

POSI CERTIFICATE

This is to certify that the Quality Management System of

Danyang New Hope Medical Equipment Co., Ltd

Business License Number: 91321181554628051Q

Registered Address: No. 99, Danyan Road, Danyang City, Jiangsu Province, China

Audit Address: No. 99, Danyan Road, Danyang City, Jiangsu Province, China

applicable to

The Production and Sales of Manual Hospital Bed, Baby Crib, Infusion Chair, Delivery Bed, Examination Couch, Treatment Trolley, Iv Stand, Stretcher, Operation Table, Blood Collection Chair, Walker & Rollator, Walking Stick, Medical Furniture (Over Bed Table, Stainless Steel Sink, Instrument Cabinet, Stepper, Ward Screen, Commode Chair, Shower & Bath Chair, Grab, Stool) (export Only); Sales of Electric Bed, Mattress, Manual Wheelchair, Electric Wheelchair, Parallel Bar, Passive Surgical Instrument (Scissors, S/S Dish and Box), Medical Radiation Protection Equipment (Clothes, Pants), Humidify Bottle, Compressor Nebulizer, Oxygen Concentrator, Stethoscope, Film Viewer, Examination Lamp, Auto Chart Projector, Light Box of Visual Chart, Trial Lens Set, View Tester, Dental Chair (export Only)

has been assessed and registered by POSI against the provisions of
GB/T19001-2016 idt ISO9001:2015

This registration is subject to the company maintaining a Quality Management System, to the above standard, which will be monitored by POSI.

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

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn> and IAF CertSearch database: www.iafcertsearch.org.



Joe Zhou

General Manager

Certificate Registration No: 38124Q0221R0S

Initial issue date: 2024.07.22

Issue date: 2024.07.22

IAF Code: 23;29

Valid until: 2027.07.21

Shanghai POSI Certification Co., Ltd.

Room 1402A, No.1500, Century Avenue, China (Shanghai) Pilot Free Trade Zone. Email: info@posicert.com



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has been assessed and registered by POSI against the provisions of

GB/T 42061-2022/ISO 13485:2016

This registration is subject to the company maintaining a Quality Management System, to the above standard, which will be monitored by POSI.

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

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



General Manager
General Manager

Certificate Registration No: 381240248R0S

Initial issue date: 2024.07.22

Issue date: 2024.07.22

Valid until: 2027.07.21

Shanghai POSI Certification Co., Ltd.

Room 1402A, No.1500, Century Avenue, China (Shanghai) Pilot Free Trade Zone. Email: info@posicert.com



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Joe Zhou

General Manager

Certificate Registration No: 38124Q0221R0S

Initial issue date: 2024.07.22

Issue date: 2024.07.22

IAF Code: 23;29

Valid until: 2027.07.21

Shanghai POSI Certification Co., Ltd.



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The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



Joe Zhou
General Manager

Certificate Registration No: 381240248R0S

Initial issue date: 2024.07.22

Issue date: 2024.07.22

Valid until: 2027.07.21

Shanghai POSI Certification Co., Ltd.

Room 1402A, No.1500, Century Avenue, China (Shanghai) Pilot Free Trade Zone. Email: info@posicert.com



	HONSUN (NANTONG) Co.,Ltd	HS-T403-01
Page: 1 / 1	DECLARATION OF CONFORMITY	Version:A/1

Manufacturer HONSUN (NANTONG) Co.,Ltd
 SRN CN-MF-000009428
 Address No.8 Tongxing Road Nantong Economic & Technological
 Development area, 226009, Jiangsu Province, P. R. China
 EU representative Shanghai International Holding Corp. GmbH (Europe)
 SRN DE-AR-000000001
 Address Eiffestrasse 80, 20537 Hamburg, Germany
 Product name Tourniquet
 Product model HS-403C
 UMDNS Code 14072
 Classification Class I (MDR, Annex VIII Rule 1)
 Basic UDI-DI 697038425TNQTY

Conforming Assessment Route: Annex II+III

We herewith declare that the above mentioned products meet the provisions of the following EC Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

Medical device regulation REGULATION (EU)2017/745
 Identification CE
 Place, Date of issue Nantong, 2021.03

江苏鹿得医疗电子股份有限公司
 HONSUN (NANTONG) CO., LTD.

Signature _____
 Name William Xiang
 Position General Manager

	HONSUN (NANTONG) Co.,LTD			
	DECLARATION OF CONFORMITY		Doc. No	NTLD-HS-02
	Effective Date	2023-01-06	Page	1/1

Manufacturer: HONSUN (NANTONG) Co.,Ltd
 SRN: CN-MF-000009428
 Address: No.8 Tongxing Road Nantong Economic & Technological Development area, 226009, Jiangsu Province, P. R. China
 EU representative: Shanghai International Holding Corp. GmbH (Europe)
 SRN: DE-AR-000000001
 Address: Eiffestrasse 80, 20537 Hamburg, Germany
 Trademark: HONSUN
 Product name: Stethoscope
 Model: HS-series((HS-30A,HS-30A1,HS-30A2,HS-30B,HS-30B1,HS-30B2,HS-30C,HS-30C1,HS-30C3,HS-30F,HS-30G,H S-30L,HS-30N,HS-30J,HS-30K,HS-30Q,HS-30E,HS-101A,HS-103A,HS-106A,HS -107A,HS-108A))
 UMDNS Code: 13755
 Classification : I (MDR, Annex VIII Rule 1)
 Basic UDI-DI: 697038425STCTH
 Conforming Assessment Route : Annex II+Annex III

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer and this declaration is issued under the sole responsibility of the manufacturer.

Medical Device Regulation COUNCIL REGULATION (EU)2017/745.
 Standard EN ISO 14971:2019; ISO 10993-5:2009
 ISO 10993-10:2010; EN ISO 13485:2016
 EN ISO 15223-1:2021

Place, Date of issue Nantong Economic & Technological
 Development Area Jiangsu Province, China
 2023.01.06

江苏鹿得医疗电子股份有限公司
 HONSUN (NANTONG) CO., LTD.

Signature _____
 Name William Xiang
 Position General Manager



HONSUN (NANTONG) CO., LTD

Declaration of conformity

CE Technical File- ANEROID SPHYGMOMANOMETER

No. NTLD-EC-01

Revision: D/1

Effective: 2023.03.29

Page: Page 1 of 2

Manufacturer: HONSUN (Nantong) Co., Ltd.
SRN number: CN-MF-000009428
Address: No.8, Tongxing Road, Economic&Technical Development Area,
Nantong City, Jiangsu, P.R.China
EU representative: Shanghai International Holding Corp. GmbH (Europe)
SRN number: DE-AR-000000001
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Product: Aneroid Sphygmomanometer
Intended use: Aneroid Sphygmomanometer is a non-automated, mechanical
blood-pressure monitor that used for the indirect measurement
(noninvasive) and display of arterial blood pressure.
EMDN code: C9006
Model Code: HS-201K1
Basic UDI-DI: 697038425ASMR8
Classification: Class I with measuring function((MDR, Annex VIII Rule 1)

Conforming Assessment Route :Annex IX

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body. We are exclusively responsible for the Declaration of Conformity.

Regulations

Medical Device regulation: COUNCIL REGULATION (EU) 2017/745.

Common standards applied: see *NTLD-EC-05 Standard list*

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339
München, Germany

Certificate: No. G21 074340 0020 Rev.00

Expiration date of the Certificate: 2029-02-22

Date CE mark was affixed: start of CE marking lot : 2006-07

Identifier of Notified Body: CE0123



HONSUN (NANTONG) CO., LTD

Declaration of conformity

CE Technical File- ANEROID SPHYGMOMANOMETER

No. NTLD-EC-01

Revision: D/1

Effective: 2023.03.29

Page: Page 1 of 2

Signature

Position: PRRC(Person responsible for regulatory compliance)

Place, Date: NANTONG, 2024-03

江苏鹿得医疗电子股份有限公司
HONSUN (NANTONG) CO., LTD



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7, 2909VA
Capelle aan den IJssel, The Netherlands
Tel: +31(0)10 3034500

Contact person: Yana Zhang (Ms.)
Email: ec.rep@sungogroup.com/
yan.zhang@sungoglobal.com

SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN
60601-1:2006+A1:2013+AC:2014+A12:2014
+A2:2020
EN 60601-1-2:2015+A1:2020
ISO-13485:2016
ISO-9001:2015

Manufacturer

Name: Nanchang Micare Medical Equipment Co.,Ltd
Address: Building 16th No.666 Yaohu West 5th Road,
Hi-Tech Zone Nanchang, Jiangxi, China
SRN: CN-MF-000027991

Product Information

Name: Examination Lights

Model: See annex

GMDN: 32037

CND CODE: Z129004

Basic UDI-DI:

JD1700: 697589906MFZZMM0001HR
JD1700L: 697589906MFZZMM0002HT
JD1700G: 697589906MFZZMM0003HV
JD1700J: 697589906MFZZMM0006J3
JD1800: 697589906MFZZMM0019JC
JD1800L: 697589906MFZZMM0020HV
JD1800G: 697589906MFZZMM0022HZ
JD1800J: 697589906MFZZMM0023J3
KL04L / KL04L.III: 697589906MFZZMM0007J5
KL05L / KL05L.III: 697589906MFZZMM0008J7
JD1200L: 697589906MFZZMM0009J9
JD1600L: 697589906MFZZMM0017J8
JD1200J: 697589906MFZZMM0010HS
JD1500: 697589906MFZZMM0013HY
JD1600J: 697589906MFZZMM0018JA

Classification: Class I, According to Rule 13, Annex
VIII, Regulation (EU) 2017/745

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z129004-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer This declaration of conformity is issued under the sole responsibility of the manufacturer

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of “NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD” Effective immediately. standards above.

Signature:

Date: 2024/04/07

Position: GM

Place: Jiangxi / China

Annex

Product Name	Model
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Examination Lights

JD1000, JD1000L, JD1000J JD1000G

JD1001, JD1001L, JD1001J JD1001G

JD1002, JD1002L, JD1002J JD1002G

JD1003, JD1003L, JD1003J JD1003G

JD1005, JD1005L, JD1005J JD1005G

JD1006, JD1006L, JD1006J JD1006G

JD1008, JD1008L, JD1008J JD1008G

JD1009, JD1009L, JD1009J JD1009G

JD1100, JD1100L, JD1100J JD1100G JD1200L, JD1200G, JD1200J,
JD1300L, JD1300J JD1300G JD1400L, JD1400J JD1400G, JD1500J,
JD1500L, JD1500G, JD1600J, JD1600L, JD1600G, JD1700J, JD1700L,
JD1700G, JD1700, JD1800L, JD1800J, JD1800G,
JD1900J, JD1900L, JD1900G, JD1800, JD1900, Or customized

Standard	Description
EN ISO14971:2019	in the Introduction: This document could be used as guidance in developing and maintaining a risk management process for other products that are not necessarily medical devices in some jurisdictions and for suppliers and other parties involved in the medical device life cycle.
EN ISO15223-1:2021	is the first part of a series of international standards that specifies which symbols should be used to express information supplied for a medical device - both on their packaging and within accompanying information
EN ISO20417:2021	This document includes the generally applicable requirements for identification and labels on a medical device or accessory, the packaging, marking of a medical device or accessory, and accompanying information. This document does not specify the means by which the information is to be supplied.
EN 60601-2-41:2009 + A11:2011+A1:2015	Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
EN60601-1:2006+A1:2013+AC:2014+A12:2014+A2:2020	This is the first in an extensive series of European standards on medical electrical

	equipment safety. It is the first “Part 1” standard and covers basic safety and essential performance for all medical electrical equipment and systems
ISO-13485:2016	Abstract. ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
ISO-9001:2015	ISO 9001:2015 is a worldwide standard that sets requirements for a strong Quality Management System. It details specific processes, procedures and activities that organizations must create, implement, maintain and improve in order to successfully manage making products or delivering services.
EN60601-1-2:2015+A1:2020	This new edition includes the following main additions: - guidance for determination of immunity test levels for special environments; - guidance for adjustment of immunity test levels when special considerations of mitigations or intended use are applicable; - guidance on risk management for basic safety and essential



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019+A11:2021
EN ISO 15223-1: 2021+A1:2025
EN ISO 20417:2021

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-011.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Document No.:MDR-TCF-011-08

Manufacturer

Name: Danyang New Hope Medical Equipment Co., Ltd.

Address: Building A-10, No. 55 Ziyuan Road, Life Science Industrial Park, Danyang Development Zone, China

SRN: CN-MF-000027193

Product Information

Name: IV Stand

Model: See Annex

EMDN: V9099

Basic UDI-DI: 697867091HS5813ATZ

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2026.02.10

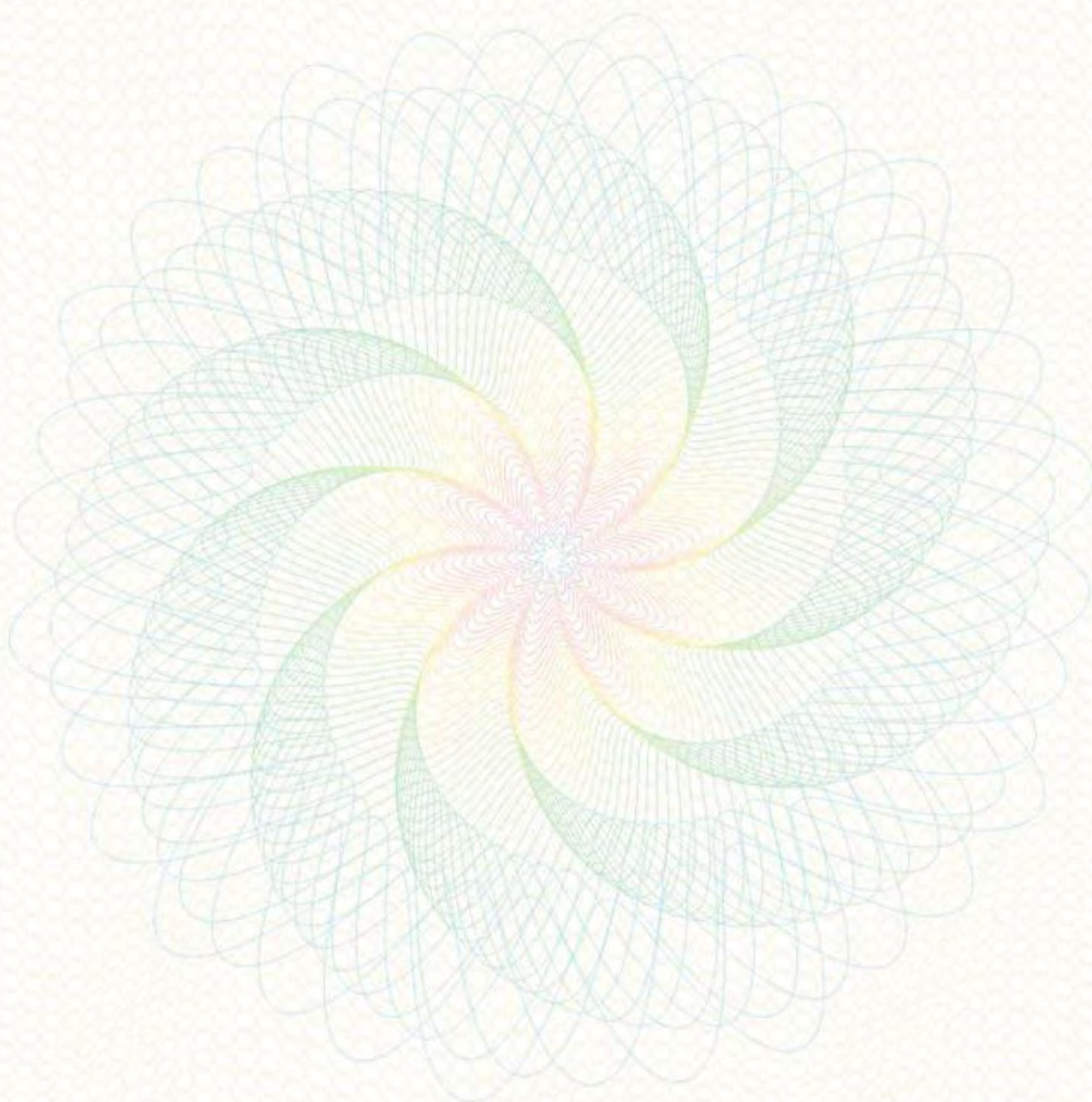
Position: GM Place: Jiangsu/China



Annex

Model

HS5809, HS5809A, HS5813, HS5810, HS5811, HS5812, HS5813A, HS5814, HS5815, HS5816, HS5817, HS5818, HS5819, HS5820, HS5821, HS5822, HS5823, HS5824, HS5825, HS5826, HS5827, HS5828, HS5810A, HS5810B, HS5810C, HS5813C, Customized



HONSUN Aim for Health	江苏鹿得医疗电子股份有限公司 HONSUN (NANTONG) CO., LTD.	NTLD-EC-01
页码: 1 / 1	DECLARATION OF CONFORMITY	版本号: 2.0

Manufacturer HONSUN (NANTONG) Co., Ltd

Address No.8 Tongxing Road Nantong Economic & Technological
Development area, 226009, Jiangsu Province, P. R. China

EU representative Shanghai International Holding Corp. GmbH (Europe)

Address Eiffestrasse 80, 20537 Hamburg, Germany

Product Cuffs for Sphygmomanometer

UMDNS-Code 11073

Classification : I (MDR, Annex VIII Rule 1)

Basic UDI-DI: 697038425CUFRA

Conforming Assessment Route: Annex II + Annex III

We herewith declare that the products mentioned as above meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer and this declaration is issued under the sole responsibility of the manufacturer.

Medical Device Regulation COUNCIL REGULATION (EU)2017/745.

Standard EN ISO 14971:2012; ISO 10993-5:2009
ISO 10993-10:2010; EN ISO 13485:2016
EN ISO 15223-1:2016

Place, Date of issue Nantong Economic & Technological Development Area

Signature _____
Name William Xiang
Position General Manager

2021.05.25

	HONSUN (NANTONG) Co.,Ltd	HS-T403-01
Page: 1 / 1	DECLARATION OF CONFORMITY	Version:A/1

DECLARATION OF CONFORMITY

Manufacturer HONSUN (NANTONG) Co.,Ltd
 Address No.8 Tongxing Road Nantong Economic & Technological Development area, 226009, Jiangsu Province, P. R. China
 EU representative Shanghai International Holding Corp. GmbH (Europe)
 Address Eiffestrasse 80, 20537 Hamburg, Germany
 Product name Tourniquet
 Product model HS-403, HS-403A, HS-403B, HS-403C, HS-403D, HS-403E, HS-403F, HS-403G, HS-403H, HS-403I, HS-403J, HS-403K, HS-403L, HS-403M, HS-403N, HS-403O, HS-403P, HS-403Q, HS-403R, HS-403S, HS-403T, HS-403U, HS-403V, HS-403W, HS-403X, HS-403Y, HS-403Z,
 UMDNS Code 14072
 Classification Class I (MDR, Annex VIII Rule 1)
Basic UDI-DI 697038425TNQTY

Conforming Assessment Route: Annex IV

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

Medical device regulation COUNCIL REGULATION (EU)2017/745

Identification

CE

Place, Date of issue

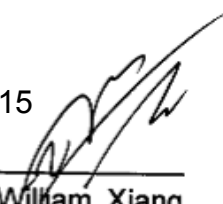
Nantong, 2022.01.15


 HONSUN (NANTONG) CO., LTD.
 项友亮

Signature

Name

Position


 William Xiang
 General Manager

DICHIARAZIONE DI CONFORMITÀ / DECLARATION OF CONFORMITY

Produttore / Manufacturer: CA-MI Srl

Indirizzo / Address: Via Ugo La Malfa n°13 - 43013 Località Pilastro, Langhirano (PR) Italia

Apparecchiatura / Equipment: Bilancia pesa bambini / Baby Scale

Nome commerciale, modello / Trade Name, model: **BAMBY BILANCIA PESA BAMBINI - REF BL 100003**

Destinazione d'uso / Intended Use: Bilancia digitale per pesa automatica del bambino / Automatic Digital Baby Scale

Dati di targa / Ratins: 3V dc - Batteria/Battery Litio Tipo/Type CR2032

Il dispositivo in oggetto è conforme alle direttive europee / The above mentioned equipment is complying with the European Directives:

2004/108/EC (EMC - Compatibilità Elettromagnetica / Electromagnetic Compatibility Directive)

2011/65/EU (Direttiva RoHS / RoHS Directive)

2012/19/EU (Direttiva WEEE / WEEE Directive)

Il dispositivo è conforme alle norme europee / The Above mentioned equipment is complying with the European Standards:

EMC Std: EN 61000-6-3:2007 / EN 61000-6-1:2007 (EN 61000-4-2:2009, EN61000-4-3:2010)

Other Std : CEI EN 50419

CA-MI Srl dichiara che questo prodotto soddisfa i requisiti fondamentali delle direttive europee 2004/108/EC (EMC - Compatibilità Elettromagnetica) / CA-MI Srl, declares that this product meets the basic requirements of European Directives 2004/108/EC (EMC - Electromagnetic Compatibility).

La dichiarazione di conformità relativa alle direttive citate e tutta la documentazione di supporto è disponibile presso CA-MI SRL. The declaration of conformity with the directives mentioned and all supporting documentation is available at CA-MI Srl

Luogo e Data di emissione / Place and Date of Issued: Langhirano (PR), 06/04/2017

Redatta da / Issued By:

Quality Assurance Manager
Manuel Sacconi



Verificata e approvata da / Verified and Approved by:

Legale Rappresentante l'Azienda / General Manager
Mario Attolini



EC Declaration of Conformity

We declare that the following products we manufacture;

Surgical Instruments, Dental Instruments, Scissors, Hemostatic Forceps, Anatomic Forceps, Diverse, ENT Instruments, Skin Grafts, Nail Cutters, Suture, Needle Holders, Retractors, General Surgery, Urology 1 Vesicle, Intestinal. Rectal, Gynecology, Obstetric, Cannulas, Neurology, Ophthalmology, Instruments Sets, Diagnostic, Dental and Hollow wares, Kidney Trays, Instruments boxes, Instruments Trays / sterilization containers.

- Surgical Instruments; Re-Useable, Non-Powered
- Dental Instruments; Re-Useable, Non-Powered
- Orthodontic Instruments; Re-Useable, Non-Powered

Classified, according as medical devices class 1 and 1R, marked with CE, and comply with the Essential Requirements of the **MDR 2017/745** Concerning Medical Devices

EC Representative:

KB INTERNATIONAL,

Aurora utca,

13. al. 1, Budapest - 1084

Hungary.

Demonstrated by compliance to ISO 9001:2015, ISO 13485:2016 (SGS Pakistan) and MDR 2017/745

Harmonized Standards: ISO 14971:2019, ASTM F 899-2011, 15223-1:2021+a1:2025 and ISO 20417:2026

This Certificate is valid for three years from 21st March, 2024

Gobble Surgical



GOBBLE SURGICAL
Head Marala Road, Gohad Pur, 51310
Sialkot - Pakistan

CEO

Certificate PK20/818842648.01

SGS

Gobble Surgical

Head Marala Road, P.O. Gohad Pur, Sialkot -51310 Pakistan

Has been assessed under the management system of the certified organisation defined in the main certificate PK20/818842648.00 as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Manufacture and Sales of Non-Sterile Single Use and Re-usable Surgical and Dental Instruments.

This certificate is valid from 27 November 2023 until 27 November 2026 and remains valid subject to satisfactory surveillance audits.
Issue 2.

The validity of this certificate depends on the validity of the main certificate.

Jonathan M. Hall

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com



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CERTIFICATO

Nr. 50 100 7022 Rev.010

SI ATTESTA CHE / THIS IS TO CERTIFY THAT

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

CA-MI S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

**VIA UGO LA MALFA - FRAZIONE PILASTRO 13
IT - 43013 LANGHIRANO (PR)**

SEDI OPERATIVE: VEDI ALLEGATO 1 / OPERATIONAL SITES: **SEE ANNEX 1**

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione e sviluppo, produzione, assistenza tecnica e commercializzazione di dispositivi medici per chirurgia e relativi accessori (aspiratori elettrici e non), tiralatte elettrici e relativi accessori, dispositivi medici per respirazione (aerosolterapia, inalatori termali) e relativi accessori, dispositivi medici per il monitoraggio di parametri fisiologici vitali (termometri), dispositivi medici per la ginnastica respiratoria, dispositivi medici per flebologia (calze medicali a compressione graduata). Distribuzione di dispositivi medici attivi e non attivi non impiantabili.
(IAF 19, 12, 29)

Design and development, production, servicing and distribution of medical equipment for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipment and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers), incentive spirometers and devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices. (IAF 19, 12, 29)



Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: **2025-08-01**

Al / To: **2028-07-31**

Data emissione /
Issuing Date

Francesco Scarlata

Direttore Divisione Business Assurance
Business Assurance Division Manager

2025-07-23

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2007-09-03

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



ALLEGATO 1 AL CERTIFICATO NR 50 100 7022 Rev.010
ANNEX 1 TO CERTIFICATE NO 50 100 7022 Rev.010
pagina 1 di 2 / page 1 of 2

IL CERTIFICATO NR 50 100 7022 Rev.010 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N 50 100 7022 Rev.010 COVERS ALSO THE FOLLOWING OFFICES:

CA-MI S.r.l.

VIA UGO LA MALFA - FRAZIONE PILASTRO 13
IT - 43013 LANGHIRANO (PR)

Progettazione e sviluppo, produzione, assistenza tecnica e commercializzazione di dispositivi medici per chirurgia e relativi accessori (aspiratori elettrici e non), tiralatte elettrici e relativi accessori, dispositivi medici per respirazione (aerosolterapia, inalatori termali) e relativi accessori, dispositivi medici per il monitoraggio di parametri fisiologici vitali (termometri), dispositivi medici per la ginnastica respiratoria, dispositivi medici per flebologia (calze medicali a compressione graduata). Distribuzione di dispositivi medici attivi e non attivi non impiantabili.

Design and development, production, servicing and distribution of medical equipment for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipment and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers), incentive spirometers and devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices.

STRADA PER PARMA 34 - FRAZIONE PILASTRO
IT - 43013 LANGHIRANO (PR)

Magazzino di dispositivi medici attivi e non attivi non impiantabili e componenti utilizzati in produzione.

Warehouse of active and non-active non implantable medical devices and components used in production.



00077

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: 2028-08-01

Al / To: 2028-07-31

Francesco Scarlata

Francesco Scarlata

Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione /
Issuing Date

2025-07-23

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2007-09-03

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



Italia

ALLEGATO 1 AL CERTIFICATO NR 50 100 7022 Rev.010
ANNEX 1 TO CERTIFICATE NO 50 100 7022 Rev.010
pagina 1 di 2 / page 1 of 2

IL CERTIFICATO NR 50 100 7022 Rev.010 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N 50 100 7022 Rev.010 COVERS ALSO THE FOLLOWING OFFICES:

CA-MI S.r.l.

VIA UGO LA MALFA 27 - FRAZIONE PILASTRO
IT - 43013 LANGHIRANO (PR)

Magazzino di dispositivi medici attivi e non attivi non impiantabili e componenti utilizzati in produzione.

Warehouse of active and non-active non implantable medical devices and components used in production.

VIA UGO LA MALFA, 15 - FRAZIONE PILASTRO
IT - 43013 LANGHIRANO (PR)

Produzione di dispositivi medici per chirurgia (aspiratori elettrici e manuali), magazzino di dispositivi medici attivi non impiantabili e componenti utilizzati in produzione.

Production of medical devices for surgery (electrical and manual suction pumps), warehouse of active non implantable medical devices and components used in production.



00077

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: 2025-08-01

Al / To: 2028-07-31

Francesco Scarlata

Data emissione /
Issuing Date

Francesco Scarlata

Direttore Divisione Business Assurance
Business Assurance Division Manager

2025-07-23

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2007-09-03

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 063105 0045 Rev. 05

Holder of Certificate:



CA-MI S.r.l.

Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

Certification Mark:



Scope of Certificate:

Design and development, production, servicing and distribution of medical equipments for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers, incentive spirometers and medical devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 063105 0045 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_063105_0045_Rev_05)

Report No.:

ITA200220009818

Valid from:

2025-08-02

Valid until:

2028-08-01

Date,

2025-07-28

Christoph Dicks

Head of Certification/Notified Body



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 063105 0045 Rev. 05

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **CA-MI S.r.l.**
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Design and development, production, servicing and distribution of medical equipments for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers, incentive spirometers and medical devices for phlebology (graduated compression medical stockings).
Distribution of active and non-active non implantable medical devices.

CA-MI S.r.l.
Strada per Parma 34, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Warehouse of active and non-active non implantable medical devices and components used in production.

CA-MI S.r.l.
Via Ugo La Malfa 27, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Warehouse of active and non-active non implantable medical devices and components used in production.

CA-MI S.r.l.
Via Ugo La Malfa, 15, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Production of medical devices for surgery (electrical and manual suction pumps), warehouse of active non implantable medical devices and components used in production.

/



Certificate

No. Q5 074340 0018 Rev. 03

Holder of Certificate: **HONSUN (NANTONG) Co., Ltd.**
No.8 Tongxing Road
Economic & Technological Development Area
226009 Nantong City
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,
Production and Distribution of
Aneroid Sphygmomanometers, Blood Pressure Monitors,
Nebulizers, Stethoscopes, Ophthalmoscopes,
Otosopes, Dental Oral Irrigators, Examination Lights,
Reflex Hammer, Medical Tourniquet, Infrared Forehead
Thermometers, ENT Irrigation Device, Oxygen Concentrator

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 074340 0018 Rev. 03

Report No.: SH2461801

Valid from: 2024-11-04

Valid until: 2026-03-08

Date, 2024-11-04

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 074340 0018 Rev. 03

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Zhejiang Honsun Medical Technology Co., Ltd.**
Sanjiang Street, Building 8 of Art & Crafts Park, Beiao Industrial
Estate, 325100 Wenzhou, Zhejiang, PEOPLE'S REPUBLIC OF
CHINA

Production and Distribution of Ophthalmoscope, Otoscope,
Examination Lights, Reflex Hammer and Medical Tourniquet

HONSUN (NANTONG) Co., Ltd.

No.8 Tongxing Road, Economic & Technological Development
Area, 226009 Nantong City, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Aneroid
Sphygmomanometers, Blood Pressure Monitors, Nebulizers,
Stethoscopes, Ophthalmoscopes, Otoscopes, Dental Oral
Irrigators, Examination Lights, Reflex Hammer, Medical
Tourniquet, Infrared Forehead Thermometers, ENT Irrigation
Device, Oxygen Concentrator



This is to certify that the Quality Management System of

Nanchang Micare Medical Equipment Co., Ltd.

Unified Social Credit Code: 91360106576136496G

Operation Address: Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Qingshanhu District, Nanchang City, Jiangxi Province, China

Registered Address: Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Nanchang City, Jiangxi Province, China

applicable to

Production and Sales of LED Surgical Light, Examination Light, Medical Headlight, Medical Film Viewer and Medical Loupes(excluding installation, within the scope of license qualifications)

has been assessed and registered by NQA against the provisions of

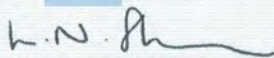
ISO 13485:2016

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: **133954**

Issue Date: 13 June 2024

Reissue Date: 15 November 2024

Valid Until: 13 June 2027



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.



This is to certify that the Quality Management System of

Nanchang Micare Medical Equipment Co., Ltd.

Unified Social Credit Code: 91360106576136496G

Operation Address: Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Qingshanhu District, Nanchang City, Jiangxi Province, China

Registered Address: Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Nanchang City, Jiangxi Province, China

applicable to

Production and Sales of LED Surgical Light, Examination Light, Medical Headlight, Medical Film Viewer and Medical Loupes(excluding installation, within the scope of license qualifications)

has been assessed and registered by NQA against the provisions of

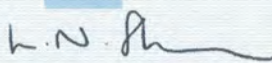
ISO 9001:2015

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: **133953**

Issue Date: 13 June 2024

Reissue Date: 15 November 2024

Valid Until: 13 June 2027

EAC Code: 23



0015





EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 074340 0020 Rev. 00

Manufacturer:

HONSUN (NANTONG) Co., Ltd.

No.8 Tongxing Road
Economic&Technological
Development Area
226009 Nantong City
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009428

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.

As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21 074340 0020 Rev. 00

Report No.:

SH2261802

Valid from:

2024-02-23

Valid until:

2029-02-22

Issue date:

2024-02-23

Christoph Dicks
Head of Certification/Notified
Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 074340 0020 Rev. 00

Classification:	Class I
Device Group:	C9006 - ANEROID SPHYGMOMANOMETERS
Device Properties:	MDS 1010 - Devices with a measuring function

The validity of this certificate depends on conditions and/or is limited to the following: NA

Revision History:

Rev.	Dated	Report	Description
00	2024-02-23	SH2261802	Initial issuance

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 15 March 2023****amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Regulations (EU) 2017/745 ⁽³⁾ and (EU) 2017/746 ⁽⁴⁾ of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC ⁽⁵⁾ and 93/42/EEC ⁽⁶⁾ and Directive 98/79/EC of the European Parliament and of the Council ⁽⁷⁾, such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and introduce provisions ensuring transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.
- (2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council ⁽⁸⁾, while 26 May 2024 was maintained as the end date of the transitional period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC can lawfully be placed on the market or put into service.

⁽¹⁾ Opinion of 24 January 2023 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 16 February 2023 (not yet published in the Official Journal) and decision of the Council of 7 March 2023.

⁽³⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽⁴⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

⁽⁵⁾ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

⁽⁶⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

⁽⁷⁾ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

⁽⁸⁾ Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).

- (3) Also due to the impact of the COVID-19 pandemic, the transitional period provided for in Regulation (EU) 2017/746 was already extended by Regulation (EU) 2022/112 of the European Parliament and of the Council ⁽⁹⁾.
- (4) Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024. It appears that a large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745, in particular when the complexity of those new requirements is taken into account. Therefore, it is very likely that many devices that can lawfully be placed on the market in accordance with the transitional provisions provided for in Regulation (EU) 2017/745 will not be certified in accordance with that Regulation before the end of the transitional period, which leads to the risk of shortages of medical devices in the Union.
- (5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and to extend the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. The extension should be of sufficient duration to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.
- (6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.
- (7) To ensure a progressive transition to Regulation (EU) 2017/745, the appropriate surveillance regarding devices benefiting from the transitional period should eventually be transferred from the notified body that issued the certificate in accordance with Directive 90/385/EEC or Directive 93/42/EEC to a notified body designated under Regulation (EU) 2017/745. For reasons of legal certainty, the notified body designated under Regulation (EU) 2017/745 should not be responsible for conformity assessment and surveillance activities carried out by the notified body that issued the certificate.
- (8) As regards the period needed to allow manufacturers and notified bodies to carry out the conformity assessment in accordance with Regulation (EU) 2017/745 of medical devices that are covered by a certificate or a declaration of conformity that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, a balance should be struck between the limited available capacity of notified bodies and ensuring a high level of patient safety and public health protection. Therefore, the length of the transitional period should depend on the risk class of the medical devices concerned, so that the period is shorter for devices belonging to a higher risk class and longer for devices belonging to a lower risk class.
- (9) Contrary to Directives 90/385/EEC and 93/42/EEC, Regulation (EU) 2017/745 requires the involvement of a notified body in the conformity assessment of class III custom-made implantable devices. Due to insufficient notified body capacity and the fact that manufacturers of custom-made devices are often small or medium-sized enterprises which lack access to a notified body under Directives 90/385/EEC and 93/42/EEC, a transitional period should be provided for, during which class III custom-made implantable devices can lawfully be placed on the market or put into service without a certificate issued by a notified body.

⁽⁹⁾ Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 3).

- (10) Article 120(4) of Regulation (EU) 2017/745 and Article 110(4) of Regulation (EU) 2017/746 prohibit the further making available on the market or putting into service of devices which are placed on the market by the end of the applicable transitional period and which are still in the supply chain one year after the end of that transitional period. To prevent the unnecessary disposal of safe medical devices and *in vitro* diagnostic medical devices that are still in the supply chain, thus adding to the imminent risk of shortages of such devices, such further making available on the market or putting into service of such devices should be unlimited in time.
- (11) Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be amended accordingly.
- (12) Since the objectives of this Regulation, namely to address risks of shortages of medical devices and *in vitro* diagnostic medical devices in the Union, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union ("TEU"). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (13) This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of medical devices and the associated risk of a public health crisis. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2024, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*. For the same reasons, it is also considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2017/745

Regulation (EU) 2017/745 is amended as follows:

(1) Article 120 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for the relevant risk class of the devices. Certificates issued by notified bodies in accordance with those Directives from 25 May 2017 that were still valid on 26 May 2021 and that have expired before 20 March 2023 shall be considered to be valid until the dates set out in paragraph 3a of this Article only if one of the following conditions is fulfilled:

(a) before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;

- (b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.’;

- (b) paragraph 3 is replaced by the following:

‘3. By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.

3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

- (a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;
- (b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3b. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

- (a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- (b) there are no significant changes in the design and intended purpose;
- (c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- (d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
- (e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

3d. By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in paragraphs 3a and 3b of this Article in place of the corresponding requirements in Directives 90/385/EEC and 93/42/EEC.

3e. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3a of this Article shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out such surveillance.

No later than 26 September 2024, the notified body that has signed the written agreement referred to in paragraph 3c, point (e), of this Article shall be responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, the surveillance shall be conducted in respect of the device that is being substituted.

The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 42 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 42 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 42 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.

3f. By way of derogation from Article 5, class III custom-made implantable devices may be placed on the market or put into service until 26 May 2026 without a certificate issued by a notified body in accordance with the conformity assessment procedure referred to in Article 52(8), second subparagraph, provided that no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.;

(c) paragraph 4 is replaced by the following:

‘4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices lawfully placed on the market from 26 May 2021 pursuant to paragraphs 3, 3a, 3b and 3f of this Article, may continue to be made available on the market or put into service.’;

(2) Article 122 is amended as follows:

(a) in the first paragraph, the introductory wording is replaced by the following:

‘Without prejudice to Article 120(3) to (3e) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2021, with the exception of:’;

(b) the second paragraph is replaced by the following:

‘As regards the devices referred to in Article 120(3) to (3e) and (4) of this Regulation, the Directives referred to in the first paragraph of this Article shall continue to apply to the extent necessary for the application of those paragraphs.’;

(3) in Article 123(3), point (d), the 24th indent is replaced by the following:

‘— Article 120(3d).’.

Article 2

Amendments to Regulation (EU) 2017/746

Regulation (EU) 2017/746 is amended as follows:

(1) in Article 110, paragraph 4 is replaced by the following:

‘4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022, and devices lawfully placed on the market from 26 May 2022 pursuant to paragraph 3 of this Article may continue to be made available on the market or put into service.’;

(2) in Article 112, the second paragraph is replaced by the following:

‘As regards the devices referred to in Article 110(3) and (4) of this Regulation, Directive 98/79/EC shall continue to apply to the extent necessary for the application of those paragraphs.’.

*Article 3***Entry into force**

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 15 March 2023.

For the European Parliament

The President

R. METSOLA

For the Council

The President

J. ROSWALL

CERTIFICATE

OF COMPLIANCE



Standard Efficient Registrar (P) Ltd. Certifies that

GOBBLE SURGICAL
Head Marala, P.O. Gohad Pur, Sialkot - 51310, Pakistan

the mentioned products has been compliance with the essential requirements specified in the EU Medical Device Regulation MDR 2017/745, including the technical file of the devices have been assessed and EU declaration of conformity according to the Annex IV



Approved Scope to which this certificate refers:

Class I & Ir Surgical, Dental, Ophthalmic, Orthopedic, Spinal Surgery, VAT, Electrosurgical, Manicure/Pedicure, Veterinary, Diagnostic Instruments and Hollowware Items, Kidney Trays, Instruments Boxes, Instruments Trays / Sterilization Containers

Certificate No:	6489462/COC/PK
Issuance Date:	27 January 2026
Expiry Date:	26 January 2027

Limitations: The Manufacturer must inform Standard Efficient Registrar (SER) of any substantial changes occurred in the product or process in order to examine whether this certificate remains valid or not.

The validity of the certificate is subject to periodic surveillance audits.

The use and validity of this certificate are subject to compliance with SER procedures.



Jane Smith
Certification Director

For more information concerning the validity of the certificate,
Please visit the site www.seregistrar.us or email to info@seregistrar.us



	HONSUN (NANTONG) Co.,LTD			
	DECLARATION OF CONFORMITY		Doc. No	NTLD-HS-02
	Effective Date	2023-03-19	Page	1/1

Manufacturer: HONSUN (NANTONG) Co.,Ltd
 SRN number: CN-MF-000009428
 Address: No.8 Tongxing Road Nantong Economic & Technological Development area, 226009, Jiangsu Province, P. R. China
 EU representative: Shanghai International Holding Corp. GmbH (Europe)
 SRN: DE-AR-000000001
 Address: Eiffestrasse 80, 20537 Hamburg, Germany
 Trademark: HONSUN
 Product name: Stethoscope
 Model: HS-series(HS-30A,HS-30A1,HS-30A2,HS-30B,HS-30B1,HS-30B2,HS-30C,HS-30C1,HS-30C3,HS-30G,HS-30L,HS-30N,HS-30J,HS-30K,HS-30R1,HS-101A,HS-103A,HS-106A,HS -107A,HS-108A)
 UMDNS Code : 13755
 Classification : I (MDR, Annex VIII Rule 1)
 Basic UDI-DI: 697038425STCTH
 Conforming Assessment Route : Annex II+Annex III

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer and this declaration is issued under the sole responsibility of the manufacturer.

Medical Device Regulation: COUNCIL REGULATION (EU)2017/745.
 Standard: EN ISO 14971:2019; ISO 10993-5:2009
 ISO 10993-10:2010; EN ISO 13485:2016
 EN ISO 15223-1:2021

Place, Date of issue: Nantong Economic & Technological Development Area Jiangsu Province, China
 2023.03.19

Signature: 
 Name: William Xiang
 Position: General Manager



HONSUN (NANTONG) CO., LTD

Declaration of conformity

CE technical file - ANEROID SPHYGMOMANOMETER

No. NTLD-EC-01
Revision: D/3
Effective: 2025.3.6
Page: Page 1 of 2

Manufacturer: HONSUN (Nantong) Co., Ltd.
SRN number: CN-MF-000009428
Address: No.8, Tongxing Road, Economic&Technical Development Area,
Nantong City, Jiangsu, P.R.China
EU representative: Shanghai International Holding Corp. GmbH (Europe)
SRN number: DE-AR-000000001
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Product: Aneroid Sphygmomanometer
Intended use: Aneroid Sphygmomanometer is a non-automated, mechanical
blood-pressure monitor that used for the indirect measurement
(noninvasive) and display of arterial blood pressure.
ENDN code: C9006
Model Code: See product list
Product picture: See the *NTLD-EC-02 Product introduction*
Classification: Class Im (MDR, Annex VIII Rule 1)
Basic UDI-DI: 697038425ASMR8

Conforming Assessment Route :Annex XI Part A

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

Regulations

General applicable regulation: Medical Device Regulation: (EU)2017/745.

Common standards applied: see *NTLD-EC-05 Standard list*

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339 München,
Germany

Certificate: No. G21 074340 0020 Rev.00

Expiration date of the Certificate: 2029-02-22

Date CE mark was affixed: start of CE marking lot: 2010-07

Identifier of Notified Body: CE0123



HONSUN (NANTONG) CO., LTD

Delcaration of conformity

CE technical file - ANEROID SPHYGMOMANOMETER

No. NTLD-EC-01

Revision: D/3

Effective: 2025.3.6

Page: Page 2 of 2

Signature:

Position: PRRC(Person responsible for regulatory compliance)

Place, Date: NANTONG, 2025.3.6

Product list:

Name	Model
Aneroid Sphygmom anometer	HS-20A/HS-20D/HS-20E/HS-20F/HS-2000/HS-20C/HS-20G/HS-20H/ HS-100/HS-100A
	HS-50A/HS-50C/HS-50D/HS-50B/HS-50E
	HS-201M/HS-201E/HS-201S/HS-201T/HS-201W/HS-201X/HS-201Y/ HS-201Z/HS-201A/HS-201C/HS-201J/HS-201K/HS-201Q/HS-201D/ HS-201DT/HS-201A2/HS-201B2/HS-201Q3/HS-201M/HS-201C2/HS- 201Q2/HS-GF-301/HS-GF-302/HS-GF-303
	HS-60A/HS-60C/HS-60D/HS-60F/HS-60E/HS-70A/HS-70B/HS-70C/ HS-70D/HS-70E/HS-70F

RE: Validity Check - Certificate of Compliance

À partir de info@seregistrar.us <info@seregistrar.us>

Date Ven 15/08/2025 14:37

À Isabelle George <igeorge@devaset.com>

Cc Alexandre Rozaire <arozaire@devaset.com>; 'Mélanie Ettori' <ettorimelanie@gmail.com>

Dear Concerns,

It is to confirm you that the certificate of compliance to (M/s. Gobble Surgical) has been issued by us. We confirm that the certificate Numbers: 6489462/COC/PK is current and valid, subject to annual surveillance audits. You may check certificate validation through our database.

If you have any other query freely contact us

Best Regards,



Vanja Zrnic
Certification Department

SER Certification LLC
Info@seregistrar.us ; www.seregistrar.us

Think Standard, Build Sustainable



Think green - Please don't print this e-mail unless you really need to!

Disclaimer: This electronic message and all contents contain information from SERs which may be privileged, confidential or otherwise protected from disclosure. The information is intended to be for the addressee only.

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From: Isabelle George [mailto:igeorge@devaset.com]

Sent: Thursday, August 14, 2025 8:16 PM

To: info@seregistrar.us

Cc: Alexandre Rozaire; Mélanie Ettori

Subject: Validity Check - Certificate of Compliance

Importance: High

Dear Mr, Ms,

While checking the Certificate number through your website, no information has been found or published for the certificate I enclose to you.

Could you please send me a confirmation.

Thank you very much,

Have a nice day

Best regards,

Mme Isabelle GEORGE

DEVASET

Tel : + 33 4 13 41 95 70

Mobile : + 33 6 62 18 99 27

infos@devaset.com

www.devaset.com

	HONSUN (NANTONG) Co.,Ltd	HS-T403-01
Page: 1 / 1	DECLARATION OF CONFORMITY	Version:A/1

Manufacturer HONSUN (NANTONG) Co.,Ltd
 SRN CN-MF-000009428
 Address No.8 Tongxing Road Nantong Economic & Technological
 Development area, 226009, Jiangsu Province, P. R. China
 EU representative Shanghai International Holding Corp. GmbH (Europe)
 SRN DE-AR-000000001
 Address Eiffestrasse 80, 20537 Hamburg, Germany
 Product name Tourniquet
 Product model HS-403C
 UMDNS Code 14072
 Classification Class I (MDR, Annex VIII Rule 1)
 Basic UDI-DI 697038425TNQTY

Conforming Assessment Route: Annex II+III

We herewith declare that the above mentioned products meet the provisions of the following EC Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

Medical device regulation REGULATION (EU)2017/745
 Identification CE
 Place, Date of issue Nantong, 2021.03

江苏鹿得医疗电子股份有限公司
 HONSUN (NANTONG) CO., LTD.

Signature 
 Name William Xiang
 Position General Manager

	HONSUN (NANTONG) Co.,LTD			
	DECLARATION OF CONFORMITY		Doc. No	NTLD-HS-02
	Effective Date	2023-01-06	Page	1/1

Manufacturer: HONSUN (NANTONG) Co.,Ltd
 SRN: CN-MF-000009428
 Address: No.8 Tongxing Road Nantong Economic & Technological Development area, 226009, Jiangsu Province, P. R. China
 EU representative: Shanghai International Holding Corp. GmbH (Europe)
 SRN: DE-AR-000000001
 Address: Eiffestrasse 80, 20537 Hamburg, Germany
 Trademark: HONSUN
 Product name: Stethoscope
 Model: HS-series((HS-30A,HS-30A1,HS-30A2,HS-30B,HS-30B1,HS-30B2,HS-30C,HS-30C1,HS-30C3,HS-30F,HS-30G,H S-30L,HS-30N,HS-30J,HS-30K,HS-30Q,HS-30E,HS-101A,HS-103A,HS-106A,HS -107A,HS-108A))
 UMDNS Code: 13755
 Classification : I (MDR, Annex VIII Rule 1)
 Basic UDI-DI: 697038425STCTH
 Conforming Assessment Route : Annex II+Annex III

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer and this declaration is issued under the sole responsibility of the manufacturer.

Medical Device Regulation COUNCIL REGULATION (EU)2017/745.
 Standard EN ISO 14971:2019; ISO 10993-5:2009
 ISO 10993-10:2010; EN ISO 13485:2016
 EN ISO 15223-1:2021

Place, Date of issue Nantong Economic & Technological
 Development Area Jiangsu Province, China
 2023.01.06

江苏鹿得医疗电子股份有限公司
 HONSUN (NANTONG) CO., LTD.

Signature _____
 Name William Xiang
 Position General Manager

**HONSUN (NANTONG) CO., LTD**

Declaration of conformity

CE Technical File- ANEROID SPHYGMOMANOMETER

No.	NTLD-EC-01
Revision:	D/1
Effective:	2023.03.29
Page:	Page 1 of 2

Manufacturer: HONSUN (Nantong) Co., Ltd.

SRN number: CN-MF-000009428

Address: No.8, Tongxing Road, Economic&Technical Development Area,
Nantong City, Jiangsu, P.R.China

EU representative: Shanghai International Holding Corp. GmbH (Europe)

SRN number: DE-AR-000000001

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product: Aneroid Sphygmomanometer

Intended use: Aneroid Sphygmomanometer is a non-automated, mechanical blood-pressure monitor that used for the indirect measurement (noninvasive) and display of arterial blood pressure.

EMDN code: C9006

Model Code: HS-201K1

Basic UDI-DI: 697038425ASMR8

Classification: Class I with measuring function((MDR, Annex VIII Rule 1)

Conforming Assessment Route :Annex IX

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body. We are exclusively responsible for the Declaration of Conformity.

Regulations

Medical Device regulation: COUNCIL REGULATION (EU) 2017/745.

Common standards applied: see *NTLD-EC-05 Standard list*

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339
München, Germany

Certificate: No. G21 074340 0020 Rev.00

Expiration date of the Certificate: 2029-02-22

Date CE mark was affixed: start of CE marking lot : 2006-07

Identifier of Notified Body: CE0123



HONSUN (NANTONG) CO., LTD

Declaration of conformity

CE Technical File- ANEROID SPHYGMOMANOMETER

No. NTLD-EC-01

Revision: D/1

Effective: 2023.03.29

Page: Page 1 of 2

Signature

Position: PRRC(Person responsible for regulatory compliance)

Place, Date: NANTONG, 2024-03

江苏鹿得医疗电子股份有限公司
HONSUN (NANTONG) CO., LTD



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7, 2909VA
Capelle aan den IJssel, The Netherlands
Tel: +31(0)10 3034500

Contact person: Yana Zhang (Ms.)

Email: ec.rep@sungogroup.com/

yan.zhang@sungoglobal.com

SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019

EN ISO 15223-1: 2021

EN ISO 20417: 2021

EN

60601-1:2006+A1:2013+AC:2014+A12:2014

+A2:2020

EN 60601-1-2:2015+A1:2020

ISO-13485:2016

ISO-9001:2015

Manufacturer

Name: Nanchang Micare Medical Equipment Co.,Ltd

Address: Building 16th No.666 Yaohu West 5th Road,
Hi-Tech Zone Nanchang, Jiangxi, China

SRN: CN-MF-000027991

Product Information

Name: Examination Lights

Model: See annex

GMDN: 32037

CND CODE: Z129004

Basic UDI-DI:

JD1700: 697589906MFZZMM0001HR

JD1700L: 697589906MFZZMM0002HT

JD1700G: 697589906MFZZMM0003HV

JD1700J: 697589906MFZZMM0006J3

JD1800: 697589906MFZZMM0019JC

JD1800L: 697589906MFZZMM0020HV

JD1800G: 697589906MFZZMM0022HZ

JD1800J: 697589906MFZZMM0023J3

KL04L / KL04L.III: 697589906MFZZMM0007J5

KL05L / KL05L.III: 697589906MFZZMM0008J7

JD1200L: 697589906MFZZMM0009J9

JD1600L: 697589906MFZZMM0017J8

JD1200J: 697589906MFZZMM0010HS

JD1500: 697589906MFZZMM0013HY

JD1600J: 697589906MFZZMM0018JA

Classification: Class I, According to Rule 13, Annex
VIII, Regulation (EU) 2017/745

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z129004-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer This declaration of conformity is issued under the sole responsibility of the manufacturer

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of “NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD” Effective immediately. standards above.

Signature:

Date: 2024/04/07

Position: GM

Place: Jiangxi / China

Annex

Product Name	Model
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Examination Lights

JD1000, JD1000L, JD1000J JD1000G

JD1001, JD1001L, JD1001J JD1001G

JD1002, JD1002L, JD1002J JD1002G

JD1003, JD1003L, JD1003J JD1003G

JD1005, JD1005L, JD1005J JD1005G

JD1006, JD1006L, JD1006J JD1006G

JD1008, JD1008L, JD1008J JD1008G

JD1009, JD1009L, JD1009J JD1009G

JD1100, JD1100L, JD1100J JD1100G JD1200L, JD1200G, JD1200J,
JD1300L, JD1300J JD1300G JD1400L, JD1400J JD1400G, JD1500J,
JD1500L, JD1500G, JD1600J, JD1600L, JD1600G, JD1700J, JD1700L,
JD1700G, JD1700, JD1800L, JD1800J, JD1800G,
JD1900J, JD1900L, JD1900G, JD1800, JD1900, Or customized

Standard	Description
EN ISO14971:2019	in the Introduction: This document could be used as guidance in developing and maintaining a risk management process for other products that are not necessarily medical devices in some jurisdictions and for suppliers and other parties involved in the medical device life cycle.
EN ISO15223-1:2021	is the first part of a series of international standards that specifies which symbols should be used to express information supplied for a medical device - both on their packaging and within accompanying information
EN ISO20417:2021	This document includes the generally applicable requirements for identification and labels on a medical device or accessory, the packaging, marking of a medical device or accessory, and accompanying information. This document does not specify the means by which the information is to be supplied.
EN 60601-2-41:2009 + A11:2011+A1:2015	Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
EN60601-1:2006+A1:2013+AC:2014+A12:2014+A2:2020	This is the first in an extensive series of European standards on medical electrical

	equipment safety. It is the first “Part 1” standard and covers basic safety and essential performance for all medical electrical equipment and systems
ISO-13485:2016	Abstract. ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
ISO-9001:2015	ISO 9001:2015 is a worldwide standard that sets requirements for a strong Quality Management System. It details specific processes, procedures and activities that organizations must create, implement, maintain and improve in order to successfully manage making products or delivering services.
EN60601-1-2:2015+A1:2020	This new edition includes the following main additions: - guidance for determination of immunity test levels for special environments; - guidance for adjustment of immunity test levels when special considerations of mitigations or intended use are applicable; - guidance on risk management for basic safety and essential



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019+A11:2021
EN ISO 15223-1: 2021+A1:2025
EN ISO 20417:2021

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-011.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Document No.:MDR-TCF-011-08

Manufacturer

Name: Danyang New Hope Medical Equipment Co., Ltd.

Address: Building A-10, No. 55 Ziyuan Road, Life Science Industrial Park,Danyang Development Zone,China

SRN: CN-MF-000027193

Product Information

Name: IV Stand

Model: See Annex

EMDN: V9099

Basic UDI-DI: 697867091HS5813ATZ

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2026.02.10

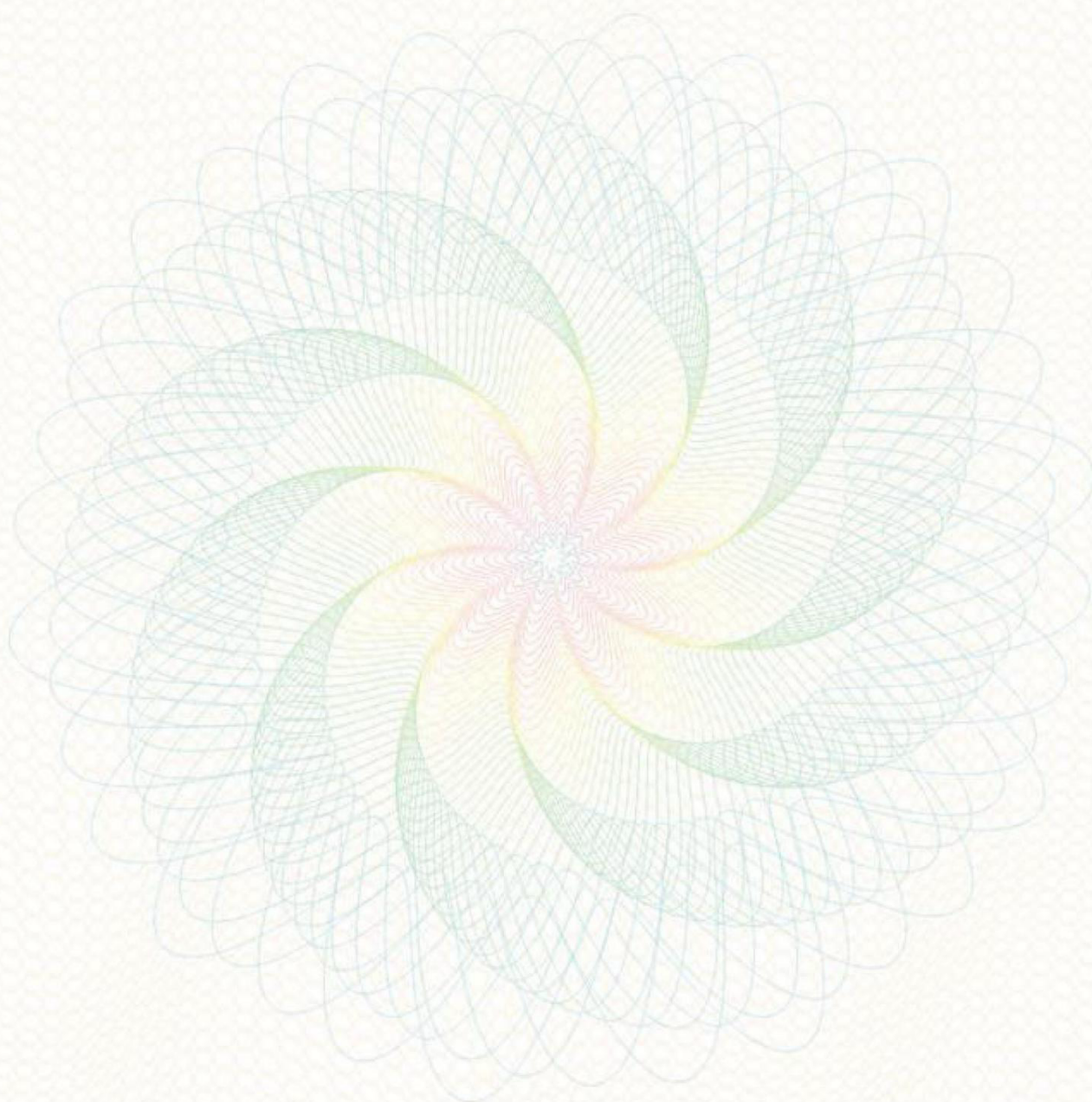
Position: GM Place: Jiangsu/China



Annex

Model

HS5809, HS5809A, HS5813, HS5810, HS5811, HS5812, HS5813A, HS5814, HS5815, HS5816, HS5817, HS5818, HS5819, HS5820, HS5821, HS5822, HS5823, HS5824, HS5825, HS5826, HS5827, HS5828, HS5810A, HS5810B, HS5810C, HS5813C, Customized



HONSUN Aim for Health	江苏鹿得医疗电子股份有限公司 HONSUN (NANTONG) CO., LTD.	NTLD-EC-01
页码: 1 / 1	DECLARATION OF CONFORMITY	版本号: 2.0

Manufacturer HONSUN (NANTONG) Co., Ltd

Address No.8 Tongxing Road Nantong Economic & Technological
Development area, 226009, Jiangsu Province, P. R. China

EU representative Shanghai International Holding Corp. GmbH (Europe)

Address Eiffestrasse 80, 20537 Hamburg, Germany

Product Cuffs for Sphygmomanometer

UMDNS-Code 11073

Classification : I (MDR, Annex VIII Rule 1)

Basic UDI-DI: 697038425CUFRA

Conforming Assessment Route: Annex II + Annex III

We herewith declare that the products mentioned as above meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer and this declaration is issued under the sole responsibility of the manufacturer.

Medical Device Regulation COUNCIL REGULATION (EU)2017/745.

Standard EN ISO 14971:2012; ISO 10993-5:2009
ISO 10993-10:2010; EN ISO 13485:2016
EN ISO 15223-1:2016

Place, Date of issue Nantong Economic & Technological Development Area

Signature _____
Name William Xiang
Position General Manager

Jiangsu Province, China

2021.05.25

	HONSUN (NANTONG) Co.,Ltd	HS-T403-01
Page: 1 / 1	DECLARATION OF CONFORMITY	Version:A/1

DECLARATION OF CONFORMITY

Manufacturer HONSUN (NANTONG) Co.,Ltd
Address No.8 Tongxing Road Nantong Economic & Technological Development area, 226009, Jiangsu Province, P. R. China
EU representative Shanghai International Holding Corp. GmbH (Europe)
Address Eiffestrasse 80, 20537 Hamburg, Germany
Product name Tourniquet
Product model HS-403, HS-403A, HS-403B, HS-403C, HS-403D, HS-403E, HS-403F, HS-403G, HS-403H, HS-403I, HS-403J, HS-403K, HS-403L, HS-403M, HS-403N, HS-403O, HS-403P, HS-403Q, HS-403R, HS-403S, HS-403T, HS-403U, HS-403V, HS-403W, HS-403X, HS-403Y, HS-403Z,
UMDNS Code 14072
Classification Class I (MDR, Annex VIII Rule 1)
Basic UDI-DI **697038425TNQTY**

Conforming Assessment Route: Annex IV

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

Medical device regulation COUNCIL REGULATION (EU)2017/745

Identification

CE

Place, Date of issue

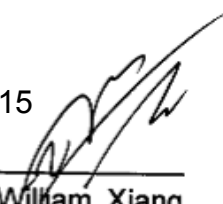
Nantong, 2022.01.15


 HONSUN (NANTONG) CO., LTD.
 项友亮

Signature

Name

Position


 William Xiang
 General Manager

DICHIARAZIONE DI CONFORMITÀ / DECLARATION OF CONFORMITY

Produttore / Manufacturer: CA-MI Srl

Indirizzo / Address: Via Ugo La Malfa n°13 - 43013 Località Pilastro, Langhirano (PR) Italia

Apparecchiatura / Equipment: Bilancia pesa bambini / Baby Scale

Nome commerciale, modello / Trade Name, model: **BAMBY BILANCIA PESA BAMBINI - REF BL 100003**

Destinazione d'uso / Intended Use: Bilancia digitale per pesa automatica del bambino / Automatic Digital Baby Scale

Dati di targa / Ratins: 3V dc - Batteria/Battery Litio Tipo/Type CR2032

Il dispositivo in oggetto è conforme alle direttive europee / The above mentioned equipment is complying with the European Directives:

2004/108/EC (EMC - Compatibilità Elettromagnetica / Electromagnetic Compatibility Directive)

2011/65/EU (Direttiva RoHS / RoHS Directive)

2012/19/EU (Direttiva WEEE / WEEE Directive)

Il dispositivo è conforme alle norme europee / The Above mentioned equipment is complying with the European Standards:

EMC Std: EN 61000-6-3:2007 / EN 61000-6-1:2007 (EN 61000-4-2:2009, EN61000-4-3:2010)

Other Std : CEI EN 50419

CA-MI Srl dichiara che questo prodotto soddisfa i requisiti fondamentali delle direttive europee 2004/108/EC (EMC - Compatibilità Elettromagnetica) / CA-MI Srl, declares that this product meets the basic requirements of European Directives 2004/108/EC (EMC - Electromagnetic Compatibility).

La dichiarazione di conformità relativa alle direttive citate e tutta la documentazione di supporto è disponibile presso CA-MI SRL. The declaration of conformity with the directives mentioned and all supporting documentation is available at CA-MI Srl

Luogo e Data di emissione / Place and Date of Issued: Langhirano (PR), 06/04/2017

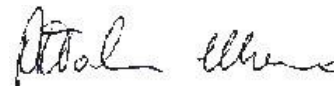
Redatta da / Issued By:

Quality Assurance Manager
Manuel Sacconi



Verificata e approvata da / Verified and Approved by:

Legale Rappresentante l'Azienda / General Manager
Mario Attolini



EC Declaration of Conformity

We declare that the following products we manufacture;

Surgical Instruments, Dental Instruments, Scissors, Hemostatic Forceps, Anatomic Forceps, Diverse, ENT Instruments, Skin Grafts, Nail Cutters, Suture, Needle Holders, Retractors, General Surgery, Urology 1 Vesicle, Intestinal. Rectal, Gynecology, Obstetric, Cannulas, Neurology, Ophthalmology, Instruments Sets, Diagnostic, Dental and Hollow wares, Kidney Trays, Instruments boxes, Instruments Trays / sterilization containers.

- Surgical Instruments; Re-Useable, Non-Powered
- Dental Instruments; Re-Useable, Non-Powered
- Orthodontic Instruments; Re-Useable, Non-Powered

Classified, according as medical devices class 1 and 1R, marked with CE, and comply with the Essential Requirements of the **MDR 2017/745** Concerning Medical Devices

EC Representative:

KB INTERNATIONAL,

Aurora utca,

13. al. 1, Budapest - 1084

Hungary.

Demonstrated by compliance to ISO 9001:2015, ISO 13485:2016 (SGS Pakistan) and MDR 2017/745

Harmonized Standards: ISO 14971:2019, ASTM F 899-2011, 15223-1:2021+a1:2025 and ISO 20417:2026

This Certificate is valid for three years from 21st March, 2024

Gobble Surgical



GOBBLE SURGICAL
Head Marala Road, Gohad Pur, 51310
Sialkot - Pakistan

CEO

C
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Certificate PK20/818842648.01

SGS

Gobble Surgical

Head Marala Road, P.O. Gohad Pur, Sialkot -51310 Pakistan

Has been assessed under the management system of the certified organisation defined in the main certificate PK20/818842648.00 as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Manufacture and Sales of Non-Sterile Single Use and Re-usable Surgical and Dental Instruments.

This certificate is valid from 27 November 2023 until 27 November 2026 and remains valid subject to satisfactory surveillance audits.
Issue 2.

The validity of this certificate depends on the validity of the main certificate.

Jonathan M. Hall

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com



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CERTIFICATO

Nr. 50 100 7022 Rev.010

SI ATTESTA CHE / THIS IS TO CERTIFY THAT

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

CA-MI S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

**VIA UGO LA MALFA - FRAZIONE PILASTRO 13
IT - 43013 LANGHIRANO (PR)**

SEDI OPERATIVE: VEDI ALLEGATO 1 / OPERATIONAL SITES: **SEE ANNEX 1**

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione e sviluppo, produzione, assistenza tecnica e commercializzazione di dispositivi medici per chirurgia e relativi accessori (aspiratori elettrici e non), tiralatte elettrici e relativi accessori, dispositivi medici per respirazione (aerosolterapia, inalatori termali) e relativi accessori, dispositivi medici per il monitoraggio di parametri fisiologici vitali (termometri), dispositivi medici per la ginnastica respiratoria, dispositivi medici per flebologia (calze medicali a compressione graduata). Distribuzione di dispositivi medici attivi e non attivi non impiantabili.
(IAF 19, 12, 29)

Design and development, production, servicing and distribution of medical equipment for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipment and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers), incentive spirometers and devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices. (IAF 19, 12, 29)



Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: **2025-08-01**

Al / To: **2028-07-31**

Data emissione /
Issuing Date

Francesco Scarlata

Direttore Divisione Business Assurance
Business Assurance Division Manager

2025-07-23

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2007-09-03

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



ALLEGATO 1 AL CERTIFICATO NR 50 100 7022 Rev.010
ANNEX 1 TO CERTIFICATE NO 50 100 7022 Rev.010
pagina 1 di 2 / page 1 of 2

IL CERTIFICATO NR 50 100 7022 Rev.010 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N 50 100 7022 Rev.010 COVERS ALSO THE FOLLOWING OFFICES:

CA-MI S.r.l.

VIA UGO LA MALFA - FRAZIONE PILASTRO 13
IT - 43013 LANGHIRANO (PR)

Progettazione e sviluppo, produzione, assistenza tecnica e commercializzazione di dispositivi medici per chirurgia e relativi accessori (aspiratori elettrici e non), tiralatte elettrici e relativi accessori, dispositivi medici per respirazione (aerosolterapia, inalatori termali) e relativi accessori, dispositivi medici per il monitoraggio di parametri fisiologici vitali (termometri), dispositivi medici per la ginnastica respiratoria, dispositivi medici per flebologia (calze medicali a compressione graduata). Distribuzione di dispositivi medici attivi e non attivi non impiantabili.

Design and development, production, servicing and distribution of medical equipment for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipment and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers), incentive spirometers and devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices.

STRADA PER PARMA 34 - FRAZIONE PILASTRO
IT - 43013 LANGHIRANO (PR)

Magazzino di dispositivi medici attivi e non attivi non impiantabili e componenti utilizzati in produzione.

Warehouse of active and non-active non implantable medical devices and components used in production.



00077

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: 2028-08-01

Al / To: 2028-07-31

Francesco Scarlata

Francesco Scarlata

Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione /
Issuing Date

2025-07-23

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2007-09-03

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



ALLEGATO 1 AL CERTIFICATO NR 50 100 7022 Rev.010
ANNEX 1 TO CERTIFICATE NO 50 100 7022 Rev.010
pagina 1 di 2 / page 1 of 2

IL CERTIFICATO NR 50 100 7022 Rev.010 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N 50 100 7022 Rev.010 COVERS ALSO THE FOLLOWING OFFICES:

CA-MI S.r.l.

VIA UGO LA MALFA 27 - FRAZIONE PILASTRO
IT - 43013 LANGHIRANO (PR)

Magazzino di dispositivi medici attivi e non attivi non impiantabili e componenti utilizzati in produzione.
Warehouse of active and non-active non implantable medical devices and components used in production.

VIA UGO LA MALFA, 15 - FRAZIONE PILASTRO
IT - 43013 LANGHIRANO (PR)

Produzione di dispositivi medici per chirurgia (aspiratori elettrici e manuali), magazzino di dispositivi medici attivi non impiantabili e componenti utilizzati in produzione.
Production of medical devices for surgery (electrical and manual suction pumps), warehouse of active non implantable medical devices and components used in production.



00077

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: 2025-08-01

Al / To: 2028-07-31

Data emissione /
Issuing Date

Francesco Scarlata

Direttore Divisione Business Assurance
Business Assurance Division Manager

2025-07-23

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2007-09-03

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 063105 0045 Rev. 05

Holder of Certificate:



CA-MI S.r.l.

Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

Certification Mark:



Scope of Certificate:

Design and development, production, servicing and distribution of medical equipments for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers, incentive spirometers and medical devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 063105 0045 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_063105_0045_Rev_05)

Report No.:

ITA200220009818

Valid from:

2025-08-02

Valid until:

2028-08-01

Date,

2025-07-28

Christoph Dicks

Head of Certification/Notified Body



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 063105 0045 Rev. 05

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **CA-MI S.r.l.**
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Design and development, production, servicing and distribution of medical equipments for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers, incentive spirometers and medical devices for phlebology (graduated compression medical stockings).
Distribution of active and non-active non implantable medical devices.

CA-MI S.r.l.
Strada per Parma 34, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Warehouse of active and non-active non implantable medical devices and components used in production.

CA-MI S.r.l.
Via Ugo La Malfa 27, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Warehouse of active and non-active non implantable medical devices and components used in production.

CA-MI S.r.l.
Via Ugo La Malfa, 15, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Production of medical devices for surgery (electrical and manual suction pumps), warehouse of active non implantable medical devices and components used in production.

/



Certificate

No. Q5 074340 0018 Rev. 03

Holder of Certificate: **HONSUN (NANTONG) Co., Ltd.**
No.8 Tongxing Road
Economic & Technological Development Area
226009 Nantong City
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,
Production and Distribution of
Aneroid Sphygmomanometers, Blood Pressure Monitors,
Nebulizers, Stethoscopes, Ophthalmoscopes,
Otosopes, Dental Oral Irrigators, Examination Lights,
Reflex Hammer, Medical Tourniquet, Infrared Forehead
Thermometers, ENT Irrigation Device, Oxygen Concentrator

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 074340 0018 Rev. 03

Report No.: SH2461801

Valid from: 2024-11-04

Valid until: 2026-03-08

Date, 2024-11-04



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 074340 0018 Rev. 03

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Zhejiang Honsun Medical Technology Co., Ltd.**
Sanjiang Street, Building 8 of Art & Crafts Park, Beiao Industrial
Estate, 325100 Wenzhou, Zhejiang, PEOPLE'S REPUBLIC OF
CHINA

Production and Distribution of Ophthalmoscope, Otoscope,
Examination Lights, Reflex Hammer and Medical Tourniquet

HONSUN (NANTONG) Co., Ltd.

No.8 Tongxing Road, Economic & Technological Development
Area, 226009 Nantong City, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Aneroid
Sphygmomanometers, Blood Pressure Monitors, Nebulizers,
Stethoscopes, Ophthalmoscopes, Otoscopes, Dental Oral
Irrigators, Examination Lights, Reflex Hammer, Medical
Tourniquet, Infrared Forehead Thermometers, ENT Irrigation
Device, Oxygen Concentrator



This is to certify that the Quality Management System of

Nanchang Micare Medical Equipment Co., Ltd.

Unified Social Credit Code: 91360106576136496G

Operation Address: Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Qingshanhu District, Nanchang City, Jiangxi Province, China

Registered Address: Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Nanchang City, Jiangxi Province, China

applicable to

Production and Sales of LED Surgical Light, Examination Light, Medical Headlight, Medical Film Viewer and Medical Loupes(excluding installation, within the scope of license qualifications)

has been assessed and registered by NQA against the provisions of

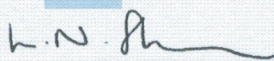
ISO 13485:2016

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: **133954**

Issue Date: 13 June 2024

Reissue Date: 15 November 2024

Valid Until: 13 June 2027



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.



This is to certify that the Quality Management System of

Nanchang Micare Medical Equipment Co., Ltd.

Unified Social Credit Code: 91360106576136496G

Operation Address: Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Qingshanhu District, Nanchang City, Jiangxi Province, China

Registered Address: Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Nanchang City, Jiangxi Province, China

applicable to

Production and Sales of LED Surgical Light, Examination Light, Medical Headlight, Medical Film Viewer and Medical Loupes(excluding installation, within the scope of license qualifications)

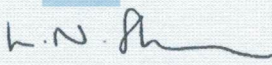
has been assessed and registered by NQA against the provisions of

ISO 9001:2015

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: **133953**

Issue Date: 13 June 2024

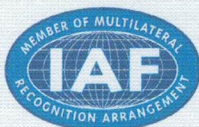
Reissue Date: 15 November 2024

Valid Until: 13 June 2027

EAC Code: 23



0015





EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 074340 0020 Rev. 00

Manufacturer:

HONSUN (NANTONG) Co., Ltd.

No.8 Tongxing Road
Economic&Technological
Development Area
226009 Nantong City
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009428

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.

As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21 074340 0020 Rev. 00

Report No.:

SH2261802

Valid from:

2024-02-23

Valid until:

2029-02-22

Issue date:

2024-02-23

Christoph Dicks
Head of Certification/Notified
Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 074340 0020 Rev. 00

Classification:	Class I
Device Group:	C9006 - ANEROID SPHYGMOMANOMETERS
Device Properties:	MDS 1010 - Devices with a measuring function

The validity of this certificate depends on conditions and/or is limited to the following: NA

Revision History:

Rev.	Dated	Report	Description
00	2024-02-23	SH2261802	Initial issuance

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 15 March 2023****amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Regulations (EU) 2017/745 ⁽³⁾ and (EU) 2017/746 ⁽⁴⁾ of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC ⁽⁵⁾ and 93/42/EEC ⁽⁶⁾ and Directive 98/79/EC of the European Parliament and of the Council ⁽⁷⁾, such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and introduce provisions ensuring transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.
- (2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council ⁽⁸⁾, while 26 May 2024 was maintained as the end date of the transitional period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC can lawfully be placed on the market or put into service.

⁽¹⁾ Opinion of 24 January 2023 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 16 February 2023 (not yet published in the Official Journal) and decision of the Council of 7 March 2023.

⁽³⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽⁴⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

⁽⁵⁾ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

⁽⁶⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

⁽⁷⁾ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

⁽⁸⁾ Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).

- (3) Also due to the impact of the COVID-19 pandemic, the transitional period provided for in Regulation (EU) 2017/746 was already extended by Regulation (EU) 2022/112 of the European Parliament and of the Council ⁽⁹⁾.
- (4) Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024. It appears that a large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745, in particular when the complexity of those new requirements is taken into account. Therefore, it is very likely that many devices that can lawfully be placed on the market in accordance with the transitional provisions provided for in Regulation (EU) 2017/745 will not be certified in accordance with that Regulation before the end of the transitional period, which leads to the risk of shortages of medical devices in the Union.
- (5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and to extend the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. The extension should be of sufficient duration to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.
- (6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.
- (7) To ensure a progressive transition to Regulation (EU) 2017/745, the appropriate surveillance regarding devices benefiting from the transitional period should eventually be transferred from the notified body that issued the certificate in accordance with Directive 90/385/EEC or Directive 93/42/EEC to a notified body designated under Regulation (EU) 2017/745. For reasons of legal certainty, the notified body designated under Regulation (EU) 2017/745 should not be responsible for conformity assessment and surveillance activities carried out by the notified body that issued the certificate.
- (8) As regards the period needed to allow manufacturers and notified bodies to carry out the conformity assessment in accordance with Regulation (EU) 2017/745 of medical devices that are covered by a certificate or a declaration of conformity that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, a balance should be struck between the limited available capacity of notified bodies and ensuring a high level of patient safety and public health protection. Therefore, the length of the transitional period should depend on the risk class of the medical devices concerned, so that the period is shorter for devices belonging to a higher risk class and longer for devices belonging to a lower risk class.
- (9) Contrary to Directives 90/385/EEC and 93/42/EEC, Regulation (EU) 2017/745 requires the involvement of a notified body in the conformity assessment of class III custom-made implantable devices. Due to insufficient notified body capacity and the fact that manufacturers of custom-made devices are often small or medium-sized enterprises which lack access to a notified body under Directives 90/385/EEC and 93/42/EEC, a transitional period should be provided for, during which class III custom-made implantable devices can lawfully be placed on the market or put into service without a certificate issued by a notified body.

⁽⁹⁾ Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 3).

- (10) Article 120(4) of Regulation (EU) 2017/745 and Article 110(4) of Regulation (EU) 2017/746 prohibit the further making available on the market or putting into service of devices which are placed on the market by the end of the applicable transitional period and which are still in the supply chain one year after the end of that transitional period. To prevent the unnecessary disposal of safe medical devices and *in vitro* diagnostic medical devices that are still in the supply chain, thus adding to the imminent risk of shortages of such devices, such further making available on the market or putting into service of such devices should be unlimited in time.
- (11) Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be amended accordingly.
- (12) Since the objectives of this Regulation, namely to address risks of shortages of medical devices and *in vitro* diagnostic medical devices in the Union, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union ("TEU"). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (13) This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of medical devices and the associated risk of a public health crisis. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2024, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*. For the same reasons, it is also considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2017/745

Regulation (EU) 2017/745 is amended as follows:

(1) Article 120 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for the relevant risk class of the devices. Certificates issued by notified bodies in accordance with those Directives from 25 May 2017 that were still valid on 26 May 2021 and that have expired before 20 March 2023 shall be considered to be valid until the dates set out in paragraph 3a of this Article only if one of the following conditions is fulfilled:

(a) before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;

- (b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.’;

- (b) paragraph 3 is replaced by the following:

‘3. By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.

3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

- (a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;
- (b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3b. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

- (a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- (b) there are no significant changes in the design and intended purpose;
- (c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- (d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
- (e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

3d. By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in paragraphs 3a and 3b of this Article in place of the corresponding requirements in Directives 90/385/EEC and 93/42/EEC.

3e. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3a of this Article shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out such surveillance.

No later than 26 September 2024, the notified body that has signed the written agreement referred to in paragraph 3c, point (e), of this Article shall be responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, the surveillance shall be conducted in respect of the device that is being substituted.

The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 42 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 42 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 42 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.

3f. By way of derogation from Article 5, class III custom-made implantable devices may be placed on the market or put into service until 26 May 2026 without a certificate issued by a notified body in accordance with the conformity assessment procedure referred to in Article 52(8), second subparagraph, provided that no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.;

(c) paragraph 4 is replaced by the following:

‘4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices lawfully placed on the market from 26 May 2021 pursuant to paragraphs 3, 3a, 3b and 3f of this Article, may continue to be made available on the market or put into service.’;

(2) Article 122 is amended as follows:

(a) in the first paragraph, the introductory wording is replaced by the following:

‘Without prejudice to Article 120(3) to (3e) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2021, with the exception of:’;

(b) the second paragraph is replaced by the following:

‘As regards the devices referred to in Article 120(3) to (3e) and (4) of this Regulation, the Directives referred to in the first paragraph of this Article shall continue to apply to the extent necessary for the application of those paragraphs.’;

(3) in Article 123(3), point (d), the 24th indent is replaced by the following:

‘— Article 120(3d).’.

Article 2

Amendments to Regulation (EU) 2017/746

Regulation (EU) 2017/746 is amended as follows:

(1) in Article 110, paragraph 4 is replaced by the following:

‘4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022, and devices lawfully placed on the market from 26 May 2022 pursuant to paragraph 3 of this Article may continue to be made available on the market or put into service.’;

(2) in Article 112, the second paragraph is replaced by the following:

‘As regards the devices referred to in Article 110(3) and (4) of this Regulation, Directive 98/79/EC shall continue to apply to the extent necessary for the application of those paragraphs.’.

*Article 3***Entry into force**

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 15 March 2023.

For the European Parliament

The President

R. METSOLA

For the Council

The President

J. ROSWALL

CERTIFICATE

OF COMPLIANCE



Standard Efficient Registrar (P) Ltd. Certifies that

GOBBLE SURGICAL
Head Marala, P.O. Gohad Pur, Sialkot - 51310, Pakistan

the mentioned products has been compliance with the essential requirements specified in the EU Medical Device Regulation MDR 2017/745, including the technical file of the devices have been assessed and EU declaration of conformity according to the Annex IV



Approved Scope to which this certificate refers:

Class I & Ir Surgical, Dental, Ophthalmic, Orthopedic, Spinal Surgery, VAT, Electrosurgical, Manicure/Pedicure, Veterinary, Diagnostic Instruments and Hollowware Items, Kidney Trays, Instruments Boxes, Instruments Trays / Sterilization Containers

Certificate No:	6489462/COC/PK
Issuance Date:	27 January 2026
Expiry Date:	26 January 2027

Limitations: The Manufacturer must inform Standard Efficient Registrar (SER) of any substantial changes occurred in the product or process in order to examine whether this certificate remains valid or not.

The validity of the certificate is subject to periodic surveillance audits.

The use and validity of this certificate are subject to compliance with SER procedures.



Jane Smith
Certification Director

For more information concerning the validity of the certificate,
Please visit the site www.seregistrar.us or email to info@seregistrar.us



	HONSUN (NANTONG) Co.,LTD			
	DECLARATION OF CONFORMITY		Doc. No	NTLD-HS-02
	Effective Date	2023-03-19	Page	1/1

Manufacturer: HONSUN (NANTONG) Co.,Ltd
 SRN number: CN-MF-000009428
 Address: No.8 Tongxing Road Nantong Economic & Technological Development area, 226009, Jiangsu Province, P. R. China
 EU representative: Shanghai International Holding Corp. GmbH (Europe)
 SRN: DE-AR-000000001
 Address: Eiffestrasse 80, 20537 Hamburg, Germany
 Trademark: HONSUN
 Product name: Stethoscope
 Model: HS-series(HS-30A,HS-30A1,HS-30A2,HS-30B,HS-30B1,HS-30B2,HS-30C,HS-30C1,HS-30C3,HS-30G,HS-30L,HS-30N,HS-30J,HS-30K,HS-30R1,HS-101A,HS-103A,HS-106A,HS -107A,HS-108A)
 UMDNS Code : 13755
 Classification : I (MDR, Annex VIII Rule 1)
 Basic UDI-DI: 697038425STCTH
 Conforming Assessment Route : Annex II+Annex III

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer and this declaration is issued under the sole responsibility of the manufacturer.

Medical Device Regulation: COUNCIL REGULATION (EU)2017/745.
 Standard: EN ISO 14971:2019; ISO 10993-5:2009
 ISO 10993-10:2010; EN ISO 13485:2016
 EN ISO 15223-1:2021

Place, Date of issue: Nantong Economic & Technological Development Area Jiangsu Province, China
 2023.03.19

Signature: 
 Name: William Xiang
 Position: General Manager

Manufacturer: HONSUN (Nantong) Co., Ltd.

SRN number: CN-MF-000009428

Address: No.8, Tongxing Road, Economic&Technical Development Area,
Nantong City, Jiangsu, P.R.China

EU representative: Shanghai International Holding Corp. GmbH (Europe)

SRN number: DE-AR-000000001

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product: Aneroid Sphygmomanometer

Intended use: Aneroid Sphygmomanometer is a non-automated, mechanical blood-pressure monitor that used for the indirect measurement (noninvasive) and display of arterial blood pressure.

ENDN code: C9006

Model Code: See product list

Product picture: See the *NTLD-EC-02 Product introduction*

Classification: Class Im (MDR, Annex VIII Rule 1)

Basic UDI-DI: 697038425ASMR8

Conforming Assessment Route :Annex XI Part A

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

Regulations

General applicable regulation: Medical Device Regulation: (EU)2017/745.

Common standards applied: see *NTLD-EC-05 Standard list*

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339 München,
Germany

Certificate: No. G21 074340 0020 Rev.00

Expiration date of the Certificate: 2029-02-22

Date CE mark was affixed: start of CE marking lot: 2010-07

Identifier of Notified Body: CE0123



HONSUN (NANTONG) CO., LTD

Delcaration of conformity

CE technical file - ANEROID SPHYGMOMANOMETER

No. NTLD-EC-01

Revision: D/3

Effective: 2025.3.6

Page: Page 2 of 2

Signature:

Position: PRRC(Person responsible for regulatory compliance)

Place, Date: NANTONG, 2025.3.6

Product list:

Name	Model
Aneroid Sphygmom anometer	HS-20A/HS-20D/HS-20E/HS-20F/HS-2000/HS-20C/HS-20G/HS-20H/ HS-100/HS-100A
	HS-50A/HS-50C/HS-50D/HS-50B/HS-50E
	HS-201M/HS-201E/HS-201S/HS-201T/HS-201W/HS-201X/HS-201Y/ HS-201Z/HS-201A/HS-201C/HS-201J/HS-201K/HS-201Q/HS-201D/ HS-201DT/HS-201A2/HS-201B2/HS-201Q3/HS-201M/HS-201C2/HS- 201Q2/HS-GF-301/HS-GF-302/HS-GF-303
	HS-60A/HS-60C/HS-60D/HS-60F/HS-60E/HS-70A/HS-70B/HS-70C/ HS-70D/HS-70E/HS-70F

RE: Validity Check - Certificate of Compliance

À partir de info@seregistrar.us <info@seregistrar.us>

Date Ven 15/08/2025 14:37

À Isabelle George <igeorge@devaset.com>

Cc Alexandre Rozaire <arozaire@devaset.com>; 'Mélanie Ettori' <ettorimelanie@gmail.com>

Dear Concerns,

It is to confirm you that the certificate of compliance to (M/s. Gobble Surgical) has been issued by us. We confirm that the certificate Numbers: 6489462/COC/PK is current and valid, subject to annual surveillance audits. You may check certificate validation through our database.

If you have any other query freely contact us

Best Regards,



Vanja Zrnic
Certification Department

SER Certification LLC
Info@seregistrar.us ; www.seregistrar.us

Think Standard, Build Sustainable



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From: Isabelle George [mailto:igeorge@devaset.com]

Sent: Thursday, August 14, 2025 8:16 PM

To: info@seregistrar.us

Cc: Alexandre Rozaire; Mélanie Ettori

Subject: Validity Check - Certificate of Compliance

Importance: High

Dear Mr, Ms,

While checking the Certificate number through your website, no information has been found or published for the certificate I enclose to you.

Could you please send me a confirmation.

Thank you very much,

Have a nice day

Best regards,

Mme Isabelle GEORGE

DEVASET

Tel : + 33 4 13 41 95 70

Mobile : + 33 6 62 18 99 27

infos@devaset.com

www.devaset.com