



This is to certify that the Quality Management System of

Ningbo Sintrue Medical Instruments Co., Ltd.

Unified Social Credit Code: 91330201MA2GRKQA4F

Operation Address: Room 9-1-5, Building 7, No.2 Zhuyi Road, Hi-Tech Zone, Ningbo City, Zhejiang Province, China

Registered Address: Room 9-1-5, Building 7, No.2 Zhuyi Road, Hi-Tech Zone, Ningbo City, Zhejiang Province, China

applicable to

Sales of medical devices (see the attached list for details) (exported to Europe, America and Southeast Asia)

has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number: **47232**

Issue Date: 10 December 2019

Reissue Date: 18 February 2024

Valid Until: 10 December 2025



0015



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.


Shanghai NQA Certification Co., Ltd. Address: Room 2201, 958 Lujiazui Ring Road, China (Shanghai) Pilot Free Trade Zone.



Ningbo Sintrue Medical Instruments Co., Ltd.

Annex

oxygen mask, nebulizer mask, nasal oxygen cannula, urine bag, urethral catheter, tracheal tube, disposable syringe, disposable infusion set, disposable hypodermic needle, disposable scalp vein set, vacuum blood collection tube, blood-collecting needle, vaginal speculum, swab, gauze swab, alcohol swab, cotton tipped applicator, dressing kit, plaster of pairs bandage, medical bandage, medical tape, face mask, isolation gown, underpad, PE apron, I.D. bracelet, urine container, pipette tip, sphygmomanometer, stethoscope, non-rebreath mask, venturi mask, CPE gown, bed sheet, bed cover, pillow cover, boot cover, urine meter, face shield, protective goggles, examination gloves, surgical gloves, three-ball spirometer, fetal heartbeat doppler detectors, oxygen concentrator, reflex hammer, suction machine, capillary tube, needle holder, PE glove, umbilical cord clamp, clip cap, round cap, doctor cap, shoe cover, coverall, surgical gown, diaper, feeding bag, wound drainage system, chest drainage bottle, amniotomy hook, ECG paper, disposable electrode, thermometer, tourniquet, microscope slide, microscope slide box, cover class, centrifuge tubes, centrifuge tubes box, test tube, test tube rack, cryovial tube, petri dishes, pipette transfer, tissue culture plate, inoculation loop, cell spreader, pipette tip box, embedding cassette, stool container, medicine cup, specimen container, humidifier, ultrasonic gel, digital thermometer cover, mouth-piece, urine bag hanger, apron roll, gauze roll, suction catheter, feeding tube, stomach tube, rectal tube, connecting tube with or without yankauer handle, mucus extractor, closed suction catheter, manual resuscitator, anesthesia mask, anesthesia breathing circuit, heat and moisture exchanger filter, bacterial/viral filter, oropharyngeal airway, laryngeal mask device, male external catheter, infusion set with burette, blood transfusion set, insulin needle, three way stopcock, heparin cap, screw cap, combi stopper, extension tube, cotton ball, cotton roll, povidone-iodine prep pad, dental bib, medical razor, electrosurgical pencil, wooden tongue depressor, ear syringe, hot water bag, ice bag, specimen bag, pill box, sharp container, oxygen regulator, needle free connector


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Center
Europe
Certification Service

Certificate No. CECS/8020198827998L

VERIFICATION OF MDD COMPLIANCE

EU COUNCIL DIRECTIVE 93/42/EEC

Applicant : Ningbo Sintree Medical Instruments Co., Ltd.

Address : Room 9-1-5, Building 7, No.2 Zhuyi Road, Hi-Tech Zone, Ningbo City, Zhejiang Province, China

Manufacturer : Ningbo Sintree Medical Instruments Co., Ltd.

Address : Room 9-1-5, Building 7, No.2 Zhuyi Road, Hi-Tech Zone, Ningbo City, Zhejiang Province, China

Sample Name : See the ANNEX

Model : See the ANNEX

Test Report No. : XMT0202110055LY/MDD

Remarks : The sample meets the requirements of the standards.

Conclusion : We Confirm That The Technical Construction File And Manufacturing, Inspection And Testing Processes For Above Mentioned Sample Comply With The Essential Safety Requirements of EU COUNCIL DIRECTIVE Of 93/42/EEC Applied Codes And Standards.

President of CECS : Robert Owen

Signature

Issuance date: 27 January 2021

Expiry date: 26 January 2026





Center Europe Certification Service

ANNEX

Product Name	Model
Round Cap	18", 21", 24"
Doctor Cap	Tie on, Elastic
Clip Cap	18", 21", 24"
Tudung Cover	40g, 35g, 30g
Shoe Cover	36x15cm, 41x15cm, 40x16cm
Boot Cover	40g, 35g, 30g
Isolation Gown	115x137cm, 120x140cm, 125x140cm, 125x150cm
Surgical Gown	S, M, L, XL, XXL, XXXL
Bed Sheet	140x210cm
Bed Cover	140x210cm
Pillow Cover	47x70cm
Plastic Apron	110x70cm, 60x90cm, 80x125cm, 80x140cm, 125x200cm
Dental Bib	33x46cm, 33x66cm, 40x45cm
Face Shield	Adult, Child
Protective Goggles	PVC, Silicone
Adult Diapers	XS, S, M, L, XL, XXL, XXXL 24x19cm, 28x40cm, 30x65cm, 50x40cm, 55x45cm, 60x40cm, 60x50cm, 60x60cm, 75x75cm, 90x60cm, 90x75cm, 90x80cm, 100x100cm, 120x80cm, 120x90cm, 130x70cm, 140x70cm, 150x60cm, 115x105cm, 150x100cm, 160x80cm, 190x70cm, 200x80cm, 200x100cm, 200x120cm, 200x150cm, 215x75cm, 220x80cm, 220x90cm, 230x75cm, 230x100cm
Disposable Underpad	
Ice Bag	6", 9", 11"
Hot Water Bag	750ml, 1000ml, 1750ml, 2000ml, 2500ml, 3000ml
Ear Syringe	30ml, 60ml, 90ml
Air Cushion	35cm, 40cm, 42.5cm, 45cm
I.D. Bracelet	Adult, Child
ECG Paper	UXB, UXJ, UDB, UDJ, UTB, UTJ
ECG Electrode	Adult, Child
Ultrasonic Gel	250ml, 1L, 2.5L, 5L



Center Europe Certification Service

Sterile Pouch/Roll	Heat-sealing(Reel), Self-sealing Flat Pouch, Heat-sealing Gusseted Pouch, Paper/paper Gusseted Pouch
Autoclave Indicator Tape	1.25cm x 50m, 2.5cm x 50m
Surgical Tape	Width: 1.25cm, 2.5cm, 5cm, 7.5cm, 10cm, 15cm Length: 4m, 4.5m, 5m, 10m
Medical Bandage	Width: 5cm, 7.5cm, 10cm, 15cm, 20cm Length: 4m, 4.5m, 5m, 10m
Gauze Swab	5 x 5cm, 7.5 x 7.5cm, 10x10cm, 15x15cm, 20x20cm
Gauze Roll	90cm x 91m, 90cm x 100m, 90cm x 1000m
Cotton Roll	50g, 100g, 200g, 454g, 500g, 1000g
Cotton Ball	0.3g, 0.5g, 1.0g, 2.0g, 3.0g, 4.0g, 5.0g
Cotton Tip Applicators	75mm, 100mm, 150mm, 190mm, 200mm
Eye Pad	5x6cm, 8x6cm
Examination Glove	S, M, L, XL
Disposable Medical Razor	Single Blade, Double Blade
Tourniquet	Adult, Child
Yankauer Handle	Standard, Sectional
Urine Bag Hanger	Standard
Suction Catheter	5Fr, 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr
Heparin Cap	Yellow, Transparent
External Male Catheter	S, M, L, XL
Amniotomy Hook	Straight, Curved
Umbilical Cord Clamp	5.0cm, 5.5cm, 6.0cm
Combi Stopper	Red, Blue
Stethoscope	Single Head, Dual Head
Health Scale	Adult, Child