Dutch Institute of Quality Certifications *(hereinafter referred as DIQC B.V.)*

'Medical Management System registration requirements

(Clause 8.1, 8.3, 8.5, 9.7,9.8 of ISO/IEC 17021-1: 2015)

Process Description	Designation	Signature
Prepared by	Programme Manager	
Reviewed & Approved by	Director Operations	

Revision History

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1	00	Not Applicable	15-07-2021	Initial Release	Document Controller
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1. Purpose

To establish Medical Management System registration requirements.

2. Scope

This procedure is applicable to all MMS registrations undertaken by DIQC B.V.

3. Responsibility

3.1 All personnel working for DIQC B.V.
3.2 DIQC B.V. clients

4. Definitions/Abbreviations

4.1 MMS: Medical Management System.
4.2 Organization: The party that is responsible for the product, process or service and is able to ensure that quality management system is established and exercised. This definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.
4.3 Quality Management System (QMS): The organizational structure, responsibilities, procedures, processes and resources for implementing a quality management system.
4.4 Registration: A decision by DIQC B.V. that an organization's quality management system meets the requirements of a specific management system standard and DIQC B.V.'s Medical Quality Management System Registration Program requirements. The registered organization shall comply with DIQC B.V. requirements and for DIQC B.V. invoices associated with the registration and associated assessments.
4.5 Certificate of Registration: DIQC B.V. will issue a certificate recognizing the scope of registration that the quality management system, implemented by the organization upon successful assessment if it is in accordance with a specific management system standard and DIQC B.V.'s Medical Quality Management System Registration Program requirements.
4.6 Initial certification audit: The evaluation performed by DIQC B.V. to determine the compliance of the organization's quality management system with the requirements of the applicable QMS standard(s).
The initial audit will be conducted in two stages: stage 1 and stage 2.
4.7 Surveillance Audit: An audit performed by DIQC B.V. to determine an organization's continued compliance with the applicable standard and program requirements subsequent to facility registration. These assessments are usually announced at least two (2) months prior to the visit date but DIQC B.V. reserves the right to perform unannounced surveillance assessments.
4.8 Recertification Audit: The evaluation performed by DIQC B.V. to confirm compliance of the organization's quality management system with the requirements of the applicable QMS standard(s) at the end of the organization's certification cycle.

4.9 Scope of Registration: The scope of registration shall include the type of activities, products, and services as applicable at each site without any misleading details or ambiguity.

4.10 Management Representative: A member of the organization's management who represents the evaluated facility and is responsible for the facility's quality management system as it pertains to the relevant products and/or services covered in the organization's scope of registration.

4.11 DIQC B.V. Registration Directory – An online directory containing facilities that have been issued certificates of registration to MMS by DIQC B.V.

4.12 DIQC B.V. Registration Reference Mark - The DIQC B.V. mark which is used by registered organizations in accordance with DIQC B.V.'s registration agreements and '' of these requirements to publicize their facility registration.

Refer 'D-MMS-G-0001 Definitions' for any further definitions.

5. References

5.1 ISO 9000:2015: Quality management systems — Fundamentals and vocabulary

5.2 ISO/IEC 17000:2020 Conformity assessment — Vocabulary and general principles

5.3 ISO/IEC 17021-1: 2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

5.4 ISO 19011: 2018 Guidelines for auditing management systems

5.5 ISO 13485:2016 Medical Devices – Quality Management Systems

6. Procedure

Medical Management System Program Requirements

6.1 General

6.1.1 DIQC B.V. is the sole authority by which DIQC B.V. certificates of registration may be issued.

6.1.2 An organization capable of demonstrating a legitimate business that complies with the DIQC B.V. Medical Quality Management System Program Requirements shall be entitled to a certificate of registration that shall remain the property of DIQC B.V. The certificate must be returned to DIQC B.V. upon request.

6.1.3 All organizations assessed under DIQC B.V.'s scope of accreditation shall be given the opportunity to have the mark of one or more of those Accreditation Bodies appear with DIQC B.V.'s reference mark on their certificate.

6.1.4 A separate certificate shall be issued for each registration for which an application is submitted.

6.1.5 Certificates are renewed as indicated on the registration certificate unless cancellation, suspension or withdrawal occurs. If an organization does not intend to renew its registration, it must notify DIQC B.V. in writing of its intentions not less than sixty days prior to its renewal.

6.1.6 An organization's right to use the certificate of registration is not transferable to any other person, organization or corporation without DIQC B.V.'s written authorization.

6.1.7 The organization agrees that it shall comply with all applicable laws, statutes and regulations (e.g. state, region, province, country, etc.).

6.1.8 Should DIQC B.V.'s representative identify items, which are not in compliance with this document or the applicable standard and other criteria, the organization shall either correct such items or cancel registration and immediately refrain from any further reference by DIQC B.V. and this program.

6.1.9 If it is reported that the organization's quality management system for products or services under their scope of registration are not in compliance with this document or applicable standards, the organization shall cooperate with and assist DIQC B.V. in obtaining the facts, including sharing such information as the organization acquires regarding the reported noncompliance, and to take and report to DIQC B.V. on such corrective action necessary to correct any noncompliance found to exist within a specified time period of time.

6.1.10 The surveillance assessment service of DIQC B.V. and any assessments conducted by DIQC B.V., are designed to serve as a verification of continued compliance of the organization's quality management system with this document and the applicable standard and other criteria. The organization is in no way relieved of its responsibility for its quality management system and its scope of registration for those products or services that are subject to the certificate issued by DIQC B.V.

6.1.11 Occasionally the assessment team may include members that are external to (not directly employed by) DIQC B.V. These individuals meet all of DIQC B.V.'s defined competency and qualification requirements and shall comply with DIQC B.V.'s criteria for confidentiality, conflict of interest and ethical standards.

6.1.12 Additionally, DIQC B.V. assessment teams may include DIQC B.V. trainee auditors, observers from accreditation bodies, regulatory authorities and other DIQC B.V. staff. As condition of registration the organization permits such persons to accompany the DIQC B.V. assessment team. DIQC B.V. shall not charge the organization for any time or expenses of such persons being present on an assessment.

6.1.13 Quality system consultants contracted by the organization are limited to the role of an observer.

6.1.1 The Organization shall:

6.1.2.1 At all times comply with their established quality management system requirements

6.1.2.2 Maintain and document a QMS in accordance with the requirements of the applicable standard(s) and make available copies of that documented quality management system (or any parts thereof) should DIQC B.V. require it for registration purposes.

6.1.2.3 Notify DIQC B.V. in writing of significant changes to the management system. Such significant changes requiring notification to DIQC B.V. are:

a) Increases/decreases in staff

b) Change of management representative

c) Change of legal entity name

d) Change of address of sites or off-sites listed on the certificate of registration, Addition/removal of sites or off sites;

e) Expansions or reductions to scope of registration

f) New manufacturing technologies used

g) Significant changes to existing manufacturing processes

h) Significant changes to outsourced processes (whole product design, product manufacturing, software design and development, sterilization)

For items c), d) and e) notification shall be provided at least 10 weeks in advance of the date of effect of the change and for other items at least 4 weeks in advance of the start of that activity. DIQC B.V. shall evaluate if additional assessment activity is necessary for verifying registration conformance in relation to any changes. All such notifications should be emailed to info@diqc.nl

6.1.2.4 Discontinue any use of the DIQC B.V. Registered mark that is unacceptable to DIQC B.V. and any form or statement of reference that in the opinion of DIQC B.V. might be misleading. The organization shall not use its certification in such a manner as to bring into disrepute or cause loss of public trust to DIQC B.V., its affiliates, representatives or the certification system.

6.1.2.5 Ensure that any purchased finished product, processes or services covered under the organization's scope of registration complies with DIQC B.V. Medical Quality Management System Registration Program. If any finished products, processes or services are produced or provided external to the organization's quality management system, the external producer or provider may also be evaluated during the registration process. This may require on-site assessment of the external producer or provider by the audit team. In cases where products described in the scope of registration are not traceable to a quality management system registration that is recognized by DIQC B.V., the organization shall establish and operate a procedure for notifying the prospective customer that the items in question have not been produced or provided within DIQC B.V.'s registration.

6.1.2.6 Give the representatives of DIQC B.V. and any such observers access (including but not limited to accreditation body representatives, regulatory body representatives, other DIQC B.V. observers and DIQC B.V. trainees) during normal working hours, for the purpose of examining systems, processes, methods of test, and records; or, if necessary, to establish that the procedures for the termination of registration described.

6.1.2.7 Extend all necessary privileges and assistance to DIQC B.V.'s representatives and observers, including health and safety conditions, so the representative may

properly perform his function under DIQC B.V.'s surveillance or surveillance assessment service, and shall make all written material utilizing the DIQC B.V. Mark and other means of displaying the mark available for audit by DIQC B.V.'s representative.

6.1.2.8 Nominate a management representative and one or more deputies authorized to act in the main nominee's absence (and replacement nominees as may be necessary) who shall be responsible for all matters in connection with the requirements of the certificate of registration.

6.1.2.9 Not use any report or certificate issued as a result of a DIQC B.V. Management System Assessment to indicate a product is Listed, Classified or Recognized by DIQC B.V., or as the basis of any oral or written representation to suggest that any product or system has been or is Listed, Classified or Recognized by DIQC B.V.

6.1.2.10 Not release any information referencing DIQC B.V. management system assessment acceptance, certification and/or registration of the facility before it is established and confirmed in writing by DIQC B.V.

6.1.2.11 Make available to DIQC B.V., when requested, the records of all complaints and corrective action taken, in accordance with the requirements of the quality management system standards or other normative documents.

6.2 DIQC B.V. shall:

6.2.1 After granting registration to an organization, DIQC B.V. shall issue a registration certificate valid for a period not exceeding three years.

6.2.2 Send an auditor to the organization at its discretion but not less than once per year to a site in which the organization is manufacturing products, operating processes or offering a service for which it is registered for the purpose of verifying that the obligations imposed by the certificate of registration are being carried out. The scope and extent of a reassessment activity shall depend on the surveillance assessment cycle and the performance and activities of the organization; The maturity and continued effectiveness of the quality management system is monitored through the surveillance audit process, including the assessment of management review, complaint handling, internal audit, corrective action, preventive action, effectiveness of meeting quality objectives, continual improvement (where applicable), conformity of regulatory requirements and use of marks (including Accreditation Body marks) and other reference to certification.

6.2.3 Not disclose any information concerning the organization which is of a confidential nature, without the organization's prior authorization in writing other than information which has been made publicly accessible by the organization; Information about a particular product or supplier shall not be disclosed to a third party without the written consent of the supplier except as required by regulatory authorities for matters of regulatory compliance or protection of public health. Where law requires information to be disclosed to a third party, DIQC B.V. shall inform the supplier of the information provided.

6.2.4 Ensure the safe handling of all customer confidential information by using secure facilities and systems for the storage and transmission of documents and records.

6.2.5 Conduct assessments and maintain registration with the highest levels of impartiality. In our assessments DIQC B.V. shall evaluate only the facts presented against the requirements of the assessment criteria with regard to no other interest.

6.2.6 Demonstrate responsibility for ensuring that all relevant and applicable information, scientific principles and ethical standards in determining the acceptability of information in all dealings with clients, accreditation bodies, regulatory authorities and other stakeholders.

6.2.7 Ensure that persons carry out assessments with demonstrated competence for the activities, which they are evaluating.

6.2.8 Provide transparency to organizations registered or seeking registration in regards to our assessments and methodology.

6.2.9 Notify the organization at its discretion of customer complaints relating to the compliance of its product, process or service with the specified requirements.

6.2.10 Direct its representative to exercise due care in complying with any safety regulations which may be applicable generally to the organization's facility personnel effecting the quality management system.

6.3 Compliance with DIQC B.V.'s Management System Program Requirements:

6.3.1 If an organization is temporarily unable to comply with these DIQC B.V. Quality Management System Registration Requirements, DIQC B.V. may require the organization to discontinue use of the Registered mark, any claim to registration under the registration, and notify customers until the conditions of registration are again achieved or pending the result of an appeal as described under section 6.8.

6.3.2 If the organization fails to comply with these DIQC B.V. Quality Management System Registration Program Requirements DIQC B.V. may, subject to:

a) Revoke the certificate of registration

b) Refuse to issue or renew the certificate of registration

c) Change/limit the scope of registration

d) Notify vendors, regulatory authorities, and potential users of improper or unauthorized use of the DIQC B.V. mark or improper or unauthorized reference to DIQC B.V.

6.3.3 DIQC B.V. may, at its discretion, may revoke or refuse to issue or renew a certificate of registration if the organization becomes subject to the bankruptcy laws or makes any arrangements or composition with its creditors, or enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purpose of reconstruction), or has a receiver of its business appointed, or is convicted of an offense tending to discredit the organization's reputation and product faith as a trader. Such

decisions, and the grounds for them shall be communicated to the organization in writing.

6.3.4 In the event that DIQC B.V. makes changes to its Quality Management System Program and/or requirements that affect the registration of registered organizations, DIQC B.V. shall:

a) Specify an effective date for the changes, which shall allow sufficient time for the DIQC B.V. registered organizations to amend their quality system,

b) Formally notify all DIQC B.V. registered organizations affected by the new requirements of the effective date of the change and new action required of them.

c) Where appropriate, afford the opportunity for DIQC B.V. registered organizations to submit comments on the proposed changes,

6.3.5 The registered organization is required to take required action by the effective date. If agreed action is not acceptably taken, withdrawal or suspension of Registration may occur. If special assessment of the system is necessary to evaluate the organization's system due to the revised requirements, the registered organization shall be responsible for the cost of the evaluation.

6.4 DIQC B.V.'s Quality Registration Services:

The following summarizes procedures for DIQC B.V.'s Quality Management System services and registration:

6.4.1 Prior to the On-site Visit:

6.4.2 The organization shall provide DIQC B.V. information about their organization by completing the Request for Quotation and Supplementary Information Forms. Upon receipt of required information, DIQC B.V. shall evaluate the scope of assessment activity and forward application forms to the organization to cover the mutually agreed activity. These application forms must be completed and returned to DIQC B.V. prior to commencement of the scheduled on-site visit. Mutually agreeable dates shall be arranged for the on-site visit. The organization at any time prior to the assessment may request a preliminary evaluation. Conditions that may warrant a preliminary evaluation depend on factors such as the overall size and capacity of a facility and/or the complexity of its operation, quality system, product and/or service.

6.4.3 DIQC B.V. shall confirm with the organization the visit date and provide the organization with the name of and, when requested, make available background information on each member of the audit team. DIQC B.V. shall give sufficient time for the organization to object to the appointment of any particular auditor or technical expert and for the certification body to reconstitute the team in response to any valid objection.

6.4.4 Prior to an onsite assessment the Organization where requested, shall provide appropriate information to allow planning of the audit to occur.

6.4.5 Office Visits

6.4.5.1 Registration Assessment - The registration assessment is scheduled when a facility is determined to be eligible for assessment based on the review of the preliminary information. The registration assessment is conducted in two stages:

a) Stage 1: Allow the DIQC B.V. audit team to evaluate the client's readiness and preparedness for the Stage 2 assessment. The DIQC B.V. audit team shall also obtain information regarding the scope of the subject QMS, site operations, processes, regulatory requirements and associated risks to provide a focus for the planning for the stage 2 audit including allocation of resources. The Stage 1 audit shall be conducted on-site.

b) Stage 2: DIQC B.V. audit team shall evaluate the effective implementation of the subject QMS. The audit shall cover all processes included in the scope of the QMS and shall be conducted at the organizations site(s). The Stage 2 audit must be conducted within six months of the completion of the Stage 1 audit for the conclusions of the Stage 1 audit to remain valid.

6.4.5.2 Surveillance Audit – An onsite audit shall assess key processes of the subject QMS to provide confidence to the DIQC B.V. audit team that the QMS continues to fulfil requirements and objectives. Surveillance audits are conducted once in a year. The lead auditor may recommend that the organization be placed on biannual visits based on a number of factors including type and number of nonconformities and immature quality management system. The first surveillance assessment following certification shall be conducted within nine to twelve months of the last day of the Stage 2 audit. The second annual surveillance audit shall be performed approximately twelve months thereafter.

6.4.5.3 Recertification Audit – Recertification shall include the continued performance of the QMS as a whole over the previous cycle of surveillance audits and examine its continued ability to meet the scope of registration. Recertification audits shall be conducted at the organization's site(s) on a three-year cycle. Audits are planned sufficiently in advance (usually three months prior to certificate expiry date) to enable recertification to occur without interruption of the organization's certification.

6.4.5.4 Special Audit - A Special audit is an additional evaluation to determine continued conformance to findings against requirements that were determined to be significant and required corrective action. An audit team shall be scheduled to perform an assessment in addition to the regular scheduled surveillance audits to verify the implementation of corrective actions. Clauses audited during a special audit shall be determined based on the audit finding, field data, complaints, client requests, major organizational or system changes, etc. Special assessments may not be considered as part of surveillance or recertification assessments or for deferment of such assessments.

6.4.5.5 Scope Expansion Audits - A Scope expansion audit is scheduled when a DIQC B.V. client requests to expand their scope of registration to include other standards,

operations, etc. This can be scheduled in conjunction with a surveillance audit or separate from the surveillance audit schedule. A scope expansion assessment normally results in additional audit time.

6.5 Issuing Registration:

6.5.1 At the completion of the audit, the DIQC B.V. assessment team shall provide the organization's Management Representative with an audit report and any action requests generated during the evaluation that itemize discrepancies uncovered during the audit. Time limits for action request responses are as per guidelines of DIQC B.V. The team shall also provide a recommendation as to the organization's eligibility for facility registration.

6.5.2 The team's recommendation provided at the end of the audit, and the entire audit report is later subject to registration review. Upon concurrence of the audit team and reviewers, the audit result shall be finalized. An appeals process is available to the organization should they disagree with the registration decision.

6.5.3 Upon certification decision, Certification documents such as audit report, non-conformities report, certificate shall be provided to client.

6.5.4 Nonconformities fall under two categories, "major" and "minor". DIQC B.V. uses definitions for major and minor nonconformities adopted from the Global Harmonization Task Force.

A major nonconformance is either:

a) Any unjustifiable exclusion or failure to address an applicable requirement in the medical device regulations such as Part 1 of the Canadian Medical Devices Regulations, Medical Devices Directive or In-Vitro Diagnostic Devices Directive

b) Failure to implement an applicable element of the quality systems standard

c) An excessive number of minor nonconformities against an element of the regulatory requirements for quality systems that indicates trend or absence of control.

d) Failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects;

e) Products which are put onto the market which cause undue risk to patient and/or users when the device is used according to the manufacturer's instructions;

f) The existence of products which clearly do not comply with the manufacturer's specifications and/or the regulatory requirements due to defective elements in the quality system;

g) Repeated nonconformities from previous audits.

Major non-conformances must be responded to within ten days of the last day of the audit where the nonconformity was raised. A major nonconformity may result in a special audit

and additionally must be resolved prior to the issuance or re-issuance of the applicable registration program certificate.

Minor nonconformities defined as a quality system non-conformance that judgment and experience indicates is not likely to:

a) Result in the failure of the quality system, or

b) Reduce its ability to assure controlled processes, or

c) Result in the probable shipment of nonconforming product

Minor nonconformities must be responded to within thirty days of the last day of the audit where the nonconformity was raised.

6.5.5 Registration is granted only if the facility evaluated fully complies with the requirements of the selected standard. The Management Representative must respond to any Action Requests generated during the audit directly to the DIQC B.V. auditor. If they are not satisfactorily resolved, DIQC B.V. shall provide an explanation of the reasons why the response did not resolve the nonconformance.

6.5.6 When Registration is granted a certificate of registration shall be issued to the organization indicating that the organization's quality system complies with a given QMS standard, for a specific group of products and/or services and to recognize the organization's registration under DIQC B.V.'s Quality Management System Registration Program. The name of the organization and a copy of the certificate shall also be published in DIQC B.V.'s online certification directory.

6.6 Maintenance of Registration:

6.6.1 Upon issuance of a DIQC B.V. certificate, a program of surveillance audits shall be established. The establishment and maintenance of DIQC B.V. registration is contingent upon the continued adherence to the terms and conditions of this document by the organization. During these visits, DIQC B.V. shall verify that the organization continues to comply with the requirements of the applicable QMS standard and other program standards, as applicable, and DIQC B.V.'s Medical Quality Management System Registration Program.

6.6.1.1 Surveillance audit visits shall be conducted either annually. Annually the surveillance audit will cover approximately one third to one half of the quality management system. A recertification audit covering all clauses of the applicable standard(s) is conducted every third year as part of an ongoing program designed to maintain the organization's registration. The recertification reassessment duration will be two thirds of the time required for a registration assessment.

6.7 Suspension or Withdrawal of Registration:

6.7.1 Registration may be suspended by DIQC B.V. under any of the following conditions,

a) The organization's quality system no longer complies with the requirements of the applicable Management System standard or DIQC B.V. Quality Management System Registration Program Requirements.

b) The organization's use of any DIQC B.V. symbol, marking, or statement that is determined by DIQC B.V. as unacceptable or misleading.

c) The organization's use of any accreditation body marking, symbol or statement that is determined by DIQC B.V. and/or the Accreditation Body as unacceptable or misleading.

d) The organization is delinquent in payments.

e) The organization violates a signed DIQC B.V. agreement during the process of or after achieving registration.

f) The organization has exhibited a lack of commitment in responding to action requests (including continued failure to provide adequate root cause analysis) or continues not to meet agreed response dates.

g) The organization delays or refuses the scheduling of a surveillance audit.

h) The organization's management system continues to demonstrate in effectivity by repetitive action requests being issued and not resolved.

i) The organization refuses to allow access to DIQC B.V. auditors or Accreditation Body observers, regulatory body observers or other DIQC B.V. observers to any facility.

While the suspension is in effect, the organization's certification is invalid. The client should refrain from any further promotion of its certification and the DIQC B.V. registered firm mark.

6.7.2 The Organization shall resolve any issues surrounding registration suspension within a period of less than three months. If the issues have not been resolved within this timeframe, DIQC B.V. shall withdraw registration. The organization may also request withdrawal of registration at any time subject to any notice period contained in this document or other agreements.

6.7.3 DIQC B.V. may reduce the scope of registration to exclude parts, services or sites that consistently fail to meet the certification requirements for those parts of the scope of the registration. DIQC B.V. shall update its certification directory and certification documents and the organization shall amend its advertising and promotional material to remove references to DIQC B.V. certification or use the DIQC B.V. Registered Mark to only products or services covered by the reduced scope of certification.

6.7.4 DIQC B.V.'s registration shall be discontinued for any quality system or products or services which, for any reason, are no longer eligible for registration.

6.7.5 Upon withdrawal of any rights or authority conferred by signed agreements, DIQC B.V. shall take one or both of the following actions:

a) Discontinue in whole or in part DIQC B.V. registration of the quality system and any products or services covered, and
b) DIQC B.V.'s representative shall have the right to acquire possession of any written material utilizing the DIQC B.V. certificate, mark, and any other form or reference to DIQC B.V., which were used in connection with any system, products or services which are no longer subject to registration.

6.7.6 Upon the termination or withdrawal of the certificate of registration the organization shall immediately discontinue the use of the DIQC B.V. Registered Firm mark and all matter which contains reference to it or its certification status. This does not in any way limit the actions that DIQC B.V. may take in the event of the termination of any rights or authority conferred by signed agreements.

6.7.7 In the event of suspension or withdrawal of registration, DIQC B.V. shall retain the registration information in the online certification directory for up to six months but denoting the status as suspended or withdrawn.

6.8 Complaints

6.8.1 Any person may lodge a complaint regarding DIQC B.V.'s auditors or services. Complaints can be lodged through an email to info@diqc.nl or through 'contact us' tab of website www.diqc.nl

6.8.2 All complaints received orally or in writing shall be investigated. If a complaint is communicated orally, the complainant will be encouraged to submit a documented complaint. If the complainant wants a formal response from DIQC B.V. regarding their complaint, they should document it and submit it to DIQC B.V. Undocumented complaints do not require a formal response from DIQC B.V.

6.8.3 Personnel handling complaints shall conduct a complete and thorough review of the facts and information acquired from all available sources. Decisions regarding all complaints shall be based on the facts and information collected and should take into account the resolutions and actions resulting from prior similar situations.

6.8.4 If a complainant wants to remain anonymous and does not request a response, the complaint shall still be evaluated and considered for possible corrective actions to be taken.

6.8.5 Upon its resolution, the individual(s) assigned to handling the complaint will communicate the actions taken to the complainant within the bounds of confidentiality as described more specifically below. Copies of documentation addressing the complaint and its resolution shall be included within DIQC B.V.'s corrective action system.

6.8.6 All customer complaints shall be acknowledged within 2 working days and where possible, resolved within that time frame.

6.8.7 If the complaint is determined to be not valid, the management involved shall communicate the results of the investigation to the complainant.

6.8.8 If the complaint is determined to be valid, the assigned individual shall take corrective action. The results of the investigation and the corrective action plan are to be

communicated to the complainant including determining (with client and complainant) whether and to what extent the subject of the complaint and resolution shall be made public. If the complainant is not satisfied with the results of the investigation and DIQC B.V.'s corrective/preventive actions, and the management cannot come to an agreeable solution with the complainant, management shall inform the complainant of their right to make their complaint to chairman of DIQC B.V.'s impartiality committee.

6.9 Complaints About DIQC B.V. registered/certified client

6.9.1 When DIQC B.V. receives a complaint about a registered client, confidentiality of the client's files and any other associated information must be maintained in accordance with DIQC B.V. policy and the agreements DIQC B.V. has signed with the client.

6.9.2 If DIQC B.V. receives a complaint(s) by a client's customer(s) about that client, management shall communicate the complaint to the client if agreeable to the customer and depending on the significance and impact on the system.

6.9.3 Only complainants who are willing to identify themselves to the DIQC B.V. client will be made aware of their complaint's resolution (i.e. the resolution would be communicated by the DIQC B.V. client during resolution). DIQC B.V. shall encourage its client to work with the complainant through their quality system's complaint handling mechanism to resolve the issue. DIQC B.V. can follow up during the subsequent routine surveillance assessment(s) by evaluating the client's resolution of the complaint.

6.9.4 DIQC B.V. shall enter all written complaints into DIQC B.V.'s corrective action system so it may be investigated and the client's resolution of the complaint tracked.

6.9.5 If the investigation into the complaint leads DIQC B.V. to determine that further investigation is necessary, yet without an on-site visit, regional management shall request that the client provide a Corrective action plan including root cause analysis, planned actions and timing.

6.9.6 If a representative of DIQC B.V. management determines after review of the complaint and any other associated evidence, that an on-site visit is required, the following shall be observed:

a) Depending on the severity of the complaint, certain elements/systems may have to be evaluated at the next Surveillance Assessment, or an immediate assessment of the client may need to be scheduled.

b) If a major nonconformance is found during the assessment of the complaint, it is to be documented in the assessment report and a response by the Organization shall be required within 10 days of the last day of the assessment.

6.9.7 DIQC B.V. shall provide monthly progress reports to the complainant should the process take in excess of one month to conclude. The complainant may also enquire at any time the status of the complaint. However DIQC B.V. shall not release any confidential information regarding the DIQC B.V. client unless as otherwise stated in the document.

6.9.8 DIQC B.V. shall determine, together with the client and the complainant whether and, if so to what extent, the subject of the complaint and its resolution shall be made public.

6.10 Complaints arisen during audit/disputes:

6.10.1 An organization may dispute the audit findings and conclusion declared by the DIQC B.V. audit team. In the first instance the dispute should be raised to the lead auditor of the audit team. If the organization is not satisfied, then the dispute can be raised to the DIQC B.V. technical head for resolution. If no agreement can still be reached and the nonconformity shall likely result in registration withdrawal then the organization is invited to make a formal appeal.

6.10.2 The client should lodge the complaint in English language only by writing or emailing the lead auditor and asking for their complaint to be considered. The lead auditor should forward the email or documentation from the client to the Technical Head, indicating the identification of the nonconformity (issuing auditor, sequential number, file number and audit date). Disputes should be submitted in English by email to info@diqc.nl and keeping the lead auditor of the audit team in 'cc' for forwarding to the technical head.

6.10.3 The complaint must be submitted within 7 days for the response to nonconformities as established by DIQC B.V.'s program requirements. Complaints received after that time may not be considered and appropriate action for no response of nonconformities shall be initiated including the invoking of the D-MMS-S-0016 Suspension, Withdrawal or Reduction in scope of Certification.

6.10.4 The DIQC B.V. technical head shall confirm receipt of the complaint. While it is being assessed no further action by the customer is required in regards to that specific nonconformity.

6.11 Appeals:

6.11.1.1 Appeals are generally not complaints. An appeal is made when there is a disagreement with a DIQC B.V. decision to not grant, or withdraw registration.

6.11.2 Appeals should be documented by the organization and submitted in English to DIQC B.V. on company letterhead with the signature of an executive officer/management. The appeal must provide full details to support the overturning of a recommendation not to grant or withdraw registration. Appeals must be made within 30 days of the audit where certification was refused or within 30 days of the notice of certification withdrawal.

6.11.3 Upon receipt of the appeal, technical head shall acknowledge the receipt of the appeal to the applicant. An appeals panel shall then be convened to assess the validity of recommendation not to grant or withdraw registration. The appeals panel shall include additional DIQC B.V. auditors independent of the assessment, recommendation and review of the audit where a recommendation not to grant or withdraw registration was made. A member of DIQC B.V.'s external impartiality committee shall chair the appeals panel.

6.11.4 Once an appeals panel is formed, it shall be verified with the appellant to ensure they have no objection to the composition of the panel. The appellant may state objections to the composition of the appeals panel. Consequently the constitution of the panel may be amended accordingly in order to resolve those objections. Once both sides agree to the

composition of the panel, both DIQC B.V. and the appellant agree to abide by the decision formed by the appeals panel.

6.11.5 The chair of the appeals panel shall verify that all facts are equally presented to the individual DIQC B.V. auditors upon the appeals panel. Each DIQC B.V. assessor shall be requested to independently weigh the organizations appeal with records generated from the audit. Additional requests for information from either the DIQC B.V. audit team of the organization shall be requested through the chair of the appeals panel.

6.11.6 The panel shall then conduct a preliminary review of the information and forward to each of the other members of the appeals panel providing them with a maximum of 7 days to respond. The panel members shall be informed that may not confer with each other or the auditors/ reviewers involved in the original decision. They are however permitted to use whatever reference documentation available to make their judgment if the appeal is valid.

6.11.7 The panel members shall then provide their decision and rationale for their decision on email directly to the panel chair. The panel chair shall ensure that each of the rationales illustrated that the member has taken into account all of the facts surrounding the appeal and that it was unbiased.

6.11.8 The panel chair shall take the majority as the decision of the appeals panel.

6.11.9 The appellant may request to DIQC B.V.'s management the status of any application at any time during the appeals process or in relation to DIQC B.V.'s corrective action should the appeal be successful.

6.11.10 DIQC B.V.'s management will provide in writing the decision and reasoning of the panel's final decision to the appellant. The final decision shall be provided within 45 days of the receipt of the written appeal.

6.11.11 The appellant is at liberty to bring the handling of their concern to the attention of an accreditation body if they believe the appeal has not been handled in accordance with DIQC B.V.'s Medical Quality Management System Registration Program requirements.

6.11.12 DIQC B.V. shall ensure that no discriminatory action is taken against an organization in any way for the submission of a dispute, appeal or complaint.

7 Associated Procedures/Documents/Formats

7.1 All documents involved in DIQC B.V. MMS registration