1. Introduction

These Scheme Rules have been written in accordance with the requirements of the applicable IAF Member National Accreditation Bodies under Accredited Certification Schemes. **GCL International LTD**, hereafter known as "**GCL INTL**" also comply with all conditions. These Scheme Regulations form a part of the contract with each client as stated on the quotation.

2. Scope

GCL INTL provides independent third party assessment and registration services for companies who have implemented management systems against the following standards/codes of practice:

- Quality Management Systems (ISO 9001)
- Environmental Management Systems (ISO 14001)
- Medical Devices Quality Management Systems (ISO 13485)
- Occupational H & S Management Systems (OHSAS 18001 / ISO 45001)
- Food Safety Management Systems (ISO 22000)
- Energy Management Systems (ISO 50001)
- Information Security Management Systems (ISO 27001)
- Codex Alimentarius (HACCP)
- Good Manufacturing Practice (GMP)
- Anti-bribery management systems (ISO 37001)
- Quality Management – Customer satisfaction – Guidelines for monitoring & measuring (ISO 10004)
- Quality management - Guidelines for training (ISO 10015)
- Quality Management – Customer satisfaction – Guidelines for complaints handling (ISO 10002)
- Health safety and environmental management system (HSE-MS)

3. Confidentiality

a) **GCL INTL** agrees not to disclose any information relating to the client's business or affairs except information, which is in their possession before the date of acceptance of the **GCL INTL** contract

b) Where information is required to be disclosed to a third party either by law or as required under maintenance of certification by an Accreditation Body, the client shall be informed of the information as required by law.

c) For the purposes of registration verification, information contained on all issued certificates can be verified using the registration number shown on the certificate from the certification check on the **GCL INTL** web site which is located from the following URL www.gcl-intl.com

For ISMS, Before the certification audit, **GCL INTL** ask the client to report if any ISMS related information (such as ISMS records or information about design and effectiveness of controls) cannot be made available for review by the audit team because it contains confidential or sensitive information. Based on these information, **GCL INTL** determine whether the ISMS can be adequately audited in the absence of such information. If the **GCL INTL** concludes that it is not possible to adequately audit the ISMS without reviewing the identified confidential or sensitive information, then the same shall be advised to the client that the certification audit cannot take place until appropriate access arrangements are granted.

4. General Conditions

4.1 GCL INTL basic conditions for gaining and maintaining registration with are that all applicants agree to and comply with the following rules:

a) All information deemed necessary by **GCL INTL** in order to complete the registration process shall be made available to the applicant company.

b) If **GCL INTL** are not satisfied that all requirements for registration have been met it shall inform the applicant in writing stating which requirements.

c) When the applicant can demonstrate that effective corrective action has been taken within a specified time limit, then GCL INTL will arrange only to repeat necessary parts that cannot be verified by the submission of documented evidence.

d) If the applicant fails to take effective corrective action within the time limit then **GCL INTL** may repeat the audit in full at additional cost.

e) Identification of conformity shall only apply to site(s) audited and within the scope of registration as shown on the **GCL INTL** certificate of registration.

f) All fees must be paid as shown on the individual quotation. No certificate shall be issued for initial assessment or re-assessment until fees have been paid in full. Registration may be suspended if annual fees are not paid in full within the time frame set out within the individual quotation.

g) In order for the registered company to demonstrate effective management reviews and internal audits these activities shall be carried out at a frequency of no less than once per year.

h) Failure to return all certificates of registration shall result in legal action being taken against the company for unauthorised use or registration and accreditation marks and on misleading and inaccurate claims of registration.

i) The applicant must allow **GCL INTL** to conduct on-going surveillance visits at the times stated within the individual quotation.

j) **GCL INTL** offices which hold national accreditation directly with a national accreditation body, or hold "critical location" status are responsible for, and retain authority for, decisions relating to accredited certification, including the granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification.

k) The management representative must be made known to **GCL INTL**, and should there be a change of management representative then **GCL INTL** shall be informed in writing

l) For ISMS, The Client's shall make all necessary arrangements for the access to internal audit reports and reports of independent reviews of information security. At- least the following information shall be provided by the client during stage 1 of the certification audit:
   a) general information concerning the ISMS and the activities it covers;
   b) a copy of the required ISMS documentation specified in ISO/IEC 27001 and, where required, associated documentation

m) ISO 13485 requires the organization to comply with the statutory and regulatory requirements applicable to the safety and performance of the medical devices. The maintenance and evaluation of legal compliance is the responsibility of the client organization. **GCI INTL** is responsible for verifying that the client organization has evaluated statutory and regulatory compliance and can show that appropriate action has been taken in cases of non-compliance with relevant legislation and regulations, including the notification to the Regulatory Authority of any incidences that require reporting

n) For ISO 13485, **GCI INTL** may release ISO 13485 related audit report information to interested parties/ regulators that recognize ISO 13485 certification.

5. Application for Assessment

On receipt of a completed Application for Quotation Form **GCL INTL** will conduct a pre-contract review of the system and a quotation shall be prepared and sent to the prospective client, together with these Scheme Rules.

6. Contract Acceptance

Prior to any arrangement being made for an assessment, the quotation is required to be signed by the Client. Signature on the quotation/contract indicates formal acceptance of these rules as stated within the quotation/contract.

7. Initial Assessment

The initial assessment is conducted in two stages, which are specified below:

a) Stage 1 Visit

Is an audit carried out on site at the client's premises. The objectives of this visit are as follows:

i. to audit management system documentation.

ii. to evaluate the location, site specific conditions and to undertake discussions with personnel.

iii. to collect information related to the scope of application and related statutory and regulatory requirements.

iv. to evaluate if management reviews and internal audits are being planned and performed to determine preparedness for the stage 2 audit.

v. to produce a process based audit plan for the stage 2 visit.

Only when it has been determined that the applicant company is prepared for the stage 2, shall a date be agreed for that visit.

b) Stage 2 Visit

Is an audit carried out on site at the client's premises to evaluate the effectiveness of implementation and covers:

i. information and objective evidence regarding the standard.

ii. performance monitoring, measuring, reporting and reviewing key performance objectives and targets.

iii. the management system performance regarding legal compliance.

iv. operational control of the management system processes.

v. internal audits and management reviews.

vi. management responsibility for policies.

vii. links between policy and legal requirements, competence of personnel, operations, procedures and data.

All audits are based upon sampling and therefore not a guarantee of 100% conformity with the standard. Therefore it is critical that effective internal audits are conducted on an on-going basis by the applicant company.

For all high risk areas where there can be a direct risk to human health, safety and well-being the audit team may be required to take photographs to provide evidence of effective implementation of safety measures. All such photographs shall remain confidential.

8. Certification

a) On completion of the on-site assessment the lead auditor reports back to **GCL INTL**. The File Reviewer of **GCL INTL** shall review the report and supporting information, including the recommendations made by the lead auditor and decide whether to grant certification.

b) For any non-conformities raised, the client shall conduct root cause analysis and send details of corrections, corrective action and preventive action to **GCL INTL** within 30 days from the last day of the assessment visit. This information shall be reviewed by a qualified lead auditor and the client shall be informed of the result via email and/or having access via the **GCL INTL** client portal.

c) Upon acceptance of the proposed actions the File Reviewer shall review the full report and make a decision on certification.

d) Certification shall only remain valid on the basis of continued conformity by the registered client. For any non-conformity or other situation that may lead to suspension the lead auditor shall report to GCL INTL and the suspension process shall take effect as defined within these rules.

9. Surveillance

a) After the issue of the certificate of registration, surveillance visits shall be carried out at the client's premises. If substantial areas of concern are identified then extra visits may be scheduled at the discretion of the File Reviewer. The client agrees to meet the extra costs relating to such additional surveillance. Should surveillance not take place when required then registration shall be removed and published in the public domain. Surveillance audits shall be conducted at least once a year. The date of the first surveillance audit following initial certification shall not be more than 12 months from the last day of the Stage 2 audit.

b) For any non-conformities raised, the client shall conduct root cause analysis and send details of corrections, corrective action and preventive action to **GCL INTL** within 30 days from the end of the surveillance visit.

c) The certificate holder shall allow **GCL INTL** the right of access for the purposes of maintenance of certification.

10. Re-Certification

a) A re-certification audit shall be planned and conducted at the client`s premises to evaluate the continued fulfilment of all of the requirements of the relevant management system standard.

b) For any non-conformities raised, the client shall conduct root cause analysis and send details of corrections, corrective action and preventive action to **GCL INTL** within 30 days from the end of the re-certification visit. In all cases where non-conformities have been raised timescales for corrections and corrective actions to be implemented shall be prior to the expiry of the certificate.

c) Prior to a review being undertaken by the File Reviewer the details sent by the client shall be reviewed by a qualified lead auditor. The client shall be informed of the results of this review via email and/or the **GCL INTL** client portal.

d) The File Reviewer shall then review the full file and decide whether to accept the lead auditor's recommendations. Should the File Reviewer accept the actions supplied and the report, then certification shall be granted.

e) All re-certification visits shall be carried out prior to the expiry date of the current certificate. Any non-conformity raised at the re-certification visit shall be closed-out prior to a new certificate being issued.

f) The decision on whether to grant re-certification shall be based upon the audit results over the period of certification plus complaints from users.

11. Use & Mis-Use of Certificates, Logos & Certification

Once a Certificate has been issued, then the client has the right to publish the fact and to apply the logo on their stationery and promotional material.
The marks can only be used as specified with clause 23 of these Scheme Rules. Other conditions are as follows related to certification:

a) That no misleading statements are implied or made regarding certification.

b) That no certification document is used in a manner that would mislead clients or registered companies or the public in general.

c) Upon suspension, withdrawal or cancellation cease with immediate effect to use of the marks on advertising, such as brochures, letterheads, business cards, web sites, etc, and return the certificate to **GCL INTL**.

d) Should a scope of registration be reduced, amend all advertising materials where details of the scope have been published. For all reductions or increases in scope the original certificate to be returned to **GCL INTL**, prior to any updated certificate being issued.

e) That nothing is implied or an impression is given that certification activities are outside of the scope of certification.

f) Not to use certification in any way as to bring into disrepute the credibility of **GCL INTL** or of Accredited Certification that could affect public trust and confidence.

12. Suspension, Scope Extension, Scope Reduction & Withdrawal

Following a successful assessment and subsequent Certification of a Client's System to the relevant Management System Standard. Some of the following activities may apply as follows:

a) Suspension

i. as a result of continued mis-use of a certificate or logo.
ii. failure to implement corrective action within the specified time scale as a result of concern identified at Assessment, Surveillance or Re-Assessment visits.

iii. any other breach of the **GCL INTL** quotation and/or Rules of Registration.

iv. when a major non-conformity is raised during any visit, after the original Assessment.

v. under suspension it is not permitted to use any logos on any advertising materials until the suspension has been lifted.

vi. the File Reviewer of **GCL INTL** shall write to the registered client outlining the suspension conditions and how the suspension can be lifted.

b) Scope Extension

For all extensions to scope the registered client has to make a request to **GCL INTL** in writing. The request shall be reviewed and a new quotation sent out. Upon acceptance **GCL INTL** shall decide the action required to verify and validate the scope extension.

c) Scope Reduction

Reductions to scope could be a result of an initial assessment, which shall be confirmed within the assessment report. Should a reduction in scope be recommended by a **GCL INTL** Lead Auditor at a surveillance or re-assessment visit this has to be noted in the report and the File Reviewer informed.

d) Withdrawal

Such withdrawals could be as a result of:

i. failure to respond to requests/time scales made by **GCL INTL** after suspension of Certification.

ii. failure of a client to settle an account with **GCL INTL** within 1 month of formal notification of a failure to settle an account.

iii. voluntary withdrawal, in such a case **GCL INTL** require this in writing.

iv. the certificate of registration shall be returned to **GCL INTL** when **GCL INTL** has informed the client that withdrawal has been complete. No copies of certificates shall be used or logos displayed after withdrawal has taken place.

13. Appeals

If the client is not in agreement with the Lead Auditor's recommendation after an Assessment, Surveillance or Re-Assessment then they are at liberty to lodge an appeal with the Standard Manager and CEO of **GCL INTL**. The Client shall support his reasons by objective evidence.

All appeals will be heard by a Sub-Committee of the **GCL INTL** Impartiality Committee. The Sub-Committee may hear evidence from the client's representative and the Lead Auditor. The decision of the Sub-Committee is final and binding on both the Client and **GCL INTL**. No counter claim will be allowed by either party. No costs, for whatever reason, will be allowed for either party as a result of an appeal.

In case of any appeal, information related to handling of appeals can be found at **(https://www.gcl.uk/about-us/appeals/)**

14. Complaints

a) General Requirements

All clients are required to maintain a log of all customer complaints raised against them. This log must be available for review during all Assessment and Surveillance Visits. This log shall also be available to **GCL INTL** Staff upon request.

b) Complaints from Clients Regarding Auditors

If a client has a complaint about the conduct of any **GCL INTL** Auditor then this should be sent in writing to the **GCL INTL** Standard Manager or CEO. If the complaint involves the Standard Manager or File Reviewer then the complaint is to be addressed to the Chairman of the Impartiality Committee of **GCL INTL**.

c) Complaints from Users of Clients Products & Services

For complaints received from users of clients products and/or services shall be lodged and then acknowledged to the complainant. Follow-up shall then be taken with the registered company in question.

d) Serious incidents and breach of legal requirements

The client must inform, without delay, **GCL INTL** of any occurence of a serious incident or breach of regulation necessitiating the involvement of the competent regulatory authority.

In the event that **GCL INTL** becomes aware of a nonconformance relating to the client being in breach of a relevent regulatory requirement, it shall notify the client without delay.

In such circumstances, **GCL INTL** may deem it necessary to conduct a special audit focussing on the incident or breach and to determine that the management system has not been compromised.

In case of any Complaint, information related to handling of complaints can be found at **(https://www.gcl.uk/about-us/complaints/)**

15. Witnessed Visits

As part of the on-going surveillance of **GCL INTL**, the client agrees to allow representatives from national accreditation bodies the right to witness **GCL INTL** conducting their audit duties. The fact that an Accreditation Body representative attends an audit will not affect the audit. Also, from time to time **GCL INTL** may have to have trainee auditors or internal audits on an assessment team.

16. Short Notice Audits

For clients that have been suspended or where **GCL INTL** has received complaints then a short notice audit maybe required for follow-up and verification/validation of the implementation of corrective and preventive measures. In such cases the client agrees to co-operate with GCL INTL audit team members and allow the required access.

For ISO 13485 short notice audits may take place for the following reasons:

a) external factors apply such as:

available post-market surveillance data known to **GCL INTL** on the subject devices indicate a possible significant deficiency in the quality management system.

significant safety related information becoming known to **GCL INTL**.

significant changes occur which have been submitted as required by the regulations or become known to **GCL INTL** and which could affect the decision on the client's state of compliance with the regulatory requirements.

The following are examples of such changes which could be significant and relevant to **GCL INTL** when considering that a special audit is required, although none of these changes should
automatically trigger a special audit:

i) QMS – impact and changes:

- new ownership
- extension to manufacturing and/or design control
- new facility, site change
- modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralising the design and/or development functions for several manufacturing sites).
- new processes, process changes
- significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on site facility or a change in the method of sterilization).
- QM management, personnel.
- modifications to the defined authority of the management representative that impact quality management system effectiveness or regulatory compliance.
- the capability and authority to assure that only safe and effective medical devices are released.

ii) Product related changes:

- new products, categories
- addition of a new device category to the manufacturing scope within the quality management system (e.g. addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment).

Iii) QMS & Product related changes:

- Changes in standards, regulations.
- Post market surveillance, vigilance

An unannounced or short-notice audit may also be necessary if GCL INTL has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

17. Terms of Payment

Payment shall be made in accordance with the individual invoice and the quotation/contract document.

18. Indemnification

In respect of any claim, loss, damage or expense however arising, **GCL INTL's** liability to the client shall in no circumstances exceed the amount of **GCL INTL's** fees paid by the client. Under no circumstance shall **GCL INTL** be liable for any consequential loss.

19. Impartiality

GCL Auditor shall receive Code of Ethics Acknowledgement letter which shall be signed by Lead Auditor and client at the opening and submit to GCL.

GCL INTL or any **GCL INTL** representative shall **NOT**:

a) provide management system consultancy which includes: preparation or production of manuals or procedures, or give specific advice, instructions or solutions towards the development, structure and implementation of a quality management system, environmental management systems and food safety management system.

b) allocate auditor(s) for a client in where provided internal audit, hazard analysis, FSMS or other related management system consultancy on the management system, within two years following the end of the consultancy.

c) certify a quality management system, environmental management systems, food safety management system on which it provides any consultancy. offer certification when relationships that threaten impartiality cannot be eliminated or minimized.

d) certify another certification body for management systems.

e) certify a client when a relationship with a management systems consultancy poses an unacceptable threat to impartiality. Provide an internal audit service to any certified clients.

f) outsource any audits to a management consultancy company involved in management systems as described with the scope of these scheme rules.

g) have within any marketing materials any linkage to management system consultancy.

Besides above, for ISMS, **GCL INTL** shall not provide internal information security reviews of the client's ISMS subject to certification. Furthermore, the **GCL INTL** shall be independent from the body or bodies (including any individuals) which provide the internal ISMS audit. However, following duties may be carried out as without considering as consultancy or potential conflict of interest as below:

a) arranging and participating as a lecturer in training courses, provided that, where these courses relate to information security management, related management systems or auditing, this must be confined to the provision of generic information and advice which is publicly available, i.e. they shall not provide company-specific advice which contravenes the requirements of b) below;

b) making available or publishing on request information describing the **GCL INTL**'s interpretation of the requirements of the certification audit standards;

c) activities prior to audit, solely aimed at determining readiness for certification audit; however, such activities shall not result in the provision of recommendations or advice that would contravene this clause and the certification body shall be able to confirm that such activities do not contravene these requirements and that they are not used to justify a reduction in the eventual certification audit duration;

d) performing second and third-party audits according to standards or regulations other than those being part of the scope of accreditation;

e) adding value during certification audits and surveillance visits, e.g. by identifying opportunities for improvement, as they become evident during the audit, without recommending specific solutions.

For any threats to impartiality that are discovered or reported, then the impartiality committee shall be informed and responses shall be made and communicated.

20. Intellectual Property

The ownership of all issued audit reports remains the property of **GCL INTL**.

21. Organisational & Management System Changes

Should there be any significant changes with the client organisation such as change of address, ownership, scope or management rep. then **GCL INTL** should be informed. Such changes will be reviewed and may require follow-up at the next scheduled surveillan visit.

22. Amendments to Scheme Rules

a) **GCL INTL** reserves the right to amend these Scheme Rules without prior notification. Should the Scheme Rules be updated the latest version shall be put on the web site and all OSPs and clients informed.

b) Client should record the Scheme Rules as an "external document" within their management system for document control.

23. Use of Certification Marks

Only **GCL INTL** certificated clients are authorised to use the certification marks, whilst registration is active, under the following conditions:

a) Holders of certificates issued by **GCL INTL** may use the appropriate logo in accordance with the requirements of these scheme rules on stationery and publicity material or other items relevant to the certificate of registration.

b) That the registration number as shown on the certificate of registration is displayed underneath the outside of the outer box, in the centre.

c) Embossed, relief, or die-stamped versions may be used. The marks may also be produced as water marks as long as clarity is maintained. Electronic reproduction of the marks is permitted provided that the organisation's certificate number is shown for traceability and verification purposes and that the logo only relates to information on the certificate of registration.

d) Reversed image versions of the accreditation marks are allowed. When the marks are printed on an advertising or stationery the marks shall be no less than 20mm in height, however, regardless of the minimum height restriction all logos shall be legible.

e) The marks must always be shown next to the **GCL INTL** logo. The accreditation body logos are not permitted to be displayed on their own without the **GCL INTL** logo both inside the outer box.

f) The logo is not permitted to be used on any product as this could be misleading and give the impression that the product has been approved under a product certification scheme.

g) The national accreditation marks shall not be used on vehicles and flags. If additional certificates are required then the client should request this in writing from **GCL INTL**.

h) Should certification be withdrawn or cancelled then the original certificate(s) must be returned to **GCL INTL**. From the date of cancellation, no web sites can display the logo nor stationery be issued displaying the logo which could mislead clients and potential clients regarding the registration status. In cases of scope reduction or increase the certificate(s) shall be returned to **GCL INTL** for re-issue.

i) At all times certificate(s) remain the property to **GCL International LTD** and can be recalled upon request.

j) The certification marks shall not be used on laboratory test reports, calibration certificates and inspection reports.

k) For FSMS, The FSMS certification mark shall not be used on the product nor the product packaging. Product packaging covers, both primary packaging (which contains the product) and any outer or secondary packaging.

l) For FSMS, GCL INTL will not permit the use of any statement on product packaging of a client that has a certified FSMS. This includes all product packaging, both primary packaging (which contains the product) and any outer or secondary packaging.

24. Privacy Notice

We take the privacy and the protection of personal information seriously. Our Privacy Notice sets our details about we gather, use and share personal information and about individual privacy rights. How we use personal infromation depends upon the context in which it is made available to us. Our Privacy Notice is available from our website: http://gcl-intl.com/privacy-policy-cookies/

25 Arbitration and Disputes
Any dispute, controversy, proceedings or claim between the parties relating to this Agreement shall be settled amicably. If no agreement is reached, the matter will then be referred to an arbitrator nominated by both parties.

26 Applicable Law and Jurisdiction
This Agreement and any dispute, controversy, proceedings or claim between the parties relating to this Agreement shall be governed by, and construed in accordance with, the laws of England and Wales.

27. GCL Policies
GCL follows policies as stated on GCL's website **(https://www.gcl.uk/about-us/policies/)**

28. GCL Anti-bribery and Corruptions
GCL follows policies as stated on GCL's website **(https://www.gcl.uk/about-us/policies/)**