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**.

1. Name and Location of the Facility:

If DQS's services are required for more than one facility, please complete a separate form for each facility. 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:

1.1	Company name:	
1.2	Facility address (please do not include P.O. boxes):	
1.3	Facility mailing address (if different from 1.2. above):	
1.4	Name of Representative:	Alternate Representative:
1.5	Representative Position:	Alternate Representative Position:
1.6	Telephone numbers:	
1.7	Fax numbers:	
1.8	Cell or mobile numbers:	
1.9	Email addresses:	

2. Company Information

2.1	Does your company trade under any other name? ☐ Yes ☐ No If yes, please list the company trade name.
2.2	Is your company part of a larger organization? ☐ Yes ☐ No
2.2	If yes, please give name of holding company.
2.4	Does your company consist of remote locations that support the main site and is contributing to the overall registration? If yes, please list locations and activities.
2.5	Does your company consist of multiple sites that perform manufacturing, distribution or service? If yes, please list locations and activities.
2.6	To which standards/specification are you seeking registration? ☐ ISO 9001 ☐ ISO 13485 Other
2.7	Is your company currently registered to ISO 9001 or similar Standards? ☐ Yes ☐ No If yes, to which standards (AS9100, ISO/TS 16949, etc.):
2.8	Is DQS your Registrar? ☐ Yes ☐ No If no, what is the name of the register? What is the effective date of the certificate? Is there a Accreditation Body marks are on the certificate? ☐ Yes ☐ No If so, what mark?
2.9	Please provide details of any other approvals granted by certifying bodies.

2.10	Are you using a Consulting Agency? ☐ Yes ☐ No If yes, list the Agency.

3. Facility Information

3.1	Total number of employees at this facility:
3.2	Total number of employees in administration:
3.3	Is your company responsible for product design including subcontracted design? ☐ Yes ☐ No If yes, provide the total number of employees in the design department: If no, list the Customer(s) who are design responsible: If all customers are design responsible, check yes. ☐ Yes
3.4	Total number of employees in the production/service department:
3.5	Please list how many shifts and employee headcount for each shift, including temporary employees:
3.6	What is the operational schedule of the facility? Explain if Seasonal. ☐ A. Continuous (year round) ☐ B. Seasonal
3.7	Please describe the scope of activity at the facility for which registration is sought.
3.8	List any processes/ products/services to be included in the scope of registration that are outsourced (for example: sterilization, lab testing, etc.)
3.9	Please list any regulatory requirements applicable to the products/services included in the scope of registration, for example RoSH, FDA CFRs:
3.10	Do you design and/or manufacture finished medical devices, components that are incorporated into medical devices or both?
3.11	Please identify key manufacturing/ service processes and key design technologies:
3.12	What is your target date for registration?
3.13	What is your target date for a Preliminary Evaluation if desired?
3.14	Is your quality manual completed?

4. Category Information

4.1	Please list the product lines and / or services that are provided under your facility's medical devices and/or components and the SIC Codes, NAICS Codes, EA Codes or NACE Codes
4.2	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 ☐ Design / R&D ☐ Warehousing, Transport and/or Distribution ☐ Contract Manufacturing ☐ Kitting and Packaging ☐ Assembly ☐ Sterilization ☐ Corporate Headquarters or Administrative Headquarters ☐ Service or Repair location ☐ Other Please specify Please list your primary manufacturing or service processes:_
4.3	Please indicate the proposed scope of activity for which facility registration is sought.

4.4	Does any work take place on customer premises, for which your organization is responsible? ☐ Yes ☐ No If yes, please provide details.
4.5	Please list your primary medical device products or components.
4.6	Please list your primary customers or end users:

5. DQS Inc. Services

5.1	Will a translator(s) be necessary in order for DQS to provide any of the following services? ☐ Yes ☐ No If so, please indicate for which language(s):
5.2	Pre-Assessment Meeting (optional service). The purpose is to enhance your company's understanding of your ISO13485, ISO 9001 medical program management system and explain the mechanics of our registration program. We can also help your company assess its needs regarding the scope of registration, selection of facilities to be registered, organizational structure and proposed schedules. Is your company interested in this service? ☐ Yes ☐ No If yes, please list a preferred date:
5.3	Preliminary Evaluation (optional service). A preliminary evaluation is a limited investigation of a facility's management system to ISO13485, ISO 90001. After the evaluation, DQS documents the investigation's findings, but will not draw conclusions regarding the eligibility of the facility for registration to the applicable standard(s). However, you can use the information obtained during a preliminary evaluation to streamline the registration assessment processes. Is your company interested in this service? ☐ Yes ☐ No If yes, please list a preferred date:
5.4	Registration Assessment The registration assessment is conducted in two stages – Stage 1 is a Readiness Review and Stage 2 is the Registration Audit. Stage 1 is normally conducted on-site and can be combined with the Preliminary Audit. As the Stage 1 will assess your level of conformity and readiness for certification, it is to be conducted after you have implemented your internal audit and management review systems. A separate Stage 1 report will be generated noting any concerns and a recommendation for whether the Stage 2 can be performed as scheduled or needs to be postponed. Stage 2 is required to determine the compliance of a Quality Management System to the requirements of ISO13485 including risk management. When the facility's QMS meets these requirements, a Certificate of Registration will be granted.
5.5	Continuous Assessments. In order to maintain your Registration, ongoing annual or semi-annual Continuous Assessments are required, including a Triennial Reassessment once every third year after Registration.

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6. Additional Information

6.1	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: