

# MEDICAL DEVICES MANAGEMENT SYSTEMS ISO 13485 CERTIFICATION QUESTIONNAIRE

PLEASE COMPLETE THIS QUESTIONNAIRE AND ATTACH ANY RELEVANT SUPPORTING INFORMATION DESCRIBING THE COMPANY'S MEDICAL DEVICES SYSTEM AND ACTIVITIES, e.g. COMPANY PUBLICITY MATERIAL. ON RECEIPT OF THE COMPLETED QUESTIONNAIRE AJA REGISTRARS WILL PREPARE AND SUBMIT FOR YOUR APPROVAL A PROPOSAL DETAILING AUDIT OR TRANSFER COSTS AND TIMESCALES.

COMPANY NAME				
COMPANY ADDRESSES TO BE CERTIFIED (ADD MORE LINES IF REQUIRED)	Head Office:			
	Address 2:			
	Address 3:			
	Address 4:			
	Address 5:			

MULTISITE APPLICANTS: DOES EACH SITE FOLLOW A COMMON SYSTEM	<input type="checkbox"/>	TOTAL NUMBER OF SITES TO BE REGISTERED AS A MULTISITE	<input type="text"/>
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CONTACT NAME		POSITION	
TELEPHONE		FAX	
E-MAIL		WEBSITE	
NAME OF CONSULTANT (IF USED)			
OTHER CERTIFICATIONS HELD			

TYPE OF APPLICATION (PLEASE SELECT FROM THE FOLLOWING OPTIONS)							
NEW	<input type="checkbox"/>	RENEWAL	<input type="checkbox"/>	TRANSFER	<input type="checkbox"/>	SCOPE EXTENSION	<input type="checkbox"/>

**IF YOU ARE TRANSFERRING FROM ANOTHER CERTIFICATION BODY, PLEASE PROVIDE A COPY OF YOUR CURRENT ACCREDITED REGISTRATION CERTIFICATE AND YOUR TWO PREVIOUS CERTIFICATION BODY REPORTS**

Have you received Training or other services from AJA in the preceding 2 year period- if YES please provide dates and detail of the service provided	<input type="text"/>
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EMPLOYEES	TOTAL NUMBER OF STAFF	MANUFACTURING STAFF	SERVICE STAFF	STAFF WORKING OFF SITE	TOTAL STAFF AVAILABLE DURING THE AUDIT
FULL TIME					
PART TIME					
TEMPORARY					
SHIFT WORK (Y/N)		NUMBER OF SHIFTS		NUMBER OF PERSONNEL ON EACH SHIFT	

PLEASE DESCRIBE THE GENERAL SCOPE OF YOUR BUSINESS ACTIVITY WHICH YOU INTENDED TO INCLUDE WITHIN THE SCOPE OF REGISTRATION. THE INFORMATION PROVIDED HERE WILL BE USED BY AJA REGISTRARS TO DEFINE YOUR COMPANY'S SCOPE OF REGISTRATION

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MEDICAL DEVICE CLASSIFICATION	ARE THE DEVICES CE MARKED (Y/N)
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IF THEY ARE NOT MARKED THEMSELVES DO THEY FORM PART OF CE MARKED DEVICES (Y/N)	
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ARE THEY PRIMARY DEVICES OR COMPONENT/SUB-ASSEMBLIES	
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ARE THE DEVICES EXPORTED TO, OR SOLD WITHIN THE E.U. (Y/N)	
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PLEASE PROVIDE DETAILS OF ANY PART OF YOUR COMPANY'S OVERALL ACTIVITY THAT IS OUTSOURCED TO OTHER SUBCONTRACTORS/CONTRACTORS

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IF YOUR COMPANY CARRIES OUT WORK AT CUSTOMER SITES PLEASE PROVIDE DETAILS BELOW OF THE WORK CARRIED OUT BY YOUR COMPANY	TYPICAL NUMBER OF SITES OPERATING AT ANY TIME
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PLEASE INDICATE ANY EXCLUSIONS FROM THE STANDARD THAT YOUR COMPANY HAVE NOMINATED

7.1	7.2	7.3	7.4	7.5.1	7.5.2	7.5.3	7.5.4	7.5.5	7.6
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PLEASE INDICATE ANY FURTHER CERTIFICATIONS YOUR COMPANY MAY BE INTERESTED IN

ISO 9001	ISO 14001	ISO 18001	ISO 22000	ISO 27001	BS 8555	OTHER
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SIGNED	DATE
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IN SIGNING, I HEREBY DECLARE THAT THE DETAILS SHOWN ABOVE ARE CORRECT AND COMPLETE TO THE BEST OF MY BELIEF

**FOR A CERTIFICATION QUOTATION PLEASE RETURN THIS QUESTIONNAIRE TO YOUR LOCAL AJA REGISTRARS OFFICE**

POSITION HELD IN COMPANY
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**THE CERTIFICATION MANAGER**

**AJA REGISTRARS LTD, UNIT 6, GORDANO COURT, GORDANO GATE BUSINESS PARK, SERBERT CLOSE, PORTISHEAD, BRISTOL, BS20 7FS. FAX: 01275 849198**