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| URS Certification Logo | CORE QUESTIONNAIRE For All Standards | O-01. A April 2018 |
| To Enable URS to provide a detailed quotation, please provide as much detail as possible. If you have more than one site you will be directed to an additional form after submission. | | |

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| Company Name\* |  | |
| Address\* | Street Address | |
| Street Address Line 2 |  | |
| City |  | |
| Region |  | |
| Postal/Zip Code |  | |
| Country |  | |
| Email\* |  | |
| Website |  | |
| Contact Name\* First |  | |
| Last |  | |
| Position |  | |
| Finance Contact First  This is optional for different invoicing contact |  | |
| Last |  | |
| Finance Email |  | |
| Type of Business  e.g., Franchise, Partnership, Corporation |  | |
| VAT Number (EU based clients) |  | |
| When describing your proposed scope below, should you have a range of products or services, please give examples of this in the scope. An example of this would be:  Design and Manufacture of Electronic Components Including; Capacitors, Resistors & Diodes.  We would not be able to accept 'Design and Manufacture of Electronic Components' as this is too generalised. | | |
| Scope of Certification\* | |  |
| Standard(s) applied for: | |  |
| Accreditation (if required) | |  |
| Please give a summary of your Main processes and Functions which relate to the desired Scope\* | |  |
| Are there any areas of special significance that may affect how we approach your audit? e.g., Special consents. | | Yes  No |
| If you are applying for more than one scheme or this is an additional management system application, please confirm if the management systems are fully integrated? | | Yes  No |
| What are your main legal or regulatory obligations and relevant industry standards (e.g.: Data Privacy, Intellectual Property rights)? | |  |
| Please identify any outsourced processes | |  |
| Mobile Number | |  |
| Phone | |  |
| Total Number of Employees | |  |
| Does the Location Operate Shifts? | | Yes  No |
| Maximum Number of Employees at this Location at any one time | |  |
| Number of Part-Time Employees | |  |
| How many Subcontractors  Not included above | |  |
| Normal Number of Hours of a Full Time Employee in a normal working day or shift | |  |
| Activity and Number of employees (not including subcontractors) Performing Same or Similar Repetitive Tasks  E.g., 300 Employees on sewing machines, 200 cleaners etc. | |  |
| Number of Employees in Design/Development Department | |  |
| Primary Language | |  |
| Currency Used | |  |
| Is this a new application or an extension to an existing Certification? | | New  Extension |
| If existing URS Certification is held for another standard, please state the certificate number and standard. | |  |
| Is this a transfer from another Certification Body (CB)? | | Yes  No |
| Have you engaged a consultant to assist with the implementation of your Management System? | | Yes  No |
| Please provide information about any non-native language spoken in your organisation | |  |
| How do you prefer to receive correspondence? | | Client Portal  Email  Letter |
| Multisites  If there is more than one site which requires Certification, please indicate here: | | Yes  No |
| **As you have selected ISO 13485, we are required to ask you for further information to conform with the Scheme Rules.** | | |
| Type of medical device(s) | |  |
| If your company does not produce the devices, are you 'Own Brand Labelling'? | | Yes  No |
| Are you a Stockist/Distributor? | | Yes  No |
| Are your devices to be placed on the European market? | | Yes  No |
| Which Directive is applicable to your medical devices? | | Medical Devices Directive  IVD Directive  Active Implantable |
| Which Annex(es) of the relevant directives apply to your medical devices? | |  |
| What Class are your medical devices? If more than one type of device, please list all products and Classifications: | |  |
| As your devices are not to be placed on the European market, please state your own country regulations: | |  |
| Which product standards are applicable to your medical devices? | |  |
| The organisation hereby undertakes to comply with the Certification Regulations of URS available on the website: | | I have read, understood and agree to comply with the Scheme Rules and Regulations at [http://www.urs-holdings.com/](javascript:;) |
| Signature | |  |
| Name | |  |
| Date MM/DD/YYYY | |  |