*DQS Medical Devices Management System Registration Program*

RP-1 MD Preliminary Information

The information is essential for DQS to understand the organization and determine the resources required for ISO 13485 assessments. If your organization requires ISO 15378, CMDCAS or CE Marking services, contact us for a different application form which will submit to our sister organization, DQS Medical. Please complete as much detail as possible. If a question does not apply, indicate with “N/A.” If you have questions about this form, or any other aspect of DQS Inc. Registration Programs, call us at **1-800-285-4476**.

#  Contact Information:

If you are currently registered to ISO 9001 with DQS, you may list the BR (certificate number) here and complete only the information which is different in this section:

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| --- | --- |
| 1.1 | Company name:       |
| 1.2 | Main facility address (please do not include P.O. boxes)and function :        |
|  | Additional Addresses: | Please list additional addresses in the section below as well as functions. |
| 1.3 | Name and title(s) of Representative(s) per facility address: |       |
| 1.4 | Representative(s) phone number(s):       |
| 1.5 | Email address(es):        |       |
| 1.6 | Does your company trade under any other name?[ ]  Yes [ ]  No If yes, please list the company trade name.        |
| 1.7 | Is your company part of a larger organization? [ ]  Yes [ ]  NoIf yes, please give name of holding company.       |

DQS Inc. Multiple location identification Sheet

You can utilize this sheet to identify the locations of your organization that will be included in the proposed scope of operations. Use multiple sheets if needed.

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| --- | --- | --- | --- | --- | --- | --- |
| Facility Address(include zip code and country) | Main functions(i.e. manufacturing, warehouse, sales, etc) | If requesting quote for Multiple standards, please indicate to which standards this location will be applicable to: | Site Scope | Head-count | No. of shifts | Comments |
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# 2. Services

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| 2.1 | To which standards/specification are you seeking registration?[ ]  ISO 9001[ ]  ISO 13485 Other        |
| 2.2 | Is your company currently registered to ISO 9001 or similar Standards? [ ]  Yes [ ]  NoIf yes, to which standards (AS9100, IATF 16949, etc.):       |

# 3. Locations, Shifts, and Employee Counts

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| 3.1 | Total number of employees at the main site- please use table above for multiple sites (including temporary, administrative, etc.)       |
| 3.2 | How many work shifts do you have (main site only)?       |
| 3.3 | How many of the total employees work in operations that are performed on multiple shifts?       |
| 3.4 | How many shift operation employees do you average per work shift?       |
| 3.5 | How many of the total employees work part time? What are the total hours per work week on average of these part time employees? Please answer N/A if you do not want this consideration       |
| 3.6 | How many of the total employees perform duties that are only partially within the scope of operation? What are the total hours per work week on average that is within the scope of certification for these employees? Please answer N/A if you do not want this consideration       |
| 3.7 | Do you have a high number of employees performing simple repetitive operations or do you have temporary unskilled labor? If yes, please provide relevant details including the number of employees involved in this type of work and the nature of work. Please answer N/A if you do not want this consideration       |

# 4. Scope and Activities

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| 4.1 | How many locations will be involved?       |
| 4.2 | Is your company responsible for product design including subcontracted design? [ ]  Yes [ ]  No If yes, provide the total number of employees in design roles:        |
| 4.3 | Please check which of the following are the primary activities of the site (check all that apply but limit to the major functions of the site): [ ] Manufacturing [ ]  Administrative Headquarters[ ]  Distribution Center [ ]  Energy Distribution[ ]  Energy Generation[ ]  Assembly [ ]  Sterilization[ ]  Corporate Headquarters [ ]  Service [ ]  Repair [ ]  Kitting and Packaging [ ]  Transportation [ ]  Warehousing [ ]  Other Please specify        |
| 4.4 | Please indicate the proposed scope for your management system:         |
| 4.5 | Does any work take place on customer premises, for which your organization is responsible? [ ]  Yes [ ]  NoIf yes, please describe.        |
| 4.6 | List any processes/activities/ products/services to be included in the scope of registration that are outsourced or write n/a.       |
| 4.7 | What are the key production and/or service processes that apply to the manufacturing, service, design, or design technology processes? (Examples include: molding, welding, and/or forming)       |

# 5. Translator and Use of Consulting Services

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| 5.1 | Is there anyone in the organization that cannot communicate verbally in English?[ ]  Yes [ ]  NoIf yes, please specify:Language(s):      Number of Employees:       Process(es) where they work:       Is there a need for written language skills other than English? [ ]  Yes [ ]  NoIf yes, please specify language(s):       |
| 5.2 | Are you using a consultant? [ ]  Yes [ ]  No If yes, please list.       |

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# 6. Core Services

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| 6.1 | Are you an existing customer?       |
| 6.2 | If you are not design responsible, please identify which of your customers are design responsible (type n/a if not applicable):       |
| 6.3 | Please list any regulatory requirements applicable to the products/services included in the scope of registration (type n/a if not applicable):       |
| 6.4 | Are you interested in integrated audits of the management system? [ ]  Yes [ ]  No  |
| **If you answered No to question 6.4, please skip questions 6.5-6.13** |
| 6.5 | Please list the standards which are integrated.        |
| 6.6 | Do you have integrated documentation including work instructions to a good extent?  [ ]  Yes [ ]  No  |
| 6.7 | Do you have an integrated management review that considers the overall business strategy and plan? [ ]  Yes [ ]  No  |
| 6.8 | Do you have an integrated approach to internal audits? [ ]  Yes [ ]  No  |
| 6.9 | Do you have an integrated approach to policy and objectives? [ ]  Yes [ ]  No  |
| 6.10 | Do you have an integrated approach to processes? [ ]  Yes [ ]  No  |
| 6.11 | Do you have an integrated approach to improvement mechanisms like corrective action, risk-based approach, measurement, and continual improvement? [ ]  Yes [ ]  No  |
| 6.12 | Do you have an integrated management with responsibility and authority for conformance of all management systems? [ ]  Yes [ ]  No  |
| 6.13 | Please add any comments in regard to the integration questions if explanations are needed.        |
| **Additional Core Services** |
| 6.14 | Does your organization fall under export control requirements which require the auditor to have a specific citizenship?[ ]  Yes [ ]  NoIf yes, please list the requirements |
| 6.15 | Please list any processes/products that cannot be assessed because they are classified (please type n/a if not applicable):       |

**Medical Devices – ISO 13485**

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| --- | --- |
| 6.16 | Do you design and/or manufacture a finished medical device? [ ]  Yes [ ]  No If yes, what type of medical device?        |
| 6.17 | Do you design and/or manufacture a component? [ ]  Yes [ ]  No  |
| 6.18 | Please list your primary medical device products or components:        |
| 6.19 | Will you require a CMDCAS and/or notified body? [ ]  Yes [ ]  No  |
| 6.20 | Are you currently registered or planning to register with the FDA or another regulatory jurisdiction?       |

# 7. Service Delivery Timeframe

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| 7.1 | If you would like an optional gap assessment, what is your preferred month you’d like to have it?       |
| 7.2 | What is your preferred month for your certification assessment?       |

# 8. Additional Information

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| 8.1 | Please provide any additional information that you feel may be helpful as we prepare and conduct the auditing activities you have requested.       |

Date:

Name:

Position: