

MANAGEMENT SYSTEMS QUOTE REQUEST FORM



Instructions for completion

Please complete all of the first section and further applicable sections based on your quotation requirements and return to NQA.

IF YOU HAVE MORE THAN ONE LOCATION PLEASE CONTACT NQA FOR A SITE SUPPLEMENT SPREADSHEET.

1. Organization details:

Company name: Company number:

Main office address:

Postcode: Telephone:

Website:

Contact name:

Job title:

Email:

Direct dial: Mobile:

2. To which management systems standards are you requiring registration? (please tick)

ISO 9001:2015 (Quality) Complete Section A	<input type="checkbox"/>	ISO 14001:2015 (Environmental) Complete Section B	<input type="checkbox"/>	ISO 45001:2018 (H&S) Complete Section C	<input type="checkbox"/>
ISO 50001:2018 (Energy) Complete Section D	<input type="checkbox"/>	ISO 27001:2013 (Info Security) Complete Section E	<input type="checkbox"/>	ISO 55001:2014 (Asset) Complete Section F	<input type="checkbox"/>
SSIP (Safety Systems in Procurement) Complete Section C	<input type="checkbox"/>	ISO 44001:2017 (Collaborative) Complete Section G	<input type="checkbox"/>	ISO 13485:2016 (Medical Devices) Complete Section H	<input type="checkbox"/>
ISO 27701 (Privacy Information) Complete Section E	<input type="checkbox"/>	Please note; you must have or be applying for ISO 27001 to gain this certification. If you are certified to ISO 27001 with another provider, then please apply to transfer this certification to NQA.			

3. Integrated management systems:

Do you require the auditing of your management system to form part of an integrated audit with other management system standards. To what extent is your management system integrated? Yes No

The management system has an integrated approach to:

	Yes - Full	Yes - Partial	No		Yes - Full	Yes - Partial	No
Document sets including work instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	System processes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Management reviews considering overall business, strategy and aspects relating to the standards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Improvement mechanisms (such as CAP, measurement etc) strategy and aspects relating to the standards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Internal audits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Management support and responsibilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Policy and objectives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				

4. Details of main office and branches

Main office address and postcode:

	Core Hours	Shift 1	Shift 2	Shift 3	Total no. of employees*
No. of staff:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Processes/ activities at this site:	<input type="text"/>				
Number of staff in similar roles: (eg. number of sales personnel, number of engineers etc.):	<input type="text"/>				

If you have more than 1 branch please contact us to request the NQA Site Supplement Spreadsheet Total no. of employees*:

Where part time workers or seasonal workers are employed, please provide full details below:

5. Are you?

	Yes	No		Yes	No
a) A new NQA client?	<input type="checkbox"/>	<input type="checkbox"/>	b) Expanding your scope of certification?	<input type="checkbox"/>	<input type="checkbox"/>
c) A transferring client?	<input type="checkbox"/>	<input type="checkbox"/>	d) Have you previously been registered with NQA?	<input type="checkbox"/>	<input type="checkbox"/>

6. Transferring your certification

Please answer the following questions if you wish to transfer your certification from your current certification body to NQA. If you are not transferring certification please skip to question 8. Please state for each certificate you wish to transfer: the certificate number, standard, valid until date and issuing certification body.

Certificate Number	Standard	Valid Until Date	Certification Body
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please highlight your reason for transferring:

	Yes	No
Are your certifications currently active and are not in suspension or withdrawal?	<input type="checkbox"/>	<input type="checkbox"/>
Have any complaints been raised against your organization to your certification body?	<input type="checkbox"/>	<input type="checkbox"/>
Is a regulatory body currently engaged with or investigating you in relation to activities you are certificated for (eg. HSE for health and safety breaches)	<input type="checkbox"/>	<input type="checkbox"/>

7. Your current audit program

	Yes	No	
Do you have any major non-conformities for which your current certification body has not verified the implementation of your corrections and corrective actions?	<input type="checkbox"/>	<input type="checkbox"/>	
Do you have any minor non-conformities for which your current certification body has not yet accepted your corrective action plans?	<input type="checkbox"/>	<input type="checkbox"/>	
How frequently do you receive audits from your current certification body:	Annually <input type="checkbox"/>	6 Monthly <input type="checkbox"/>	Other <input type="checkbox"/>

Please detail your last audits upto and including the latest recertification or stage 2 audit:

Audit Type (Surveillance/Recert/Stage 2/Special)	Audit Duration	Audit Date
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

To support your transfer please provide the following:

Copies of your certificates Audit reports for all audits conducted up to and including your last Recertification or Stage 2 audit

If the required supporting documents are not provided a transfer may not be possible. Please note that NQA will contact your existing certification body to verify the validity of your certification.

Please note: Do not cancel your certification with your existing certification body until the transfer process has been completed by NQA and you have received an NQA Certificate

8. 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, not how it does it. E.g. The provision of architectural design services, or Information security management for...

9. Do you provide installation, contract site works or undertake your business activity at client locations? Yes No

10. Do you have outsourced or subcontracted activities? Yes No

Please provide details of outsourced or subcontracted activities:

11. Organizational and process complexity:

	Yes	No
Does the organization have a simple structure with vertical lines of management communication and few decision makers?	<input type="checkbox"/>	<input type="checkbox"/>
Is the management system highly complex with numerous specific processes? (e.g. a manufacturer where each process is critical to the end product may have many procedures and references to legislative and regulatory documentation)	<input type="checkbox"/>	<input type="checkbox"/>
Is the organization highly regulated by external agencies? (typical industry sectors would be food preparation, aerospace, automotive, electricity generation & gas/oil production etc)	<input type="checkbox"/>	<input type="checkbox"/>
Do stakeholders have specific expectations of the organization? (e.g. security, health/safety inspections, dangerous waste processing etc)	<input type="checkbox"/>	<input type="checkbox"/>
Does the organization work within/operate areas having strict security controls? (e.g. chemical plants, oil/gas refineries, electricity generating stations etc)	<input type="checkbox"/>	<input type="checkbox"/>
Are the organization's operations managed as part of or influenced by a larger organization's management system? (e.g. controlled by parent company or heavily influenced by local/central government etc)	<input type="checkbox"/>	<input type="checkbox"/>
Are there any other factors which affect the complexity of the organization's management and processes?	<input type="checkbox"/>	<input type="checkbox"/>

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

12. Do you have a target assessment date?

13. At what stage of implementation are you in?

Researching Implementing System in place Already certified

14. 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, or contact NQA to be referred to a consultant.)

Consultancy name:

Contact details:

15. Completed by:

Name:

Job title:

16. 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)

Please ensure that sections **B, **C**, **D**, **E**, **F**, **G** and **H** of this form are also completed (as appropriate)**

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

If you choose to give us any personal information (for example your e-mail address) we will treat this information in line with our privacy notice which can be located here: <https://www.nqa.com/en-gb/privacy>
We will only use the information provided to respond to your enquiry and provide you with any information or materials requested. By submitting this information you are requesting a quote for services from NQA and a subsequent quote letter will be issued to you based on the information provided within this form.

Or print and send to: NQA Sales, Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, Bedfordshire, LU5 5ZX, UK.

 **Contact us**
NQA, Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, Bedfordshire LU5 5ZX, UK
T: 0800 052 2424 E: info@nqa.com www.nqa.com
NEVER STOP IMPROVING

SECTION A - ISO 9001:2015

Only complete this section if applying for certification against this standard.

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

2. Do you undertake design and development of products and services?

Yes

No

Number of staff engaged in design activity:

3. Please list the requirements of ISO 9001 that you do not deem applicable to the proposed scope of the management system:

Clause:

Reason:

SECTION B - ISO 14001:2015

Only complete this section if applying for certification against this standard.

1. How long has your environmental management system been in place?

Please complete the following questions (3-9) considering ALL locations applying for certification

2. Permits to operate:

Are your operations subject to an authorisation/permit/licence/registration from a regulatory body?
(e.g. environmental permit, hazardous waste producer registration, abstraction licences, registered waste or water discharge exemptions, etc.)

Yes No

If yes, please provide details (including permit/licence/registration numbers):

Numbers and which location(s) this applies to:

3. Discharges to water/sewer:

Do you produce any industrial effluent (other than domestic sewage and surface water)?

Frequently

Occasionally

Never

If yes, please provide details, including which location(s) this applies to:

4. Waste:

Do you produce hazardous, special or clinical waste?

Frequently

Occasionally

Never

If yes, please provide details, including which location(s) this applies to:

5. Noise and nuisance:

Have you had complaints with respect to noise or other nuisances (smoke, dust, fumes, odours or other escapes) from your premises?

Frequently Occasionally Never

If yes, please provide details, including which location(s) this applies to:

Details, including which location(s) this applies to:

6. Incidents/prosecutions:

Have you had any environmental incidents leading to high clean-up costs or a breach of legislation (including prosecution)?

Yes No

If you have answered yes to any of the above questions, please provide details, including which location(s) this applies to:

7. Site sensitivity:

Are there any surface waters (rivers, lakes, streams, etc.) or boreholes within or adjacent to the site boundaries?

Yes No

Is your site overlying groundwater of significance (e.g. major / minor aquifer)?

Yes No

Do you have listed buildings (Grade I, Grade II*, Grade II) or archaeological sites (tumuli, burial mounds etc.) on site?

Yes No

Is the site within or adjacent to any designated nature conservation sites including Site of Special Scientific Interest (SSSI), National Park, or Special Areas of Conservation?

Yes No

Are there any other conservation issues at the site?

Yes No

Is there evidence to suggest land contamination requiring clean-up is present at the site?

Yes No

If you have answered yes to any of the above questions, please provide details, including which location(s) this applies to:

SECTION C - ISO 45001:2018

Only complete this section if applying for certification against this standard.

1. If you are applying for SSIP please identify which role(s) you would like approving against:

Designer Principal Designer Contractor Principal Contractor Non-construction

2. How long has your health and safety management system been in place?

3. Please provide details of the hazards associated with your activities:

Hazards	Please Tick	Please detail which processes these hazards relate to?
Working with asbestos	<input type="checkbox"/>	<input type="text"/>
Working with explosives	<input type="checkbox"/>	<input type="text"/>
Working with and storage of flammable substances	<input type="checkbox"/>	<input type="text"/>
Transport of dangerous goods	<input type="checkbox"/>	<input type="text"/>
Underwater diving at work	<input type="checkbox"/>	<input type="text"/>
Working with materials at extreme temperatures	<input type="checkbox"/>	<input type="text"/>
Working with dangerous animals	<input type="checkbox"/>	<input type="text"/>
Working in proximity to water (risk of drowning)	<input type="checkbox"/>	<input type="text"/>
Working with gas	<input type="checkbox"/>	<input type="text"/>
Working with ionising radiation	<input type="checkbox"/>	<input type="text"/>
Working with lifting equipment and lifting operations	<input type="checkbox"/>	<input type="text"/>
Working with biological hazards	<input type="checkbox"/>	<input type="text"/>
Working in proximity to moving vehicles	<input type="checkbox"/>	<input type="text"/>
Food preparation for other parties	<input type="checkbox"/>	<input type="text"/>
Working in compressed air (risk of decompression illness)	<input type="checkbox"/>	<input type="text"/>
Working at heights	<input type="checkbox"/>	<input type="text"/>
Working in confined spaces	<input type="checkbox"/>	<input type="text"/>
Working with pressure systems	<input type="checkbox"/>	<input type="text"/>
Use of lead and heavy metals at work	<input type="checkbox"/>	<input type="text"/>
Working with fumes/gasses/dust	<input type="checkbox"/>	<input type="text"/>
Working with chemical hazards	<input type="checkbox"/>	<input type="text"/>
Use of work equipment (PUWER)	<input type="checkbox"/>	<input type="text"/>
Other (please specify)	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>

4. Please identify the main hazardous materials associated with your processes and provide details:

5. Radioactive and dangerous substances:

Do you keep, use, accumulate or dispose of radioactive substances?

Yes No

Does your business handle, produce, use or store dangerous substances (including toxic, oxidising, explosive, flammable, etc.) in large quantities and could therefore be subjected to COMAH (Control of Major Accident Hazards)?

Yes No

If you have answered yes to any of the above questions, please provide details, including which location(s) this applies to:

6. Are there members of the public present at your organization's sites?

Yes No

If yes please specify which sites:

7. Please provide details of legislation, regulations, obligations and guidance notes applicable to the business:

(e.g. Construction Design and Management Regulations, Control of Major Accident Hazards Regulations, etc.)

8. Have you had any incidents leading to or pending prosecution/insurance claims/enforcement notices in the last five years

Yes No

If yes, please provide details:

9. Please provide a description of any formal involvement with a competent regulatory authority (e.g. HSE in the UK):

10. Please state accurately all injuries, diseases and dangerous occurrences (RIDDOR) for the past 12 months:

Number of reportable injuries: Fatal Major Over seven days

Number of reportable dangerous occurrences: Number of reportable accidents involving a member of the public:

Details of reportable diseases:

Details of reportable injuries:

Note: Disclosure of information is a requirement for contractual obligation. The applicant may be contacted before issue of a quotation.

11. Are there any additional personnel that are not detailed in your employed personnel number (e.g. contractors / subcontractors personnel) performing work or work-related activities under the control or influence of the organization's system?

Yes No

If yes, please state how many:

12. Please provide a brief description of subcontract activities (if necessary):

SECTION D - ISO 50001:2018

Only complete this section if applying for certification against this standard.

1. How long has your management system been in place?

Site Address

Number of EnMS Effective Personnel on site

Role(s) of EnMS Personnel

Postcode

Processes / Activities of Site

Annual Energy Consumption (Terajoules)

Energy Sources

Significant Energy Uses

Energy Regulations Applicable to Site

SECTION E - ISO 27001:2013

Only complete this section if applying for certification against this standard.

1. How long has your management system been in place?

2. Are you aware of any standards, regulations or laws with which your company or industry must comply? If so list these below.

Legal (e.g. Data Protection Act, Computer Misuse Act etc):

Regulatory (e.g. PCI DSS, Information Governance Statement of Compliance (IG SoC)):

3. Risk level & complexity:

Type	Criteria	Examples	Yes	No	Comments
Government Classification	Information handled includes government classification at or above secret.	E.g. military bases, defence supply chain, government departments.	<input type="checkbox"/>	<input type="checkbox"/>	
Nature of information managed	<p>Nature of information held would result in a breach or loss having material financial, personal or reputational impact to any interested party. Information handled includes:</p> <ul style="list-style-type: none"> Customers, end users, staff contractors or others sensitive personal information e.g. health records or financial information Intellectual property (e.g. designs, software source code) 	E.g. Solicitors, law firms, banks, insurers, credit agencies (regulated by FCA), organizations providing payroll services or pension administration etc.	<input type="checkbox"/>	<input type="checkbox"/>	
Volume of data managed - aggregated data sets	Information held includes a large set of sensitive personal information that could be used for identity theft or fraud. This can include individuals' usernames and passwords used to access web portals or other systems .	E.g. E-commerce websites, utility companies, online payment websites, organizations collecting individual's data via web portals, organizations processing and analysing customer data.	<input type="checkbox"/>	<input type="checkbox"/>	
Complexity of technology used	<p>Technology used includes a diverse or complex infrastructure: many servers (>100 physical or virtual servers).</p> <p>OR "Bring your own device" (BYOD) is permitted.</p>	E.g. Large IT infrastructure, many servers, multiple different platforms, any organization permitting BYOD ("bring your own device") is included in this criterion, regardless of size.	<input type="checkbox"/>	<input type="checkbox"/>	
Regulation	<p>Your organization is regulated (e.g. regulated by Financial Conduct Authority, Ofcom, Ofsted, Ofiel, Solicitors Regulatory Authority, Law Society, GMC).</p> <p>OR subject to sector specific rules e.g. Cheque Printers Accreditation Scheme C & CCC Standard 55, UK Health Service's Information Governance Statement of Compliance (IG SoC), ADISA (Asset Disposal and Information Security Alliance), PCI DSS.</p>	E.g. Banking, cheque printers, hospitals, education.	<input type="checkbox"/>	<input type="checkbox"/>	

Type	Criteria	Examples	Yes	No	Comments
Complex tasks	Your organization develops software		<input type="checkbox"/>	<input type="checkbox"/>	
National importance of products/services & high availability requirements	Your services are: Part of critical national infrastructure (e.g. emergency services, communications, financial services, health, transport, utilities) or an essential part of national infrastructure supply chain (e.g. data centre hosting national infrastructure systems) OR potential terrorist target OR Non-availability of your services or product may severely affect the health, well-being, safety or security of people	E.g. broadcasting support providers, utilities (power, water, gas), internet and mobile service providers, air traffic control, examination boards Or banking services, borders and immigration controls, health management systems.	<input type="checkbox"/>	<input type="checkbox"/>	
Supply Chain	Sensitive information is shared with third parties e.g: - Customers'/end users'/staff or others personal information .e.g. outsourced payroll, third party vetting services (criminal records, credit checks) - Intellectual property (designs, source code or other sensitive proprietary information)	E.g. Criminal records, credit checks, outsourced payroll etc.	<input type="checkbox"/>	<input type="checkbox"/>	
Importance of integrity of information	If the information produced by your organization is incorrect or incomplete there is a threat to individual or collective health/wellbeing/safety/security/miscarriage of justice or risk of fraud	E.g. Organizations such as secure printers (passport/visa printers/ prescription/medical instruction printers), health providers (clinical information/medical record systems), gambling service providers.	<input type="checkbox"/>	<input type="checkbox"/>	
Susceptibility to fraud or targeted disruption	Theft of information (by staff/contractors or others) managed by your organization could result in fraud or targeted disruption, for example: - Theft of personal information by staff working in finance/insurance, call centres, clinics (e.g. theft of customer lists), pharmacies - Hacking of software/website/IT systems	E.g. Organizations susceptible to fraud (e.g. by theft or misuse of data) or heightened risk of attempted fraud.	<input type="checkbox"/>	<input type="checkbox"/>	
Information not available to audit	Do you hold any ISMS related information that cannot be made available for review by the audit team because it contains confidential or sensitive information	N/A	<input type="checkbox"/>	<input type="checkbox"/>	
Clearance	Does the audit team require security clearance to attend the site		<input type="checkbox"/>	<input type="checkbox"/>	

4. At what stage in the implementation of your ISMS are you?

Please indicate your progress in relation to the following phases:

Phase:	Description:	Completed:		Planned completion date:	Required for	
		Yes	No		Stage 1	Stage 2
Step 1	Definition of Policy Statement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Y	Y
Step 2	Defined the scope of your ISMS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Y	Y
Step 3	Completed your Risk Assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Y	Y
Step 4	Completed your Risk Treatment Plan document	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Y	Y
Step 5	Selected control objectives and controls to be implemented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Y	Y
Step 6	Prepared a Statement of Applicability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Y	Y
Step 7	Completed security awareness training	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Preferable	Y
	Completed Internal Audit Of The Isms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Preferable	Y
	Completed management review of the ISMS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Preferable	Y
	Completed and test business continuity plans	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Preferable	Y
	Operated the ISMS for at least 3 months	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	Preferable	Y

(If YES to Step 7 b) how long has your ISMS been implemented?

ISO 27701:2013 (Privacy Information Management)

1. Please detail below the data protection/privacy legislation applicable to your organisation e.g GDPR

2. Are you currently or has your business ever been under investigation/fined by a data enforcement agency e.g ICO. If yes please provide details below.

Yes No

3. Please confirm whether your organisation is a data processor, data controller or both.

Data Processor Data Controller Both Data Processor and Data Controller

SECTION F - ISO 55001:2014

If you are a multi-site client please detail on a separate sheet the Asset Groups pertaining to each site, unless these are uniform across all sites. Only complete this section if applying for certification against this standard.

1. What boundaries and applicability of the asset management system have been determined to establish the scope above? The boundaries should be aligned to your scope of certification and avoid being function specific.

2. How long has your Asset Management System been in place?

3. Please list the different categories of Asset Groups below: (use a separate sheet if necessary)

	Asset Group Name	Asset Group Description
e.g.	Vehicle Fleet	Lorries within vehicle fleet
1		
2		
3		
4		
5		
6		
7		
8		

4. Asset portfolio scale and complexity:

(please select the most appropriate description applicable to your scope of Asset Management):

- The asset portfolio is a complex networked system of assets. It is a highly interdependent system
- The asset portfolio is complex, but has discrete locations with partially interdependent systems
- The asset portfolio is at a discrete location with independent functional systems

5. Business impact of asset failure:

(please select the most appropriate description applicable to the criticality of your business assets within the scope of your AMS):

- High impact on business and stakeholders of asset failure
- Medium impact on business and stakeholders of asset failure
- Low impact on business and stakeholders of asset failure

6. Are there significant business continuity and supply chain risks

Yes

No

If Yes please provide details:

7. Are there any statutory requirements for recording financial and non-financial information relevant to asset management, risk management, management of change, complexity of the outsourced processes etc.

Yes

No

If Yes please provide details:

SECTION G - ISO 44001:2017

Only complete this section if applying for certification against this standard.

1. Please provide the details below of the relationships you would like certifying:

	Collaborative Business Relationship to be certifie	Number of employees involved in the Collaborative Business Relationship	Details of the Collaborative Business Relationship
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

SECTION H - ISO 13485:2016

Only complete this section if applying for certification against this standard.

1. How long has your medical device management system been in place?

2. What is the intended use of your product?

3. Are your products sterile?

Yes

No

If yes, please provide details of sterilization method:

When/how was the sterilization conducted?

During production

Outsource

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

4. Is software used in the product?

Yes

No

If yes, please provide details for software:

As an independent medical used software

Yes

No

As a component part of the finished medical device

Yes

No

As an embedded part of the finished medical device

Yes

No

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

If yes, please provide details:

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

7. Please list the requirements of ISO 13485 that you do not deem applicable to the proposed scope of the management system:

Clause

Reason

8. Organizational and process complexity:

Does the organization have a large product range and/or complexity of medical device	<input type="checkbox"/> Yes	<input type="checkbox"/> 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?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the organization install products on the customer's premises?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the organization have poor regulatory compliance	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the organization have multiple shifts / a number of production lines?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the organization have staff speaking in more than one language and/or use an interpreter?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the organization have no production (e.g. wholesale, retail, transportation or maintenance of equipment)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the organization reduce the production range since last audit?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

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