

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. din 14 decembrie 2023

Solicitantul ANCOTEC-SISTEM SRL, cu sediul mun. Chișinău, str. Cuza Vodă nr. 44, of 111, MD-2060, tel./fax: 079781169, e-mail achizitii@ancotec.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Pat multifuncțional pentru adulți (6-8 poziții) caracteristici avansate – model **E7302 (YF/D-7-S)**, producător Yufeng Medical, Țara de origine – China;
- Pat multifuncțional pentru adulți (6-8 poziții) caracteristici avansate – model **E6302 (YF/D-6-S)**, producător Yufeng Medical, Țara de origine – China.

Se anexează următoarele acte:

Declarație de conformitate CE emisă de producător;
Certificat de conformitate CE valabil pentru dispozitivele fabricate;
Autorizație producător reprezentant autorizat;
Declarație pe propria răspundere privind veridicitatea datelor prezentate.

Data 14.12.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **ANCOTEC-SISTEM SRL**, cu sediul mun. Chișinău, str. Cuza Vodă nr. 44, of. 111, MD-2060, declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Pat multifuncțional pentru adulți (6-8 poziții) caracteristici avansate – model E7302 (YF/D-7-S), producător Yufeng Medical, Țara de origine – China;
- Pat multifuncțional pentru adulți (6-8 poziții) caracteristici avansate – model E6302 (YF/D-6-S),, producător Yufeng Medical, Țara de origine – China.

Sunt autentice și corespund realității.

Andrei MATEI

Administrator ANCOTEC-SISTEM SRL

Semnătura _____

Data 14.12.2023

MANUFACTURER'S AUTHORISATION

Date: 18th of December 2023

To: **Medicines and Medical Devices Agency**

WHEREAS

We Sichuan Yufeng Medical Equipment Co., Ltd., who are official manufacturers of medical electric beds, having factories at Wanjia Community, Jiujiang Street, Shuangliu District, Chengdu, China, do authorize **ANCOTEC-SISTEM SRL** with business office at 44 Cuza-Voda str., Chisinau MD-2060, Republic of Moldova as our local authorized representative to submit the registration file to the Medicines and Medical Devices Agency and to register the following products in the State Register of Medical Devices, as follows:

- Six Functions Electric ICU Bed- model E6302 (YF/D-6-S), manufacturer Sichuan Yufeng Medical Equipment Co., Ltd., Country of origin - China;
- Seven Functions Electric ICU Bed- model E7302 (YF/D-7-S), manufacturer Sichuan Yufeng Medical Equipment Co., Ltd., Country of origin - China;

Signed: 

Name: Zoe Xiang

Title: International Sales Manager

Date: 18th of December 2023

Place: Wanjia Community, Jiujiang Street, Shuangliu District, Chengdu, China,



EC Declaration of Conformity



ACCORDING TO(EU)2017/745 MEDICAL DEVICE REGULATION

Manufacturer

Name: Sichuan Yufeng Medical Equipment Co., Ltd.

Address: Building 1-7, No.204, Group 1, Wanjia Community, Jiujiang Street, Shuangliu District, Chengdu, Sichuan

Product

Electric ICU Bed-E6302 (YF/D-6-S), E7302 (YF/D-7-S)

Classification: Class I,

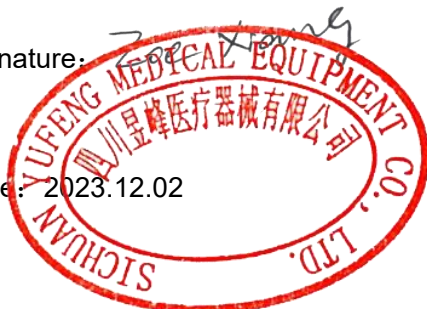
Rule: According to Rule 13, AnnexVIII, Regulation(EU) 2017/745

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

EN ISO 14971:2019,EN
1041:2008+A1:2013,EN ISO 15223-1:
2016, ISO 10993-1:2018,EN ISO
10993-5:2009,EN SO 10993-10:2013,
IEC60601-1:1988,IEC 60601-1-2:2004

Signature:

Date: 2023.12.02





Registration No. 04723Q10140R5M

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that:

Sichuan Yufeng Medical Equipment Co., Ltd

Registered address: **Wanjia Community, Jiujiang Street, Shuangliu District, Chengdu, China.**

Manufacturing address: **No. 204, Group 1, Wanjia Community, Jiujiang Street, Shuangliu District, Chengdu, China.**

Operates a Quality Management System which complies with the requirements of:

GB/T 19001-2016 idt ISO 9001:2015

For the following scope:

The design, production of electric nursing bed, patient trolley, pediatric bed, gynecological examination bed, flat bed, obstetric table, manual two-fold hospital bed, manual three-fold hospital bed, manual three-cranks hospital bed, medical transfer stretcher, baby bed, examination bed, X-ray film viewing lamp, orthopedic traction bed, ABS anesthesia trolley, ABS emergency trolley, ABS infusion trolley, ABS medicine trolley, ABS treatment trolley, ABS instrument trolley, ABS roller shutter trolley, medical record trolley, housekeeping trolley, ABS material storage trolley, stainless steel instrument trolley, transport trolley, cloth trolley, stainless steel sterile trolley, bedside cabinet, Chinese medicine cabinet, stainless steel medicine cabinet, endoscope cabinet, stainless steel anesthetic safety cabinet, shoe cabinet, clothes disinfection cabinet, locker, clothes preparation table, stainless steel treatment table, instrument table, workbench, packing table, inspection table, clothes rack, mop rack, vertical infusion stand, warehouse rack, dense warehouse rack, combined medicine rack, sterile bag rack, stainless steel parallel bar tray rack, medicine tray, surgical scrub sink, cleaning tank, mop cleaning pool, infusion chair, nursing chair, folding companion bed, medical combination cabinet system, aluminum alloy triple-leaf screen, and stainless steel instrument cabinet.

Date of issue: **April 07, 2023**

Date of expiry: **April 06, 2026**

General manager: 

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



Registration No. 04723Q10000140

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that:

Sichuan Yufeng Medical Equipment Co., Ltd

Registered address: **Wanjia Community, Jiujiang Street, Shuangliu District, Chengdu, China.**

Manufacturing address: **No. 204, Group 1, Wanjia Community, Jiujiang Street, Shuangliu District, Chengdu, China.**

Operates a Quality Management System which complies with the requirements of:

YY/T 0287-2017 idt ISO 13485:2016

For the following scope:

The design, production of electric nursing bed, patient trolley, pediatric bed, gynecological examination bed, flat bed, obstetric table, manual two-fold hospital bed, manual three-fold hospital bed, manual three-cranks hospital bed, medical transfer stretcher, baby bed, examination bed, X-ray film viewing lamp, orthopedic traction bed, ABS anesthesia trolley, ABS emergency trolley, ABS infusion trolley, ABS medicine trolley, ABS treatment trolley, ABS instrument trolley, ABS roller shutter trolley, medical record trolley, housekeeping trolley, ABS material storage trolley, stainless steel instrument trolley, transport trolley, cloth trolley, stainless steel sterile trolley, bedside cabinet, Chinese medicine cabinet, stainless steel medicine cabinet, endoscope cabinet, stainless steel anesthetic safety cabinet, shoe cabinet, clothes disinfection cabinet, locker, clothes preparation table, stainless steel treatment table, instrument table, workbench, packing table, inspection table, clothes rack, mop rack, vertical infusion stand, warehouse rack, dense warehouse rack, combined medicine rack, sterile bag rack, stainless steel parallel bar tray rack, medicine tray, surgical scrub sink, cleaning tank, mop cleaning pool, infusion chair, nursing chair, folding companion bed, medical combination cabinet system, aluminum alloy triple-leaf screen, and stainless steel instrument cabinet.

Date of issue: **April 07, 2023**

Date of expiry: **April 06, 2026**

General manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



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证书编号: 04723Q10140R5M

质量管理体系认证证书

兹证明

四川昱峰医疗器械有限公司

(统一社会信用代码: 91510122762296565T)

住 所: 成都市双流区九江街道万家社区

生产地址: 成都市双流区九江街道万家社区 1 组 204 号 1~7 栋

质量管理体系符合:

GB/T 19001-2016 idt ISO 9001:2015

体系覆盖:

电动护理病床、病人推车、儿童病床、妇科检查床、平型病床、普通产床、手摇式二折病床、手摇式三折病床、手动三摇病床、医用转移车、婴儿床、诊疗床、X 射线胶片观片灯、骨科牵引床、ABS 麻醉车、急救车、输液车、ABS 发药车、ABS 治疗车、ABS 送药车、ABS 卷帘门推车、病例推车、护理车、换药车、污物车、ABS 物资存储车、不锈钢器械套车、运转车、布料推车、不锈钢无菌推车、床头柜、中药柜、不锈钢药品柜、内窥镜柜、不锈钢毒麻柜、鞋柜、衣帽消毒柜、更衣柜、衣帽准备台、不锈钢治疗台、器械台、工作台、打包台、检查台、衣帽架、拖把架、立式输液架、库架、密集库架、组合药架、无菌包架、不锈钢双杠托盘架、药盘、洗手池、清洗槽、拖帕清洗池、输液椅、陪护椅、叠陪伴床、医疗组合箱柜系统、铝合金三联屏风、不锈钢器械柜的设计开发、生产和服务。

颁证日期: 2023 年 04 月 07 日

有效期至: 2026 年 04 月 06 日

总经理:

李朝晖

北京国医械华光认证有限公司



管理体系

MANAGEMENT SYSTEM

CNAS C047-M

注: 认证组织需通过年度监督审核后, 此证书方为持续有效。 本证书信息可在国家认证认可监督管理委员会官方网站 (<http://www.cnca.gov.cn>) 或北京国医械华光认证有限公司网站 (<http://www.cmdc.com.cn>) 上查询。 地址: 北京市东城区安定门外大街甲 88 号中联大厦第 5 层 邮编: 100011 电话: 010-62351993



证书编号: 04723Q10000140

医疗器械 质量管理体系认证证书

兹证明

四川昱峰医疗器械有限公司

(统一社会信用代码: 91510122762296565T)

住 所: 成都市双流区九江街道万家社区

生产地址: 成都市双流区九江街道万家社区 1 组 204 号 1~7 栋

质量管理体系符合:

YY/T 0287-2017 idt ISO 13485:2016

体系覆盖:

电动护理病床、病人推车、儿童病床、妇科检查床、平型病床、普通产床、手摇式二折病床、手摇式三折病床、手动三摇病床、医用转移车、婴儿床、诊疗床、X 射线胶片观片灯、骨科牵引床、ABS 麻醉车、急救车、输液车、ABS 发药车、ABS 治疗车、ABS 送药车、ABS 卷帘门推车、病例推车、护理车、换药车、污物车、ABS 物资存储车、不锈钢器械套车、运转车、布料推车、不锈钢无菌推车、床头柜、中药柜、不锈钢药品柜、内窥镜柜、不锈钢毒麻柜、鞋柜、衣帽消毒柜、更衣柜、衣帽准备台、不锈钢治疗台、器械台、工作台、打包台、检查台、衣帽架、拖把架、立式输液架、库架、密集库架、组合药架、无菌包架、不锈钢双杠托盘架、药盘、洗手池、清洗槽、拖帕清洗池、输液椅、陪护椅、叠陪伴床、医疗组合箱柜系统、铝合金三联屏风、不锈钢器械柜的设计开发、生产和服务。

颁证日期: 2023 年 04 月 07 日

有效期至: 2026 年 04 月 06 日

总经理:

李朝晖

北京国医械华光认证有限公司

