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 GITCHIA LIMITED 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		TOTAL NUMBER OF SITES TO BE REGISTERED AS A MULTISITE	

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		RENEWAL		TRANSFER		SCOPE EXTENSION	

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 GITCHIA in the preceding 2 year period- if YES please provide dates and detail of the service provided

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 GITCHIA LIMITEDTO DEFINE YOUR COMPANY'S SCOPE OF REGISTRATION

MEDICAL DEVICE CLASSIFICATION		ARE THE DEVICES CE MARKED (Y/N)	

IF THEY ARE NOT MARKED THEMSELVES DO THEY FORM PART OF CE MARKED DEVICES (Y/N)
ARE THEY PRIMARY DEVICES OR COMPONENT/SUB-ASSEMBLIES
ARE THE DEVICES EXPORTED TO, OR SOLD WITHIN THE E.U. (Y/N)

PLEASE PROVIDE DETAILS OF ANY PART OF YOUR COMPANY'S OVERALL ACTIVITY THAT IS OUTSOURCED TO OTHER SUBCONTRACTORS/CONTRACTORS

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	

PLEASE INDICATE ANY EXCLUSIONS FROM THE STANDARD THAT YOUR COMPANY HAVE NOMINATED

6.1		6.2		6.3		6.4		7.1		7.2		7.3		7.4		7.5		7.6		8.1		8.2		8.3		8. 4	

Do you consider that the exclusion of any of these clauses will affect your ability to meet customer and regulatory requirements Y/N?

PLEASE INDICATE ANY FURTHER CERTIFICATIONS YOUR COMPANY MAY BE INTERESTED IN

ISO 9001 ISO 14001 ISO 18001 ISO 22000 ISO 27001 ISO 22301 OTHER

PRIVACY

By signing this form, we declare that the data shown here are correct and complete. We also declare to have read the GITCHIA information published on the Certification Body's website. The data provided will be processed for the purpose of technical / economic offer formulation.
I authorize GITCHIA to process personal data for marketing, direct sales and market research purposes.

SIGNED		DATE	

IN SIGNING, I HEREBY DECLARE THAT THE DETAILS SHOWN ABOVE ARE CORRECT AND COMPLETE TO THE BEST OF MY BELIEF

POSITION HELD IN COMPANY

FOR A CERTIFICATION QUOTATION PLEASE RETURN THIS QUESTIONNAIRE TO YOUR LOCAL GITCHIA

Info@gitchiagroup.com

THE COMPLIANCE MANAGER

GITCHIA Limited, Unit 5, Middle Bridge Business Park, Bristol Road, Portishead, BS 20 6PN, UK

TO BE COMPLETED BY GITCHIA LIMITED REGISTRARS STAGE 1/ RE-ASSESSMENT AUDITOR ONLY:		
I confirm that the information provided in the above Questionnaire has been verified. Where further information is available this has been recorded in the Stage 1 Report	**Name:**	
	Signature:	