CERTIFICATION

AGREEMENT FOR CERTIFICATION SERVICES

SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.

CONTRACT NUMBER: **CN/SZX/22250**

EFFECTIVE DATE: **2022/11/7**

BE **THE BENCHMARK**

Welcome to SGS,

We would like to thank you for giving us the opportunity to present our proposal for Medical Device Regulation (EU) 2017/785. The following document sets out our formal proposal of fees for certification needs. We are sure you expect us to be environmentally responsible, and so we have included only basic information about our services and the certification process with this proposal that is part of the Master service agreement signed in between your and SGS nv as Notified Body NB1639 .

Please ensure that you have read and understood the MDR Conformity Assessment Process Explained documents which form part of this contract offer.

General Conditions for Certification Services | SGS
MDR Conformity Assessment Process Explained (sgs.com)
EU Medical Devices Regulations Information Center | SGS
MDR Contract Proposal Supplementary Documents

Further information about certification process can be provided upon request or for general information about our company and services please visit: www.sgs.com

Overview of SGS Medical Devices Services Medical Devices | SGS

Should you require any clarification, please do not hesitate to contact us. We look forward to being of service to your company.

I trust you will find our proposal meets your requirement. Please complete and return this document as soon as possible so that we can accommodate your preferred audit date.

Yours sincerely,

Mr. Effort Zhou
Regional Manager

CERTIFICATE REQUIREMENTS			
COMPANY	SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.		
ADDRESS	Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district,		
CONTACT	Gang Duan	POSITION	Regulatory Manager
PHONE	+86-755-26408879	EMAIL	hongbo@szcomen.com
Authorized Representative	Lotus NL B.V.	SRN :	NL-AR-000000121
Company Site	Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.		
Relevant Subcontractors & Suppliers	Please refer to questionnaire		

STANDARDS(S)	MDR Annex 9 QMS
ACCREDITATION BODY(S)	CE1639 (Accredited Body:SGS Belgium NV)
Relevant Technical codes	Please refer to CWS
TOTAL NO. EMPLOYEES	1236

PROPOSED SCOPE(S)

Annex IX (Section 1, 2, 3)

Electrocardiograph (CM300, CM300A, CM1200, CM1200A, CM1200B, H3, H12, H12A)

Multi-parameter Patient Monitor (C30, C70, C90, Datalys 770, Datalys 790, C30A, C70A, C90A, C50,C500,C80,C800, C86, C860,Datalys 750, Datalys 780, K12Pro, K12APro, K15Pro, K15APro, K18Pro, K18APro, K22Pro, K22APro, NC8, NC8A, NC10, NC10A, NC12, NC12A, STAR8000A, STAR8000B, STAR8000C,OPUS i8 ,OPUS i10, OPUS i10 Expert, OPUS i12, OPUS i15, NC19, NC19A, STAR8000D, STAR8000, STAR8000E, STAR8000F, STAR8000H, OPUS i12 pro, C100A, K1, K1A).

Fetal & Maternal Monitor (STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H)

Specialized Fetal & Maternal Monitor (C10, C11, C20, C26, C29, C22, C22A, C21, C21A)

Specialized Cardiovascular Monitor (C100, C100B)

Central Monitoring System Software (STAR8800)

Vital Signs Monitor (NC3, NC3A, NC3B, OPUS i3, NC5, NC5A)

Specialized Neonatal Monitor (C60, C66, C68, Datalys 760)

Infrared Ear thermometer (IRT10, IRT10A)

Anesthetic Gas Scavenging System (AGSS-L, AGSS-H)

T-piece Infant Resuscitation System (BQ70, BQ70A)

Infant Radiant Warmer (BQ80, BQ80A)

Catheter-positioning guiding system (U8, U8A)

Infant Phototherapy equipment (BL70,BL70A,BL70B)

Sequential Compression System (SCD600)

Ceiling Pendant (D5, D7, D6, D8, D9, D9A, D9B)

Anesthesia Machine (AX-400, AX-400A, AX-500, AX-500A, AX-600, AX-700, AX-700A, AX-800, AX-900, AX-900A)

Syringe Pump (M300, M500)

STANDARDS(S)	MDR Annex 9 TD
ACCREDITATION BODY(S)	CE1639 (Accredited Body:SGS Belgium NV)
Relevant Technical codes	Please refer to CWS
TOTAL NO. EMPLOYEES	1236
PROPOSED SCOPE(S)	
Defibrillator Monitor （S3, S5, S6, S8）	

STANDARDS(S)	ISO 13485:2016
ACCREDITATION BODY(S)	UKAS (Accredited Body:SGS United Kingdom Ltd.)
Relevant Technical codes	Please refer to CWS
TOTAL NO. EMPLOYEES	1236
PROPOSED SCOPE(S)	
Design, Manufacture and Distribution of - Electrocardiograph, - Fetal & Maternal Monitor, - Multi-parameter Patient Monitor, - Specialized Cardiovascular Monitor, - Vital Signs Monitor, - Specialized Neonatal Monitor, - Specialized Fetal & Maternal Monitor, - Central Monitoring System Software - Infrared Ear thermometer - Anaesthetic Gas Scavenging System - LED Surgical Light - Ceiling Pendant - T piece Infant Resuscitation System - Anesthesia Machine, - Infant Radiant Warmer. - Infant Phototherapy equipment - Catheter-positioning guiding system (including Sterile Disposable electrode with extension wire) - Syringe Pump - Temperature Control System for management patient body temperature and vital physiological parameters Monitor - Video Laryngoscope - Sterile Disposable Laryngoscope blade - Sequential Compression System for Prophylaxis of Vein Thrombosis and for alleviation of limb venous edema and pain - Defibrillator Monitor - High flow heated respiratory humidifier - Emergency and Transport Ventilator - Ventilator - Operating table	

STANDARDS(S)	MDR Annex 9 TD
ACCREDITATION BODY(S)	CE1639 (Accredited Body:SGS Belgium NV)
Relevant Technical codes	Please refer to CWS
TOTAL NO. EMPLOYEES	1236
PROPOSED SCOPE(S)	
Temperature Control System	

STANDARDS(S)	MDR Annex 11 PRODQMS
ACCREDITATION BODY(S)	CE1639 (Accredited Body:SGS Belgium NV)
Relevant Technical codes	Please refer to CWS
TOTAL NO. EMPLOYEES	1236
PROPOSED SCOPE(S)	
Sterility aspects only Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. Disposable Laryngoscope Blade (CVL-1-1, CVL-2-1, CVL-3-1, CVL-5-1) Sterile disposable electrode with extension wire (98ME01AC019)	

STANDARDS(S)	93/42/EEC
ACCREDITATION BODY(S)	CE1639 (Accredited Body:SGS Belgium NV)
Relevant Technical codes	Please refer to CWS
TOTAL NO. EMPLOYEES	1236

PROPOSED SCOPE(S)

- Electrocardiograph (Model: CM300, CM300A, CM1200, CM1200A, CM1200B, H3, H12, H12A)
- Multi-parameter Patient Monitor for vital physiological parameters (Model: C30, C50, C70, C80, C86, C90, C500, C800, C860, NC19, NC19A, Datalys 750, Datalys 770, Datalys 780, Datalys 790, STAR8000, STAR8000A,STAR8000B, STAR8000C, STAR8000D, STAR8000E, STAR8000H, NC8, NC10, NC12, C100A, NC8A, NC10A, NC12A, C90A, C30A, C70A, STAR8000F, OPUS i8, OPUS i10, OPUS i10 Expert, OPUS i12, OPUS i12 pro, OPUS i15, K12 pro, K12A pro, K15 pro, K15A pro, K18 pro, K18A pro, K22 pro, K22A pro, K1, K1A)
- Fetal & Maternal Monitor for vital physiological parameters (Model: STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H)
- Specialized Fetal & Maternal Monitor for monitoring or measurement of fetal heart rate, fetal movement, uterine pressure, ECG, CO2, NIBP, SpO2, body temperature, respiration, pulse/pulse frequency (Model: C20, C26, C29, C22, C22A, C21, C21A, C10, C11)
- Specialized Cardiovascular Monitor for processing, displaying and recording the patient's electrocardiogram and for vital physiological parameters (Model: C100, C100B)
- Central Monitoring System Software for intensively monitoring vital physiological parameters from patient monitoring system (Model: STAR8800)
- Vital Signs Monitor for routine check of NIBP, SpO2, Temperature and Pulse rate (Model: NC3, NC3A, NC3B, OPUS i3, NC5A)
- Vital Signs Monitor for routine check of NIBP, SpO2, ECG, Temperature and Pulse rate (Model: NC5)
- Specialized Neonatal Monitor for vital physiological parameters (Model: C60, C66, C68, Datalys 760)
- Infrared Ear thermometer (Model: IRT10, IRT10A)
- Anaesthetic Gas Scavenging System (Model: AGSS-L, AGSS-H)
- Ceiling Pendant (Model: D5, D7, D6, D8, D9, D9A, D9B)
- T piece Infant Resuscitation System (model: BQ70, BQ70A)
- Anaesthesia Machine (Model: AX-400A, AX-500A, AX-700A, AX-800, AX-900, AX-900A, AX-400, AX-500, AX-600, AX-700)
- Infant Radiant Warmer (Model: BQ80, BQ80A)
- Catheter-positioning guiding system (Model: U8, U8A）
- Syringe Pump (Model: M300, M500)
- Infant Phototherapy equipment (Model: BL70, BL70A, BL70B)
- Temperature Control System for management patient body temperature and vital physiological parameters Monitor (Model: P3, P6)
- Sequential Compression System for prevention of deep vein thrombosis and pulmonary embolism (Model: SCD600)
- Defibrillator Monitor (Model: S8, S6, S5, S3)

Sterility aspect only Restricted to the Aspect of manufacture concerned with securing and maintaining sterile conditions:
- Sterile disposable laryngoscope blade (Model: CVL-2-1, CVL-3-1)
- Sterile disposable electrode with extension wire used for Catheter-positioning guiding system (Model: 98ME01AC019)

FREQUENCY OF VISITS	12 Month
TOTAL NO. OF SITES	6
PROPOSED AUDIT SITES	Floor 3 and floor 8 of Ruihui Building, Intersection of Fuli South Road and Fangyuan Road, Matian Street, Guangming District, Shenzhen, Guangdong, P.R. China

PROPOSED AUDIT SITES	Floor 7 of EBOHR Building A & Floor 5 of EBOHR Building B, Timepieces Base, Guangming District, Shenzhen, Guangdong Province, P. R. China
PROPOSED AUDIT SITES	Floor 2 of Building 108B, 7th Industrial Zone, Mashantou, Matian Street, Guangming District, Shenzhen, Guangdong, P.R. China
PROPOSED AUDIT SITES	Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, 518106, Guangdong, P.R. China
PROPOSED AUDIT SITES	Unit 501, West Side, 5th Floor, Machinery Plant (No. 2 Chuangxiangdi), Yanxiang Science and Technology Industrial Park, No. 11, Gaoxin West Road, Guangming Street, Guangming District, Shenzhen City, Guangdong Province, China

We remind you that the requirements concerning the technical documentation files of medical devices are increased (see below) and we propose you to take necessary actions, if any.
Our proposal is based on the available information.
The number of man days in this proposal is according to the rules of IAF (International Accreditation Forum) and BELAC/FAGG.

Additional conditions for the conformity assessment of a medical device (according to appendix II, V or VI).

All critical subcontractors should have a valid and relevant ISO13485:2016 certificate (or accepted equivalent certificate).
Certification of outsourced activities has not be assessed at the Proposal stage, therefore if control of critical subcontractors is found to be inadequate an audit may be required at additional cost.
This proposal is valid if the technical file(s) is/are in English and can be sent to the technical file reviewer or auditor in electronic form.
The clinical team will use "MEDDEV_2_7_1 (3) clinical evaluation" as a reference and will complete (as a minimum) the checklist in Annex F of this MEDDEV document.
A detailed Post- Market Surveillance and Clinical Follow-Up as required by MDD93/42/EEC Annex X and by the applicable MEDDEV documents will be studied.
The risk analysis needs to be up-to-date: conformity to EN ISO14971:2019 (or fully equivalent alternative) will be checked (e.g. verification of the risk management plan etc.)
This proposal is made for the conformity assessment of the products stated above in accordance with the Council Directive 93/42/EEC concerning Medical Devices as amended by the Directive 2007/47/EC (Medical Device Directive MDD) for the CE certification of the medical device as specified in this proposal. For Belgium, this Medical Device Directive is transposed in the Medical Directive Royal Decree of March 18, 1999 and amended by the Royal Decree of 17 March 2009.

SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. classified this medical device, in accordance with article 9 of the MDD, as of class <fill in the classification of the Medical Device> and has chosen annex <fill in the annex chosen by the client> of the MDD as the conformity assessment route.
This proposal, when signed by SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD., is

- a written declaration that the name and address of SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. and any additional manufacturing site covered by the quality system are specified in this proposal,
- a written declaration of SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. that the Notified Body 1639 (SGS Belgium) is provided with all the relevant information on the product or product category covered by the
- a written declaration that the documentation on the quality system is available for the Notified Body 1639 (SGS Belgium).

After signing of this offer by SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD., same implies at the same time

- a written declaration that the name and address of SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. and any additional manufacturing site covered by the quality system are specified in this proposal,
  1. that has or may have a possible pharmacological, immunological, metabolic or antimicrobial activity (according to European Directive 93/42/EEC + amendments)
  2. that contains animal tissue or derivatives thereof (according to European Directive 2003/32/EC)
  3. that contains phthalate (according to European Directive 67/548/EEC)
  4. that contains human cells, blood, tissue or derivatives thereof (according to European Directive 2000/70/EC)
  5. that contains nanomaterials (e.g. nano-hydroxyapatite, nano-silver) or may generate nanosized particles (e.g. due to wear-and-tear)
- a written declaration by SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. that
  1. the technical documentation which is available for assessment by the Notified Body, either contains or identifies documents defining all the quality management system requirements and that thus no process related to the certified medical devices (design, manufacture, purchase, inspections, ...) is kept hidden or secret for the Notified Body. This both for SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. as for
  2. the technical documentation which is available for assessment by the Notified Body, either contains or identifies documents defining the full product specifications (composition and components list, both quantitatively and qualitatively) and that thus no product specifications of the certified medical devices are kept hidden or secret for the Notified Body. This concerns both purchased as self-fabricated parts / components.
- [only if annex V or VI of the MDD as the conformity assessment route are chosen] a written declaration that, where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates is available for the Notified Body 1639 (SGS Belgium),
- a written declaration of SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. that no application has been lodged with any other notified body for the same product-related quality system,

- an undertaking by SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. to fulfill the obligations imposed by the quality system approved,
- an undertaking by SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. to keep the approved quality system
- an undertaking by SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X of the MDD and to implement appropriate means to apply any necessary corrective action. This undertaking includes an obligation for SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. to notify the competent authorities and Notified Body 1639 (SGS Belgium) of the following incidents immediately on
- any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
  - i) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph i) to systematic recall of devices of the same type by the SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD..

As a result of article 14a of the MDD, next data cannot be treated by the Notified Body as confidential data:

a) data relating to registration of manufacturers and authorized representatives and devices in accordance with Article 14 of the MDD excluding data related to custom-made devices;
b) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures, as laid down in Annexes II to VII of the MDD;
c) data obtained in accordance with the vigilance procedure as defined in Article 10 of the MDD;
d) data relating to clinical investigations referred to in Article 15 of the MDD

SGS Belgium shall ensure that confidentiality of the information which comes into its possession during the performance of the conformity assessment activities is observed by its personnel, committees, subsidiaries, subcontractors or any associated body, except when disclosure is required by law.

ADDITIONAL COSTS

Unannounced audits:
Additional information for MDD clients on costs for Unannounced Audits : "The EU Commission Recommendation on the audits and assessments performed by notified bodies in the field of medical devices 2013/473/EU was published in September 2013 and must be implemented by all notified bodies. This requires that SGS undertakes unannounced audits, usually at the location of physical manufacture of devices, and this would be at one or more of the sites listed in the latest audit report relevant for your certification. If some of the sites are not managed by you, it is your legal obligation to ensure you have contracts in place with these suppliers and/or subcontractors, which give SGS the right to make unannounced audits at their sites. Frequency of Unannounced Audits will be a minimum of once every 3 years. There is a requirement that the frequency is increased for high risk devices and for devices with a high incidence of non conformities."

The costs and fees shown for unannounced audits and other assessment processes are only an indication of the likely minimum cost for each assessment step. Once a contract is agreed with and SGS has conducted its initial on site audit, a confirmation of potential unannounced audit sites and estimated costs will be issued.

Product Additional Information

When the product additional information conflicts with the above Generic, the special requirements of the product shall prevail.

SGS operates a system of continuous certification. As part of this program it is not necessary to conduct a complete assessment. Rather, we conduct a recertification review which is more in depth than a surveillance visit and will ensure that we review all aspects of your system. The recertification activities must be carried out and nonconformities closed prior to the expiry of your current certificate.

This proposal has been prepared in accordance with the requirements of IAF (International Accreditation Forum) MD9 details of audit time determination and justification is available on request.

Change notifications

Every change notification will be charged on the following base: Yuan (Chinese) Renminbi

Additional certificates

The prices always include one certificate in English. The price of an additional certificate in accordance with the original shall add cost in local currency. The price of a first bi-lingual certificate (English and requested language) shall be determined in accordance with the specifications.

Amendments

If an amendment of a previously issued certificate is needed, an additional administrative, registration and certification fee of add cost in local currency will be charged. All critical relevant subcontractors and crucial suppliers should have a valid and relevant EN ISO13485 certificate (or accepted equivalent certificate). Certification of outsourced activities has not been assessed at the Proposal stage, therefore if control of critical relevant subcontractors/crucial suppliers is found to be inadequate an audit may be required at additional cost.

DECLARATION

On behalf of SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.

By signing this document, we apply for assessment by SGS-CSTC Standards Technical Services Co. Ltd. on behalf of SGS Belgium NV who are the Accredited Legal Entity for CE1639 Accredited Certification and on behalf of SGS United Kingdom Ltd. who are the Accredited Legal Entity for UKAS Accredited Certification and agree to abide by the SGS CBE Codes of Practice, the Rules governing the use of the SGS certification mark and SGS General Conditions for certification services accessible at: https://www.sgsgroup.com.cn/zh-cn/terms-and-conditions as well as the conditions contained in this proposal.

If any of the details provided in this document change prior to your assessment, you must inform us in writing, as this may have an impact on this proposal and the assessment process.

We confirm that our attention was drawn to the clauses on limitations of liability and indemnification and jurisdiction. We also confirm that the above information provided to SGS for application process is accurate and agree to pay all costs as stated in this application.

NAME	Gong Dunli	POSITION	Management Representative
SIGNATURE	2022.11.10	DATE	2022.11.10
COMPANY STAMP (IF ANY)			