



REGISTRATION NO. 04722Q10000191

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

NANTONG MEDICAL APPARATUS CO.,LTD

Registered Address: No.68,South Area of Industrial Park,Shigang Town,Tongzhou District,Nantong, Jiangsu Province

Manufacturing Address: No.68,South Area of Industrial Park,Shigang Town,Tongzhou District,Nantong, Jiangsu Province

Has been assessed and conformed to the following standard(s)
YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design , Development , Production and Service of Ordinary Operating Tables, Bed for Babies, Manual Hospital Beds , Orthopedics Operating Table , Stretcher Vehicle , Ordinary Delivery Beds , Head Rack , Photography beds, Medical Flat Bed, Spine Surgery Bracket , Examination beds, Children's Hospital Bed, Operating Auxiliary Lights, Multi-purpose Parturition Bed , Electric Parturition Bed , Traction Bed , Electric Nursing Bed , Operating Shadowless Lamp, Electric Obstetrics hospital bed, LED Operating Shadowless Lamp,Ophthalmology Operating Table , Multi-purpose Operation Table Model , side-controlled ,Electric Operating Table, Multi-purpose Operation Table Model , head-controlled , Electric Photography beds, Bed-unit Ozone Sterilizer ,

The Design , Development ,Production, installation and Service of Medical Pendant(Not medical) Processes involved: design development

Date of issue: May 27,2022

Date of expiry: May 26,2025

General Manager:

BEIJING HUAGUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.





Annex to Report (No. 02684)

Nantong Medical Apparatus Co.,Ltd

Product Name	Type
Ordinary Operating Table	BS
Orthopedics Traction Table	98, 2000, 2008
Gynecological Examination Bed	99A, 99B, 99C, 2000
Infant Bed	YEA, YEB, YEC
Hospital Bed	A2, A3, A4, A7, A8, A10, A11, A12, A13, 83, 99, 99A, 2000
Medical Bed	A5, A6
Pediatrics Bed	A9, A9-1
Ordinary Parturition Bed	QZC-83, QZC-83A
Examination Bed	SJC-1, SJC-1S, SJC-2, SJC-2S
Photography Bed	JH-SYCA
Stretcher	B1, B2, B3, B4, B5, B6, B7, B8
Multi-purpose Head Rack	A, B, C, D
Backbone Operation Bracket	TJ-00
Ophthalmology Operating Table	99, 99A
Multi-purpose Operating Table(Side-controlled)	3001A, 3001B, 3001C, 3001D, 3001E, 3001F, 3001G, 3002
Multi-purpose Operating Table (Head controlled)	3008B, 3008B-I,3008C, 3008A, 3008AB
Multi-purpose Parturition Bed	JHC-78, JHC-99B, JHC-99C, JHC-06A, JHC-06B, JHC-08A
Electric Operating Table	JHDS-99A, JHDS-99B, JHDS-99C, JHDS-99C- I, JHDS-99D, JHDS-99D- I, JHDS-99E-1, JHDS-99E-2, JHDS-99E-3, JHDS-99E-4, JHDS-2000A, JHDS-2000B, JHDS-2000C, JHDS-2000H
Electric Parturition Bed	JHDC-99A, JHDC-99A-I, JHDC-99C-I, JHDC-99B, JHDC-99B-I, JHDC-99B-II, JHDC-99F, JHDC-99F-I, JHDC-99B-III, JHDJ-A

This annex is only valid if attached to the report mentioned above.



Annex to Report (No. 02684)

Nantong Medical Apparatus Co.,Ltd

Product Name	Type
Operating Shadowless Lamp	JHDZF-700, JHDZF-500, JHDZF-500L, JHDZF-700/700, JHDZF-700/500
LED Operating Shadowless Lamp	JHLED-Z7, JHLED-Z5, JHLED-Z5L, JHLED-Z7/7, JHLED-Z7/5, JHLED-M5-1, JHLED-M7-1, JHLED-M5L-1, JHLED-M7/7-1, JHLED-M7/5-1, JHLED-M5/5-1
Operating Auxiliary Light	JHJCD-A, JHJCD-B
Electric Nursing Bed	JHDH-A1, JHDH-A1-1, JHDH-B, JHDH-B1
Electric Obstetrics Hospital Bed	JHDCB-B
Traction Bed	JHDQ-00A(B、B-I), JHDQ-02A(B), JHDQ-06A(A-I,A-II,A-III,B,B-I) (Note: other type of products as required by the customers)

This annex is only valid if attached to the report mentioned above.



Compliance Report

Applicant: Nantong Medical Apparatus Co.,Ltd
Address: 68 South Area Of Shigang Town, Tongzhou, Nantong, Jiangsu, China
Product: Ordinary Operating Table, Orthopedics Traction Table, Gynecological Examination Bed, Infant Bed, Hospital Bed, Medical Bed, Pediatrics Bed, Ordinary Parturition Bed, Examination Bed, Photography Bed, Stretcher, Multi-purpose Head Rack, Backbone Operation Bracket, Ophthalmology Operating Table, Multi-purpose Operating Table(Side-controlled), Multi-purpose Operating Table(Head controlled), Multi-purpose Parturition Bed, Operating Shadowless Lamp, LED Operating Shadowless Lamp, Operating Auxiliary Light, Electric Operating Table, Electric Parturition Bed, Electric Nursing Bed, Electric Obstetrics Hospital Bed, Traction Bed
Type: See annex for details
Product Class I

Classification:

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

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

This report is not a certificate of conformity.

No. **02684**

Initial Issue Date: **10 Apr 2017**



General Manager (Signature)



REGISTRATION NO. 04722Q10191R5M

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

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GB/T 19001-2016 idt ISO 9001:2015

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design development

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管理体系
MANAGEMENT SYSTEM
CNAS C047-M