

Certificate No: UKZB22MD20021R0S

CERTIFICATE OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATION

Date of Initial Issuance:Mar. 14, 2022/ Date of Issuance:Aug. 25, 2023
Date of Expiration:Mar. 13, 2025

This is to Certify that the Medical Device Quality Management System of

NANCHANG KINDLY MEDICAL TECHNOLOGY CO., LTD.

is in conformity with
ISO13485:2016 idt YY/T 0287-2017 Standard, applies to
SALES OF CLASS II AND CLASS III MEDICAL DEVICES WITHIN THE SCOPE OF BUSINESS LICENSE (SEE
APPENDIX FOR DETAILS)

BCC Inc.
President:

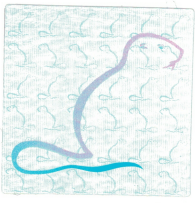


Unified social credit code:91360100792811281E
REGISTERED ADDRESS:ROOM 712, BUILDING 12, WUYUE PLAZA OFFICE, NO. 77 AIXIHU NORTH ROAD, HIGH TECH INDUSTRIAL DEVELOPMENT ZONE, NANCHANG CITY, JIANGXI PROVINCE, CHINA
OPERATION ADDRESS:ROOM 712, BUILDING 12, WUYUE PLAZA OFFICE, NO. 77 AIXIHU NORTH ROAD, HIGH TECH INDUSTRIAL DEVELOPMENT ZONE, NANCHANG CITY, JIANGXI PROVINCE (BUSINESS);
BUILDING 2 (1-6), WORKSHOP 9, YUHU WEST 1ST ROAD, XIAOLAN ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, NANCHANG COUNTY, NANCHANG CITY, JIANGXI PROVINCE, CHINA
(WAREHOUSE)

CERTIFICATE



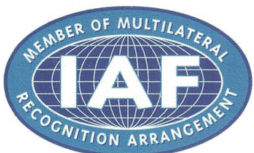
BCC Address:Room 45-(05)-02, Floor 5, No.45 Guangqumennei Street, Dongcheng District, Beijing, CHINA. This certificate is valid within state - specified validities of administrative and qualification licensing.The effectiveness of this certificate shall be maintained by regular surveillance audit, the validity of the certificate can be inquired through www.bcc.com.cn or by QR code.The information of this certificate available for inquiry on CNCA's website: www.cnca.gov.cn.Accreditation by UKAS is granted to BCC for providing audits and certifications of ISO13485



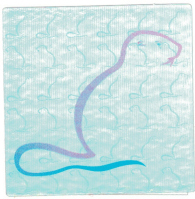
ANNEX

CLASS II MEDICAL DEVICES 02/12: 6801 BASIC SURGICAL INSTRUMENTS, 6803 NEUROSURGICAL INSTRUMENTS, 6807 THORACIC AND CARDIOVASCULAR SURGICAL INSTRUMENTS, 6809 UROLOGICAL AND ANORECTAL SURGICAL INSTRUMENTS, 6810 ORTHOPAEDIC SURGICAL INSTRUMENTS, 6815 INJECTION PUNCTURE INSTRUMENTS, 6820 GENERAL EXAMINATION ROOM INSTRUMENTS, 6821 MEDICAL ELECTRONIC INSTRUMENTS AND EQUIPMENT, 6822 MEDICAL OPTICAL INSTRUMENTS, INSTRUMENTS AND ENDOSCOPE EQUIPMENT, 6823 MEDICAL ULTRASONIC INSTRUMENTS AND RELATED EQUIPMENT, 6824 MEDICAL LASER INSTRUMENTS AND EQUIPMENT, 6825 MEDICAL HIGH-FREQUENCY INSTRUMENTS AND EQUIPMENT, 6826 PHYSICAL THERAPY AND REHABILITATION EQUIPMENT, 6827 TRADITIONAL CHINESE MEDICINE INSTRUMENTS, 6830 MEDICAL X-RAY EQUIPMENT, 6831 MEDICAL X-RAY AUXILIARY EQUIPMENT AND COMPONENTS, 6833 MEDICAL RADIONUCLIDE EQUIPMENT, 6841 MEDICAL LABORATORY AND BASIC EQUIPMENT AND INSTRUMENTS, 6845 EXTRACORPOREAL CIRCULATION AND BLOOD PROCESSING EQUIPMENT, 6846 IMPLANT MATERIALS AND ARTIFICIAL ORGANS (EXCEPT HEARING AIDS), 6854 OPERATING ROOM, EMERGENCY ROOM, CONSULTING ROOM EQUIPMENT AND INSTRUMENTS, 6855 STOMATOLOGY EQUIPMENT AND INSTRUMENTS, 6856 WARD NURSING EQUIPMENT AND INSTRUMENTS, 6857 DISINFECTION AND STERILIZATION EQUIPMENT AND INSTRUMENTS, 6858 MEDICAL COLD TREATMENT, LOW TEMPERATURE, REFRIGERATION EQUIPMENT AND INSTRUMENTS, 6863 DENTAL MATERIALS, 6864 MEDICAL HYGIENE MATERIALS AND DRESSINGS, 6865 MEDICAL SUTURE MATERIALS AND ADHESIVES, 6866 MEDICAL POLYMER MATERIALS AND PRODUCTS, 6870 SOFTWARE

CERTIFICATE



8631

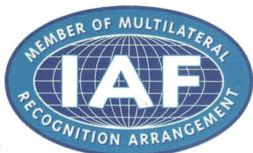


CERTIFICATE

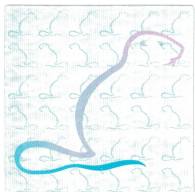
ANNEX

CATEGORY OF CLASS II MEDICAL DEVICES 2017: PASSIVE SURGICAL INSTRUMENTS 01 ACTIVE SURGICAL INSTRUMENTS, 02, 03 NEUROLOGICAL AND CARDIOVASCULAR SURGICAL INSTRUMENTS, 04 ORTHOPEDIC SURGICAL INSTRUMENTS, 05 RADIOTHERAPY EQUIPMENT, 06 MEDICAL IMAGING EQUIPMENT, 07 MEDICAL DIAGNOSIS AND MONITORING INSTRUMENT, 08 BREATHING, ANESTHESIA AND EMERGENCY EQUIPMENT, 09 PHYSICAL THERAPY EQUIPMENT, 10 DIALYSIS, BLOOD TRANSFUSION AND CARDIOPULMONARY BYPASS INSTRUMENTS, 11 MEDICAL INSTRUMENT, DISINFECTION STERILIZATION EQUIPMENT, 12 ACTIVE IMPLANT DEVICES, 14 INFUSION, NURSING AND PROTECTIVE DEVICES, 15 PATIENT CARRYING DEVICES, 16 OPHTHALMOLOGICAL INSTRUMENTS, 17 STOMATOLOGY DEVICES, 18 OBSTETRICS AND GYNECOLOGY, ASSISTED REPRODUCTION AND CONTRACEPTIVE DEVICES, 19 MEDICAL REHABILITATION DEVICES, 20 TRADITIONAL CHINESE MEDICINE DEVICES, 21 MEDICAL SOFTWARE, 22 CLINICAL TESTING DEVICES.

CATALOG OF IN VITRO DIAGNOSTIC REAGENT: 6840 (EXCLUDING IN VITRO DIAGNOSTIC REAGENTS)



8631



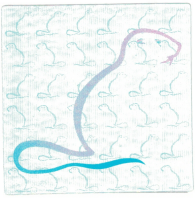
ANNEX

CATEGORY III MEDICAL DEVICES 02/12: 6804 OPHTHALMIC SURGICAL INSTRUMENTS, 6815 INJECTION PUNCTURE INSTRUMENTS, 6821 MEDICAL ELECTRONIC INSTRUMENTS AND EQUIPMENT, 6822 MEDICAL OPTICAL INSTRUMENTS, INSTRUMENTS AND ENDOSCOPE EQUIPMENT (EXCEPT SOFT AND HARD CORNEAL CONTACT LENSES AND NURSING FLUIDS), 6823 MEDICAL ULTRASONIC INSTRUMENTS AND RELATED EQUIPMENT, 6824 MEDICAL LASER INSTRUMENTS AND EQUIPMENT, 6825 MEDICAL HIGH-FREQUENCY INSTRUMENTS AND EQUIPMENT, 6826 PHYSICAL THERAPY AND REHABILITATION EQUIPMENT, 6828 MEDICAL MAGNETIC RESONANCE EQUIPMENT, 6830 MEDICAL X-RAY EQUIPMENT, 6832 MEDICAL HIGH-ENERGY RAY EQUIPMENT, 6833 MEDICAL NUCLIDE EQUIPMENT, 6845 EXTRACORPOREAL CIRCULATION AND BLOOD PROCESSING EQUIPMENT, 6846 IMPLANT MATERIALS AND ARTIFICIAL ORGANS, 6854 OPERATING ROOM, EMERGENCY ROOM, CONSULTING ROOM EQUIPMENT AND APPLIANCES, 6858 MEDICAL COLD TREATMENT, LOW TEMPERATURE, REFRIGERATION EQUIPMENT AND APPLIANCES, 6863 DENTAL MATERIALS, 6864 MEDICAL HYGIENE MATERIALS AND DRESSINGS, 6865 MEDICAL SUTURE MATERIALS AND ADHESIVES, 6866 MEDICAL POLYMER MATERIALS AND PRODUCTS, 6870 SOFTWARE, 6877 INTERVENTIONAL EQUIPMENT.

CERTIFICATE



8631



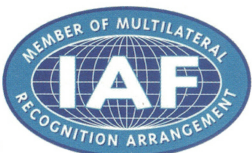
ANNEX

CATEGORY III MEDICAL DEVICES 2017 : 01 ACTIVE SURGICAL INSTRUMENTS, 02 PASSIVE SURGICAL INSTRUMENTS, 03 NEUROLOGICAL AND CARDIOVASCULAR SURGICAL INSTRUMENTS, 04 ORTHOPEDIC SURGICAL INSTRUMENTS, 05 RADIOTHERAPY EQUIPMENT, 06 MEDICAL IMAGING EQUIPMENT, 07 MEDICAL DIAGNOSIS AND MONITORING INSTRUMENT, 08 BREATHING, ANESTHESIA AND EMERGENCY EQUIPMENT, 09 PHYSICAL THERAPY EQUIPMENT, 10, DIALYSIS, BLOOD TRANSFUSION AND CARDIOPULMONARY BYPASS INSTRUMENTS, 12 ACTIVE IMPLANTED DEVICES, 13 PASSIVE IMPLANT DEVICES, 14 INJECTION, NURSING AND PROTECTIVE DEVICES, 16 OPHTHALMIC DEVICES (EXCEPT 16-06 OPHTHALMIC CORRECTION AND PROTECTIVE DEVICES), 17 DENTAL DEVICES, 18 OBSTETRICS AND GYNECOLOGY, ASSISTED REPRODUCTION AND CONTRACEPTIVE DEVICES, 20 TRADITIONAL CHINESE MEDICINE DEVICES, 21 MEDICAL SOFTWARE, 22 CLINICAL TESTING DEVICES.

CATALOG OF IN VITRO DIAGNOSTIC REAGENT: 6840 (EXCLUDING IN VITRO DIAGNOSTIC REAGENTS)



CERTIFICATE



8631