QUALITY MANAGEMENT SYSTEM

TECHNICAL QUESTIONNAIRE

Applicable to

ISO 13485:2016

*Review and verification of new requirements –vs- ISO 13485:2003

Please complete the response / evidence requirements and email the completed questionnaire to your NSAI Auditor for verification prior to the audit

GENERAL INFORMATION

Company Name:	
Address:	
Contact Name:	
Telephone No.:	
Email Address:	

Sites relevant to this application:

☐ Single Site ☐ Multiple Locations as listed beneath

Address	Employee Headcount	Site Contact	Email

Major products / services provided at this location(s):

	SCOPE (CLAUSE 1)			
	Requirement	**Response / Evidence**	**Auditor verification** *For office use only*	**Compliant (Y / N)**
1	Have the company justified the exclusions from the quality management system? Have the company records to justify the non applications (in Clauses 6, 7 or 8) from the quality management system?			

A	QUALITY MANAGEMENT SYSTEM (CLAUSE 4)			
	Requirement	**Response / Evidence**	**Auditor verification** *For office use only*	**Compliant (Y / N)**
1	4.1.1 Are the role(s) undertaken by the organization documented in the Quality Management System? *(.e.g. Manufacturer, Authorized Rep., Distributor, Importer, etc.)*			
2	4.1.2 Has the organization determined and applied the processes needed in accordance with their role?			
3	4.1.2 Has the organization implemented a risk-based approach to the control of processes?			
4	4.1.4 Are changes to these processes evaluated for: - Impact on the Quality Management System - Impact on the medical device produced - Controlled			
4b	4.1.5 Outsourcing of processes Do the company have written Quality Agreements?			
5	4.1.6 Does the organization have **documented procedures** for the validation of software?			
6	4.1.6 Is software used in the Quality Management System validated prior to initial use, and as appropriate, after changes?			
7	4.2.3 If applicable, has the organization established and maintains a **Medical Device File** for each medical device type or medical device family?			
8	4.2.3 Do **Medical Device Files** contain: ❑ General description of the medical device, intended use/purpose, and labeling, including any instructions for use; ❑ Specifications for product, ❑ Specifications or procedures for manufacturing, packaging, storage, handling and distribution; ❑ Procedures for measuring and monitoring; ❑ As appropriate, requirements for installation; and ❑ As appropriate, procedures for servicing.			

B	MANAGEMENT RESPONSIBILITY (CLAUSE 5)			
	Requirement	**Response / Evidence**	**Auditor verification** *For office use only*	**Compliant (Y / N)**
1	5.6 Does the organization have **documented procedures** for Management Review?			
2	5.6. Does Top Management review the QMS at **documented planned** intervals?			
3	5.6.2 Does Management Review include the following "new" input items: (b) Complaint Handling (c) Reporting to Regulatory Authorities			
4	5.6.3 Is the output from Management Reviews recorded and includes the inputs reviewed?			
5	5.6.3 Do Management Review records include and document any decisions and actions related to: ❑ improvement needed to maintain **the suitability, adequacy, and** effectiveness of the quality management system and its processes; ❑ improvement of product related to customer requirements ❑ **changes needed to respond to applicable new or revised regulatory requirements; and** ❑ resource needs.			

C	RESOURCE MANAGEMENT (CLAUSE 6)			
	Requirement	**Response / Evidence**	**Auditor verification** *For office use only*	**Compliant (Y / N)**
1	6.2 **Human Resources**: Does the organization have documented process (es) for establishing competence, maintaining competence, providing needed training, and ensuring awareness of personnel?			
2	6.3 **Infrastructure**: Does the organization have documented requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. *Infrastructure includes: • Buildings, workspace, and associated utilities • Process equipment (hardware and software) • Supporting services (transport, communication, IT)			
3	6.3 As appropriate, does the organization have documented requirements, including intervals for performing, for the maintenance of equipment used in production, work environment, and monitoring and measurement			
4	6.4.2 **Contamination Control:** As appropriate, does the organization have planned and documented arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.			
5	6.4.2 **Contamination Control**: For sterile medical devices, does the organization have documented requirements for control of contamination with micro-organisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.			

D	PRODUCT REALIZATION (CLAUSE 7)			
	Requirement	**Response / Evidence**	**Auditor verification** *For office use only*	**Compliant (Y / N)**
1	7.1 **Product Planning**: During product planning does the organization determine and document the following, as appropriate: (c) required verification, validation, monitoring, **measurement**, inspection and test, **handling, storage, distribution and traceability activities** specific to the product together with the criteria for product acceptance			
2	7.2.1 **Determination of Product Requirements**: Does the determination of product requirements also include: d) any user training needed to ensure specified performance and safe use of the medical device			
3	7.2.2 **Review of Product Requirements:** Does the review of product requirements also ensure that: c) applicable regulatory requirements are met, d) any user training identified in accordance with 7.2.1 is available or planned to be available			
4	7.2.3 **Communication:** Does the organization have procedures in place for communicating with regulatory authorities in accordance with applicable regulatory requirements			
5	7.3.2 **Design and Development Planning**: Does the organization have documented procedures in place to ensure the following: ❑ The organization plans and controls the design and development of product. ❑ As appropriate, design and development planning documents are maintained and updated as the design and development progresses. ❑ During design and development planning, the organization shall document: ❑ the methods to ensure traceability of design and development outputs to design and development inputs; and ❑ the resources needed including necessary			

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	competence of personnel.			
6	7.3.3 **Design Inputs**: Do design and development documents also include the following "new" design input requirements: a) functional, performance, **usability** and safety requirements, according to the intended use,… e) other requirements essential for design and development of the product **and processes**.			
	7.3.4 Are design & development outputs in a form suitable for verification against the design & development inputs? Are design outputs approved prior to release?			
7	7.3.5 **Design Review**: Do Design Review records include the identification of the design under review, the participants involved and the date of the review			
8	7.3.6 **Design and Development Verification**: Does the organization document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.			
9	7.3.6 **Design and Development Verification**: If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), does verification include confirmation that the design outputs meet design inputs when so connected or interfaced			
10	7.3.7 **Design and Development Validation**: Does the organization have documented validation plans that include methods, acceptance criteria, and, as appropriate, statistical techniques with rationale for sample size.			
11	7.3.7 **Design and Development Validation**: Do Design Validation procedures ensure the following: ❑ Design validations are conducted on representative product. Representative product includes initial production units, batches, or their equivalents.			

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	❑ The rationale for the choice of product used for validation is recorded ❑ If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation includes confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. ❑ Validation is completed prior to release for use of the product to the customer			
12	7.3.8 **Design and Development Transfer**: Does the organization have: ❑ **Documented procedures** for transfer of design and development outputs to manufacturing. ❑ Do these procedures ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements ❑ Does the transfer procedure(s) ensure that results and conclusions of the transfer are recorded			
13	7.3.9 **Design and Development Changes**: Does the organization have **documented procedures** to control design and development changes?			
14	7.3.9 **Design and Development Changes**: Does the procedure ensure the organization determines the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use			
15	7.3.9 **Design and Development Changes**: Does the procedure ensure that, bbefore implementation**,** design and development changes are: ❑ reviewed; ❑ verified;			

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	❑ validated, as appropriate; and ❑ approved			
16	7.3.9 **Design and Development Changes**; Does the change process include an evaluation of the effect of the changes on constituent parts and product **in process or** already delivered**, inputs or outputs of risk management and product realization processes**			
17	7.3.10 **Design and Development Files**: Does the organization maintain a design and development file for each medical device type or medical device family. ❑ Does the file include or reference records generated to demonstrate conformity to the requirements for design and development, and ❑ Records for design and development changes.			
18	7.4.1 **Purchasing Process**: Has the organization documented criteria for the evaluation and selection of suppliers			
19	7.4.1 **Purchasing Process**: Is criteria established and documented for the evaluation and selection of suppliers: ❑ Based on the supplier's ability to provide product that meets the organizations' requirements, ❑ Based on the performance of the supplier, ❑ Based on the effect of the purchased product on the quality of the medical device, and ❑ Proportionate to the risk associated with the medical device.			
20	7.4.1 **Purchasing Process**: Does the purchasing process: ❑ Plan the evaluation and monitoring of suppliers ❑ Monitor the suppliers performance in meeting requirements ❑ Ensure that monitoring results provide input into the supplier re-evaluation process			

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	❑ Ensure non-fulfilment of purchasing requirements is addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements			
21	7.4.2 **Purchasing Information**: Does purchasing information include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements			
22	7.4.3 **Verification of Purchased Product**: Are verification activities based on the supplier evaluation results and proportionate to the risks associated with the purchased product**.**			
23	7.4.3 **Verification of Purchased Product**: When the organization becomes aware of any changes to purchased product, does the organization have documented processes in place to determine whether these changes affect the product realization process or the medical device.			
24	7.5.1.1 Control of Production: Does the organization have documented procedures to ensure that production / service activities are planned, carried out, **monitored** and controlled to ensure that product conforms to specification			
25	7.5.1 **Control of Production:** As appropriate, do production controls also address the "new" requirements below: ❑ **b) qualification of infrastructure,** ❑ c) implementation of monitoring and measurement **of process parameters and product characteristics**			
26	7.5.2 **Cleanliness of Product**: Does the organization have documented procedures for the cleanliness of product or **contamination control** if			

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	the product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use			
27	7.5.4 **Servicing**: Does the organization have documented procedures for analyzing records of servicing activities carried out by the organization or its supplier: ❑ to determine if the information is to be handled as a complaint and ❑ b) as appropriate, for input to the improvement process			
28	7.5.6 **Validation of Processes**: Does the organization have procedures in place for the validation of any production and service processes where the resulting output cannot be **or is not verified** by subsequent monitoring or measurement			
29	7.5.6 **Validation of Processes**: Does the organizations **documented validation procedure(s)** include the following: ❑ defined criteria for review and approval of the processes; ❑ equipment qualification and qualification of personnel; ❑ use of specific methods, procedures **and acceptance criteria**; ❑ **as appropriate, statistical techniques with rationale for sample sizes** ❑ requirements for records (see 4.2.5); ❑ revalidation, **including criteria for revalidation**; and ❑ **approval of changes to the processes.**			
30	7.5.6 **Validation of Processes** (Software): Does the organizations have a documented procedure for the validation of software used in production or service. ❑ Does the procedure require validation of software prior to initial use, and as appropriate, after changes ❑ Are the activities associated with software			

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	validation and revalidation determined proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications ❑ Are records of the results and any conclusion of the validation and necessary actions from the validation maintained?			
31	7.5.7 **Particular Requirements for the Validation of Sterile Barrier Systems**: Does the organization have documented procedures for the validation of the sterile barrier system and associated processes. ❑ Are sterile barrier systems validated prior to implementation and following product or process changes as appropriate ❑ Are records of sterile barrier validation retained, including results, conclusion, and necessary actions from the validation			
32	7.5.8 **Identification**: If required by applicable regulatory requirements, does the organization have a procedure for assigning unique device identification to the medical device			
33	7.5.11 **Preservation of Product**: Does the organization have procedures in place to protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: ❑ designing and constructing suitable packaging and shipping containers, or ❑ b) documenting requirements for special conditions needed if packaging alone cannot provide preservation			

E	MEASUREMENT, ANALYSIS AND IMPROVEMENT (CLAUSE 8)			
	Requirement	**Response / Evidence**	**Auditor verification** *For office use only*	**Compliant (Y / N)**
1	8.2.1 **Feedback**: Does the organization have documented procedure(s) for the feedback process, and ❑ Does the feedback process include provisions to gather data from production as well as post-production activities ❑ Does information gathered serve as potential input into the risk management process			
2	8.2.2 **Complaint Handling**: Does the organization have a **documented procedure** for timely complaint handling in accordance with applicable regulatory requirements			
3	8.2.2 **Complaint Handling**: Does the complaint handling procedure include, at minimum, requirements and responsibilities for: ❑ receiving and recording information, ❑ evaluating information to determine if the feedback constitutes a complaint, ❑ investigating complaints, ❑ determining the need to report the information to the appropriate regulatory authorities, ❑ handling of complaint-related product, and ❑ determining the need to initiate corrections or corrective actions.			
4	8.2.2 **Complaint Handling:** ❑ If any complaint is not investigated, is the justification documented? ❑ Is any correction or corrective action resulting from complaints documented? ❑ If an investigation determines activities outside the organization contributed to the complaint, is relevant information exchanged between the organization and the external party involved? ❑ Are complaint handling records maintained?			
5	8.2.3 **Reporting to Regulatory Authorities**: Does the organization have a **documented procedure** for			

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	the notification of appropriate regulatory authorities for complaints that meet the specified reporting criteria of adverse events or for issuance of advisory notices ❑ Are records of notifications to Regulatory Authorities maintained?			
6	8.2.6 **Monitoring and Measuring of Product:** As appropriate, does evidence of conformity with acceptance criteria identify the test equipment used to perform the measurement activity?			
7	8.3.1 **Control of Non-Conforming Product – General**: Does the organization have a documented procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. ❑ Does the evaluation of nonconformity include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. ❑ Are records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions maintained			
8	8.3.2 **Actions in Response to Non-Conforming Product Detected Before Delivery**: Does the organization have a documented procedure to ensure that nonconforming product is accepted by concession only if **the justification is provided, approval is obtained**, and applicable regulatory requirements are met. ❑ Are records of the acceptance by concession and **the identity of the person authorizing the concession maintained**			
9	8.3.2 **Actions in Response to Non-conforming Product Detected After Delivery**:			

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	Does the organization have a **documented procedure** for issuing advisory notices in accordance with applicable regulatory requirements ❑ Is the procedure capable of being put into effect at any time ❑ Are records of actions relating to the issuance of advisory notices maintained			
10	8.4 Analysis of Data: Does the organization have documented procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system ❑ Does the procedure include a determination of appropriate methods, **including statistical techniques and the extent of their use** ❑ Does the analysis of data include data generated as a result of **monitoring and measurement** and from other relevant sources. ❑ Does the data analyzed include, at minimum, input from the areas below: ❑ Feedback ❑ Conformity to product requirements ❑ Characteristics and trends of processes and product, including opportunities for improvement ❑ Suppliers ❑ **audits, and** ❑ **service reports, as appropriate**			
11	8.4 **Analysis of Data**: If the analysis of data shows that the quality management system is not suitable, adequate or effective, does the organization use this analysis as input for improvement as required in 8.5			
12	8.5.2 **Corrective Action**: Does the organization have documented procedure(s) for taking action to eliminate the cause of nonconformities and prevent recurrence. ❑ **Does the procedure(s) specify that any**			

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	necessary corrective actions shall be taken without undue delay?			
13	8.5.2 **Corrective Action**: Does the procedure(s) for corrective action define requirements for verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device			
14	8.5.3 **Preventive Action**: Does the organization have documented procedures to describe the requirements for: ❑ Determining potential nonconformities and their causes; ❑ Evaluating the need for action to prevent occurrence of nonconformities; ❑ Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; ❑ **Verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; and** ❑ Reviewing the effectiveness of the preventive action taken, as appropriate			

SIGNATURES:							
Client Representative:				**Auditor:**			
Signature:		**Date:**		**Signature:**		**Date:**	