MEDICAL DEVICE MANAGEMENT SYSTEM QUOTE REQUEST FORM

Please provide the following information to enable us to confirm the costs of ISO 13485 certification.

1. Organization details:

Company name:

Company number

Main office address:

Postcode: Tel: Website:

Contact name: Job title:

Email: Direct dial: Mobile:

2. Details of main office and branches:

Address and postcode

Main office:

Branch 1:

Branch 2:

Branch 3:

Branch 4:

Branch 5:

	Core hours	Shift 1	Shift 2	Shift 3	Total no. of employees
No. of staff					
Activities					

If you have more than 5 branches, please contact us

Total no. of employees:

3. Which management system standard requires registration? (please tick)

	Standalone	Integrated/combined
Medical Device Quality Management Systems (ISO 13485)	☐	☐
Quality management systems (ISO 9001)	☐	☐

4. Combined and integrated management systems:

Do you require the auditing of your quality management system to form part of a combined audit with other management system standards? ☐ Yes ☐ No

If yes, please provide details of the management systems which are integrated and an outline of the structure. Fully integrated systems shall be recorded as 100% integrated. If the management systems are only partially integrated, then the level of integration should be indicated

5. Integration

For integration, provide details as below:

An integrated documentation set, including work instructions to a good level of development, as appropriate;	☐ Yes	☐ No
Management Reviews that consider the overall business strategy and plan;	☐ Yes	☐ No
An integrated approach to internal audits;	☐ Yes	☐ No
An integrated approach to policy and objectives;	☐ Yes	☐ No
An integrated approach to systems processes;	☐ Yes	☐ No
An integrated approach to improvement mechanisms (corrective and preventive action; measurement and continual Improvement);	☐ Yes	☐ No
Integrated management support and responsibilities.	☐ Yes	☐ No

6. Are you?

a. A new NQA client ☐ Yes ☐ No b. A transferring client ☐ Yes ☐ No

If you are a transferring client, please provide details of previous registration(s):

Note: Copies of current certificates of registration and previous audit reports will need to be supplied.

c. Extending your scope? ☐ Yes ☐ No d. Have you previously been registered with NQA? ☐ Yes ☐ No

e. A transition client ☐ Yes ☐ No

Type: ☐ Recertification ☐ Surveillance ☐ Special

If you are a transition client, please complete the ISO 13485 gap analysis tool.

7. Requested scope of certification:

Note: The scope should explain succinctly the purpose and output covered by the management system; it should describe what the organization does and not how it does it. E.g. Design, manufacture and sales of sterile suture needles.

8. What is the intended use of your product?

9. Do you provide installation or other contract site works? ☐ Yes ☐ No

10. Do you have outsourced or subcontracted activities?

☐ Yes ☐ No

If yes, please provide details of outsourced or subcontracted activities:

11. Are your products sterile?

☐ Yes ☐ No

If yes, please provide details of sterilization method:

When/how was the sterilization conducted? ☐ During production ☐ Outsourced ☐ Intend for end-user sterilization

Sterilization methods	Please Tick	Details
Ethylene oxide gas; E.g.: Ethylene oxide gas sterilization	☐	
Moist heat; E.g. pressure steam sterilizer	☐	
Aseptic processing; E.g. sterilization by boiling; Disinfection; Ozone disinfection	☐	
Radiation sterilization; E.g. Gamma, x-ray, electron beam	☐	
Sterilization method other than specified above	☐	

12. Organizational and process complexity:

Does the organization have a large product range and/or complexity of medical device	☐ Yes	☐ No
Does the organization use suppliers to supply processes or parts that are critical to the function of the medical device and/or the safety of the user or finished product?	☐ Yes	☐ No
Does the organization install products on the customer's premises?	☐ Yes	☐ No
Does the organization have poor regulatory compliance?	☐ Yes	☐ No
Does the organization have multiple shifts / a number of production lines?	☐ Yes	☐ No
Does the organization have staff speaking in more than one language and/or use an interpreter?	☐ Yes	☐ No
Does the organization have no production (e.g. wholesale, retail, transportation or maintenance of equipment?	☐ Yes	☐ No
Does the organization reduce the production range since last audit?	☐ Yes	☐ No

If you have answered yes to any of the above questions, please provide details below:

13. Do you have a target assessment date?

14. How long has your quality management system been in place?

15. Have you had any incidents leading to or pending prosecution/insurance claims/ enforcement notices in the last year?

☐ Yes ☐ No

If yes, please provide details:

16. Legal Obligation: Please list below legal obligation relevant to the proposed scope of certification.

17. Please list the requirements that you do not deem applicable to the proposed scope of the management system

Clause:	Exclusion/not applicable:	Justification:

18. Consultant use:

Will you be using a consultant to help you implement/manage the management system? ☐ Yes ☐ No

(If yes, please complete their details below).

Consultancy name:

Contact name:

Postcode:

Tel: Email:

19. Completed by:

Name:

Job Title:

20. Where did you hear about NQA's service? (Tick all that apply)

Existing client ☐	Consultant ☐	NQA's web site ☐
Recommendation from another company ☐	Search engine: e.g. Google ☐	Trade press ☐
Exhibition ☐	Social media ☐	

Other (please specify)

If you have any problems completing this form please call 0800 052 2424 or email info@nqa.com.

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