52部分: 醫用病床的基本安全和基本性能專用要求

電動移位機 Electric Mobile Hoist

- ISO 10535 輔助產品: 人員轉移用起重機: 要求和試驗方法
- 《工廠及工業經營(起重機械及起重裝置)規例》表格五

電動爬樓梯輪椅 Electric-assisted Stair Climbing Wheelchair

- EN 12183 手動輪椅: 要求和試驗方法
- EN 12184 電動輪椅: 電動代步車及其充電器:要求和試驗方法

IEC 60601-1 醫用電氣設備 第1部分: 基本安全性和基本性能的通用要求

針對使用醫用電氣設備的相關風險

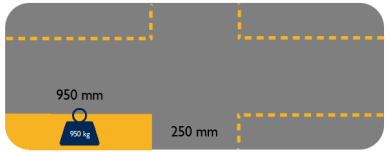
- **防止觸電**
- **機械風險防護 (移動部件、 活動時的阻礙、不穩定性)**
- **輻射防護:意外釋出、游離或雜散輻射的照射**
- **避免達到具潛在危險的溫度**
- **保護病人及使用者免因一般醫療儀器向其供應的能量或物質而蒙受風險**

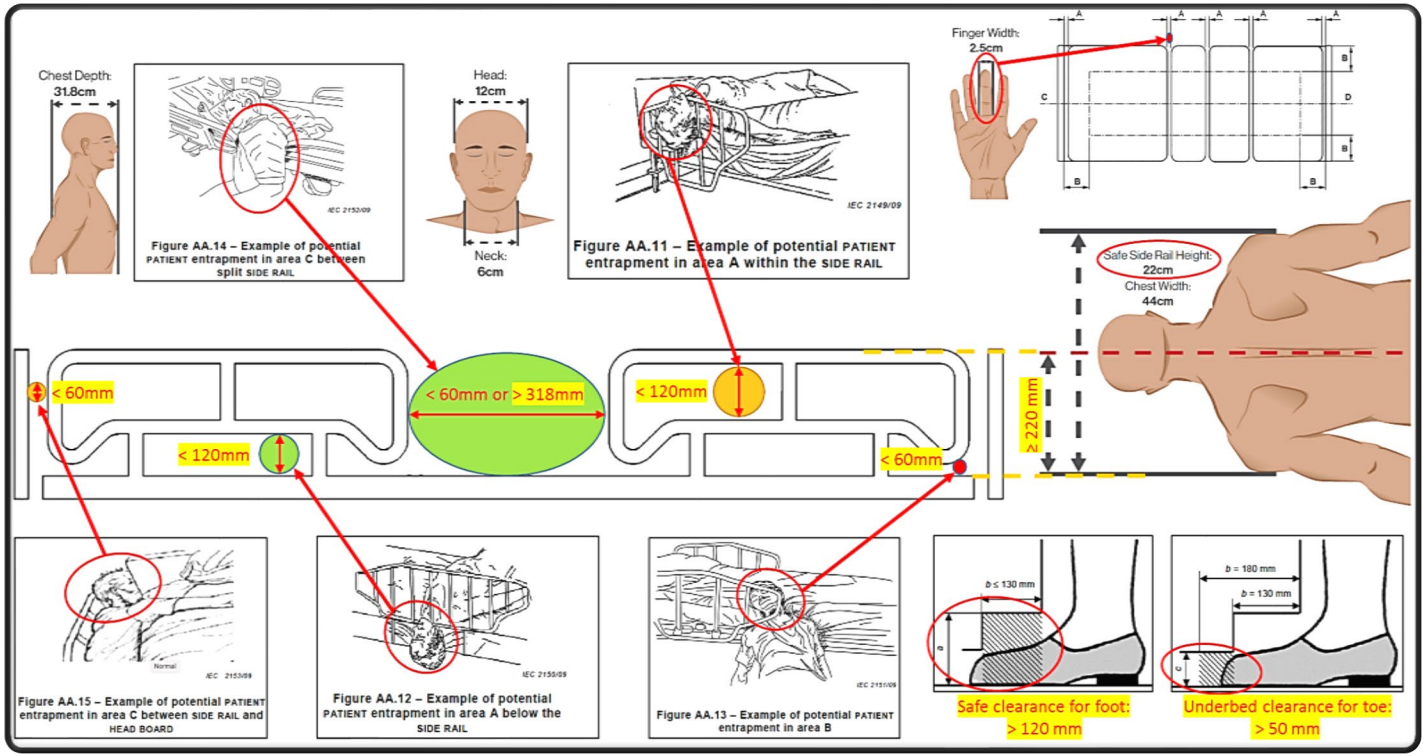
圖片來源: BS EN 60601-1:2006+A2:2021

IEC 60601-2-52 醫用電氣設備 第2-52部分: 醫用病床的基本安全和基本性能專用要求

- 適用於長期護理
- 機械風險防護：
  - 被困、擠壓
  - 不穩定性
  - 足夠强度支撐用家或操作者
- 避免用家意外跌倒

Lateral Stability Test

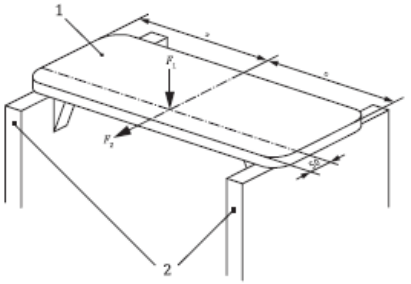




圖片來源: [Online] Available: https://www.medstrom.com/wp-content/uploads/2021/02/SM614-Understanding-2-52-Brochure-Rev2-Feb2021.pdf , BS EN 60601-2-52

ISO 17966 用於支撐使用者的個人衛生輔助器具: 要求和試驗方法

- **用於減輕或替補殘疾**
- **防水設計**
- **機械風險防護： - 防止用家跌落**
  - 防止用家被困、被擠壓
  - 支撐部分 / 摺疊部件的耐用性
- **避免達到具潛在危險的溫度**
- **與用家長期直接接觸：避免引致壓瘡**



Key
1 rim-mounted bath bench or bath board
2 supporting stands

Figure 35 — Forward stability test of transfer bench, bath board or seat

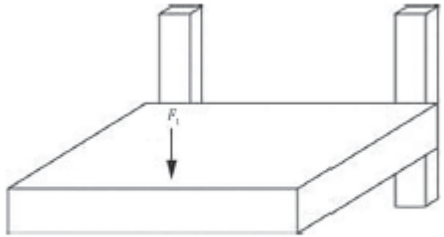
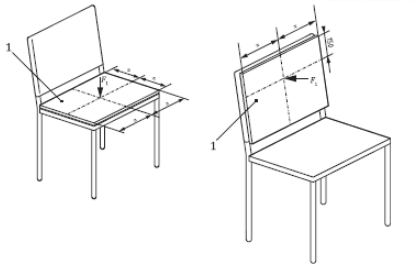
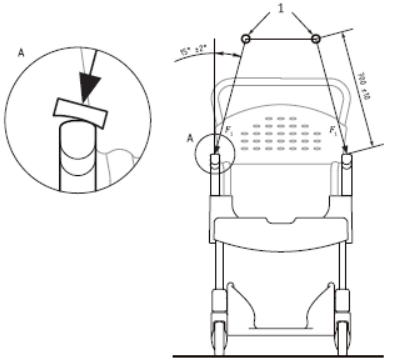


Figure 31 — Static test of height adjustable plinth/bracket



Key
1 loading pad

Figure 16 — Placing of load on seat/back support surface



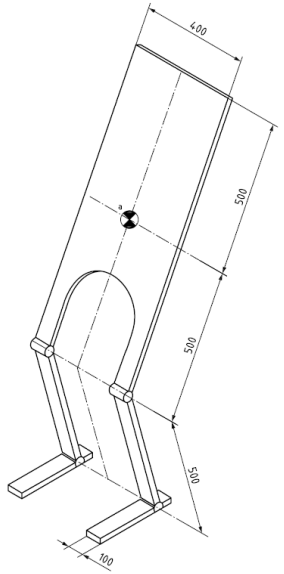
Key
1 pivots for load application

Figure 18 — Downward forces on arm supports: Front view

圖片來源: BS ISO 17966:2016

ISO 10535 輔助產品: 人員轉移用起重機: 要求和試驗方法

- **用於轉移殘疾人士的起重器和身體支撐裝置**
- **機械風險防護：**
  - **被困、擠壓**
  - **防止傾斜/移動**
  - **承重安全系數**
  - **防止扶手意外鬆脫**
- **紅色緊急裝置供隔斷電源及以電力方法停止機械活動**
- **點動控制 (‘Hold to run’ control) 具風險的操作**
- **起重機經清洗後可正常運作**



[a] Centre of gravity.

Figure 2 — Test dummy for mobile hoists for transferring a person in standing position

圖片來源: BS EN 10535:2021

證明文件

- 安全標準測試證書
- 安全標準測試報告
- 符合安全規格證明書

IEC IECEE CB SCHEME

Ref. Certif. No.

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

Name and address of the applicant
Nom et adresse du demandeur

Name and address of the manufacturer
Nom et adresse du fabricant

Name and address of the factory
Nom et adresse de l'usine

Ratings and principal characteristics
Valeurs nominales et caractéristiques principales

Trademark (if any)
Marque de fabrique (si elle existe)

Type of Manufacturer's Testing Laboratories used
Type de programme du laboratoire d'essais constructeur

Model / Type Ref.
Ref. De type

Additional information (if necessary may also be reported on page 2)
Les informations complémentaires (si nécessaire, peuvent être indiqués sur la 2ème page

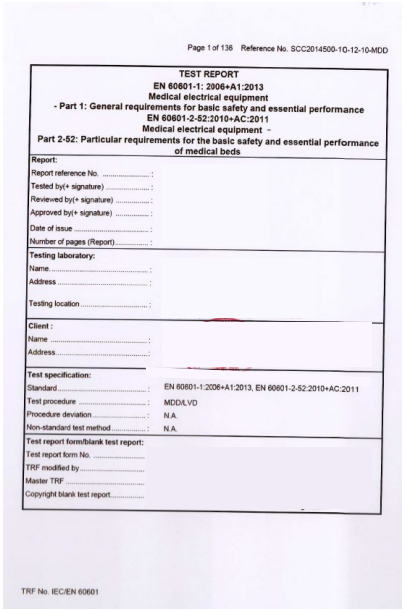
A sample of the product was tested and found to be in conformity with
Un echantillon de ce produit a été essayé et a été considéré conforme à la

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

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

Date: 2013-12-20

Signature



Page 1 of 136 Reference No. SCC2014500-10-12-10-MDD

TEST REPORT
EN 60601-1: 2006+A1:2013
Medical electrical equipment
- Part 1: General requirements for basic safety and essential performance
EN 60601-2-52:2010+AC:2011
Medical electrical equipment –
Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

Report:
Report reference No. ..... :
Tested by(+ signature) ..... :
Reviewed by(+ signature) ..... :
Approved by(+ signature) ..... :
Date of issue ..... :
Number of pages (Report)..... :

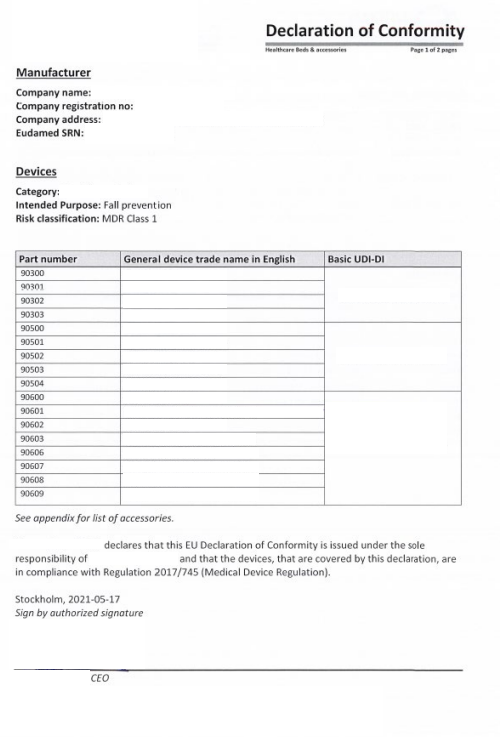
Testing laboratory:
Name ..... :
Address ..... :
Testing location ..... :

Client :
Name ..... :
Address ..... :

Test specification:
Standard ..... : EN 60601-1:2006+A1:2013, EN 60601-2-52:2010+AC:2011
Test procedure ..... : MDD/LVD
Procedure deviation ..... : N.A.
Non-standard test method ..... : N.A.

Test report form/blank test report:
Test report form No. .....
TRF modified by .....
Master TRF .....
Copyright blank test report .....

TRF No. IEC/EN 60601



Declaration of Conformity

Healthcare Beds & accessories Page 1 of 2 pages

Manufacturer

Company name:
Company registration no:
Company address:
Eudamed SRN:

Devices

Category:
Intended Purpose: Fall prevention
Risk classification: MDR Class 1

Part number	General device trade name in English	Basic UDI-DI
90300		
90301		
90302		
90303		
90500		
90501		
90502		
90503		
90504		
90600		
90601		
90602		
90603		
90606		
90607		
90608		
90609		

See appendix for list of accessories.

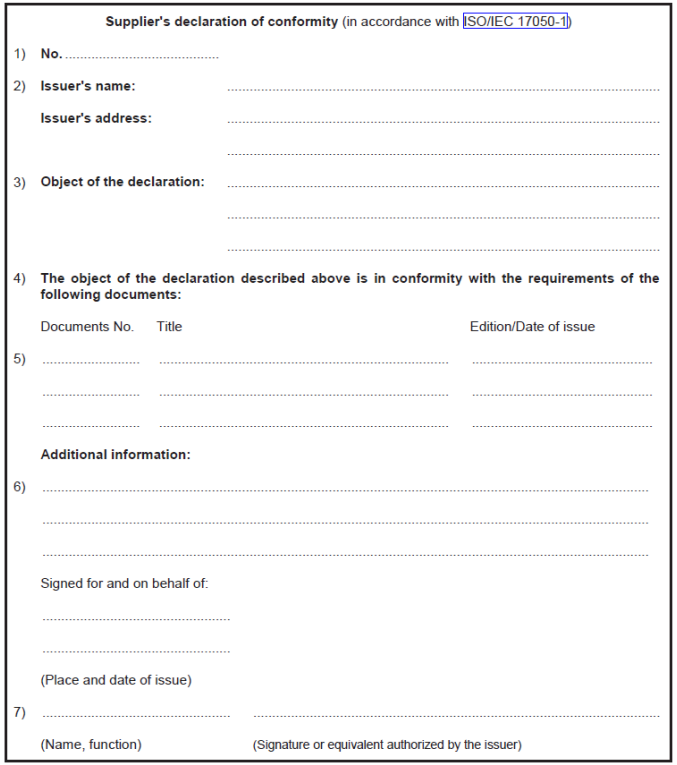
declares that this EU Declaration of Conformity is issued under the sole responsibility of and that the devices, that are covered by this declaration, are in compliance with Regulation 2017/745 (Medical Device Regulation).

Stockholm, 2021-05-17
Sign by authorized signature

CEO

符合安全標準聲明

- 產品型號
- 製造商名稱及地址
- 製造商對有關產品負上全部責任的聲明
- 確保有關產品具可追溯性的標記
- 有關產品符合的安全標準/法例要求
- 為有關產品作出安全標準評核的核證機構名稱及識別編號
- 任何相關的額外資訊
- 聲明的簽發日期、認可人員簽署、簽署人士姓名和職銜



Supplier's declaration of conformity (in accordance with ISO/IEC 17050-1)

1) **No.** .....

2) **Issuer's name:** .....

Issuer's address: .....

.....

3) **Object of the declaration:** .....

.....

.....

4) **The object of the declaration described above is in conformity with the requirements of the following documents:**

	Documents No.	Title	Edition/Date of issue
5)	.....	.....	.....
	.....	.....	.....
	.....	.....	.....

Additional information:

6) .....

.....

.....

Signed for and on behalf of:

.....

.....

(Place and date of issue)

7) ....

(Name, function) (Signature or equivalent authorized by the issuer)

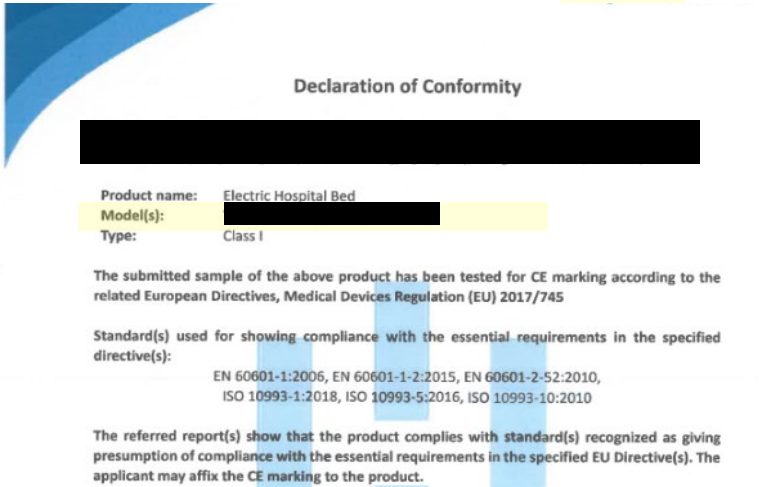
圖片來源: BS EN 17050-1:2010

注意事項

1. 有關證明文件應適用於購買的產品

(3) Product Name/ Model Number

3-Function Extra Low Electric Nursing Bed / [redacted]



Declaration of Conformity

[redacted]

Product name: Electric Hospital Bed
Model(s): [redacted]
Type: Class I

The submitted sample of the above product has been tested for CE marking according to the related European Directives, Medical Devices Regulation (EU) 2017/745

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN 60601-1:2006, EN 60601-1-2:2015, EN 60601-2-52:2010,
ISO 10993-1:2018, ISO 10993-5:2016, ISO 10993-10:2010

The referred report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The applicant may affix the CE marking to the product.

2. 有關證明文件內容應涵蓋整件產品

[redacted] 是選用[redacted]電機摩打

控制器：[redacted]，乎合 IEC60601-1:2005/AMD1：2012 Reference No.：713182211 （有關證書詳情請參閱附件。）

驅動器：[redacted]，乎合 IEC60601-1-2:2014 Reference No.：4789649474-1 （有關證書詳情請參閱附件。）

驅動器：[redacted] 乎合 IEC60601-1:2005/AMD1：2012 Reference No.：713102780（有關證書詳情請參閱附件。）

手控器：[redacted]，乎合 IEC60601-1:2005/AMD1：2012 Reference No.：713187709（有關證書詳情請參閱附件。）

[redacted]

2023-8-4

TEST (IECEE) SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Control units

[redacted]

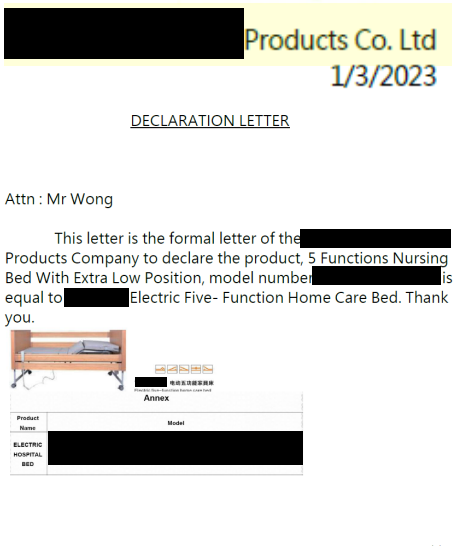
For further information please see attachment

Rated voltage:	100 – 240 VAC, 50/60 Hz
Rated current:	Max. 3.15 A
Degree of protection:	IPX4, IP44, IP54, IPX6, IP66
Protection class:	II
Intermitted operation:	2min / 18min (ON / OFF)

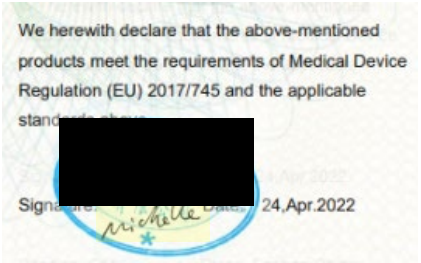
注意事項

3. 有關聲明文件應由製造商簽發

- 確保產品回收時的可追溯性



4. 簽署聲明文件的人士應可透過名稱、職銜識別

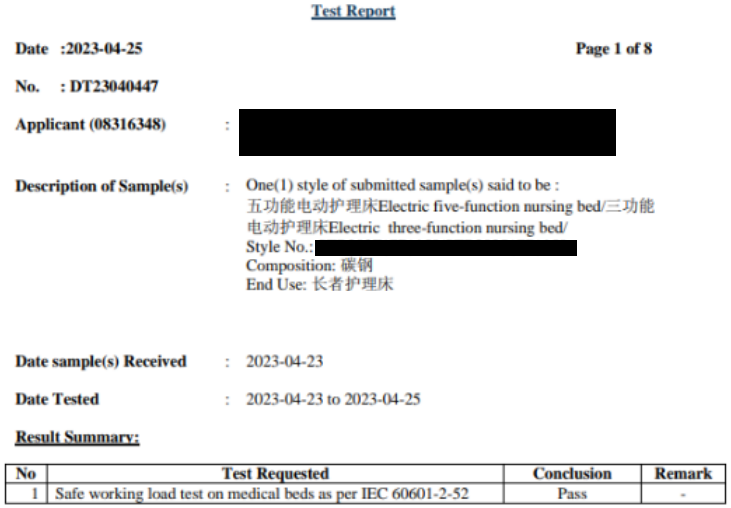


注意事項

5. 產品經過基本安全標準和特定安全標準評核，可確保多方面潛在風險均已考慮/測試

The supplier is yet to provide relevant documents to substantiate the compliance of the electric bed with electrical safety standards (e.g. IEC 60601-1 and IEC 60601-2-52, or equivalent). Specifically, the subject model is not covered in the Declaration of Conformity.

6.有關安全標準測試報告應涵蓋安全標準全部內容



Test Report

Date :2023-04-25 **Page 1 of 8**

No. : DT23040447

Applicant (08316348) : [redacted]

Description of Sample(s) : One(1) style of submitted sample(s) said to be :
五功能电动护理床Electric five-function nursing bed/三功能电动护理床Electric three-function nursing bed/
Style No.: [redacted]
Composition: 碳钢
End Use: 长者护理床

Date sample(s) Received : 2023-04-23

Date Tested : 2023-04-23 to 2023-04-25

Result Summary:

No	Test Requested	Conclusion	Remark
1	Safe working load test on medical beds as per IEC 60601-2-52	Pass	-