MDMS - ISO 13485 MEDICAL DEVICES MANAGEMENT SYSTEM CERTIFICATION QUESTIONNAIRE

PLEASE COMPLETE THIS QUESTIONNAIRE AND ATTACH ANY RELEVANT SUPPORTING INFORMATION DESCRIBING THE COMPANY'S QMS AND ACTIVITIES, (e.g. COMPANY PUBLICITY MATERIAL). ON RECEIPT OF THE COMPLETED QUESTIONNAIRE A CUBE TIC LIMITED WILL PREPARE AND SUBMIT FOR YOUR APPROVAL A PROPOSAL DETAILING AUDIT OR TRANSFER COSTS AND TIMESCALES.

SECTION 1 – ENQUIRY DETAILS

HOW DID YOU LEARN OF A CUBE TIC's?

REFERRAL FROM CONSULTANTS?	YES ❑	NO❑
A CUBE TIC LIMITED WEB SITE?	YES❑	NO❑
DIRECT CONTACT FROM A CUBE TIC LIMITED PERSONNEL?	YES❑	NO❑
ADVERTISING?	YES❑	NO❑
ACCREDITATION BODY WEB SITE	YES❑	NO❑

SECTION 2 – HEAD OFFICE/MAIN SITE DETAILS

TYPE OF APPLICATION	NEW ❑	RE ASSESSMENT ❑	TRANSFER ❑	SCOPE EXTENSION ❑
REASON FOR TRANSFER (WHEN APPLICABLE)				
(if this is a transfer, please provide the valid certificate and previous reports of the current 3-year certification cycle)				
LEGALLY REGISTERED COMPANY NAME				
COMPANY ADDRESS (including post or Zip code)				
IS THIS ENQUIRY FOR MORE THAN ONE PHYSICAL SITE/LOCATION.	YES ❑	NO ❑	IF "YES" PLEASE ALSO COMPLETE SECTION 8 OF THIS QUESTIONNAIRE.	
PLEASE DESCRIBE THE COMPANY'S BUSINESS ACTIVITY (SCOPE)				

SECTION 3: EMPLOYEES/WORK FORCE

TOTAL NUMBER OF STAFF	
NUMBER OF PART TIME STAFF	
TOTAL NUMBER OF OFFICE STAFF	
TOTAL NUMBER OF PRODUCTION/SERVICE STAFF	
NUMBER OF EMPLOYEES WORKING OFF SITE	
NUMBER OF EMPLOYEES SEASONAL WORK (IF ANY)	
TOTAL STAFF AVAILABLE DURING THE AUDIT	

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SHIFT WORK

IS SHIFT WORK OPERATED ON THE SITE OR SITES INVOLVED IN THIS ENQUIRY?	YES ❑	NO ❑
IF "YES" - HOW MANY SHIFTS?		
TOTAL NUMBER OF STAFF ON EACH SHIFTS		
ARE THE ACTIVITIES OF EACH SHIFT IDENTICAL?	YES ❑	NO ❑
IF "NO" PLEASE DETAIL THE DIFFERENT ACTIVITIES BETWEEN EACH SHIFT		
PLEASE PROVIDE THE SHIFT START AND FINISH TIMES		

SECTION 4 – PROCESS DETAILS

PLEASE DESCRIBE THE GENERAL SCOPE OF YOUR BUSINESS ACTIVITY (SALES, MANUFACTURE, DESIGN AND MANUFACTRE, PROVISION OF SERVICES ETC) WHICH YOU INTEND TO INCLUDE WITHIN THE SCOPE OF REGISTRATION. IN ADDITION, CLEARLY DESCIBE THE DIVICES, COMPNENTS OR SERVICES PROVIDED. THE INFORMATION PROVIDED HERE WILL BE USED BY A CUBE TIC LIMITED (TRADING AS ACT & A CUBE) TO DEFINE YOUR COMPANY'S SCOPE OF REGISTRATION					
DEVICE CLASSIFICATIONS (LOCAL)					
ARE THE DEVICES CE MARKED (Y/N)	YES❑	NO❑	ARE THE DEVICES UKCA MARKED?	YES❑	NO❑
ARE THEY PRIMARY DEVICES OR COMPONENT/SUB-ASSEMBLIES?					
COMPETENT AUTHORITY REGISTRATION NUMBER			NAME OF COMPETENT AUTHORITY		
ARE THE DEVICES EXPORTED TO, OR SOLD WITHIN THE EEC? (Y/N)	YES❑	NO❑	WHO IS YOUR APOINTED REPRESENTATIVE		
ARE THE DEVICES EXPORTED TO, OR SOLD WITHIN THE UK? (Y/N)	YES❑	NO❑	WHO IS YOUR APOINTED REPRESENTATIVE		

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ARE YOU INTENDING TO SELF-DECLARE FOR CE AND/OR UKCA MARKING?	
IF YOU MANUFACTURE IVD DEVICES, WHAT CLASSIFICATION ARE THEY*	

**Manufacturers of IVD medical devices will have to comply with the requirements of the new European Regulation by 26 May 2022 in order to continue to place their devices on the European Union market.*

IF YOU ARE A MANUFACTURER OF PARTS FOR USE IN MEDICAL DEVICES, OR YOU PROVIDE SUPPORT SERVICES, WHAT TYPE OF DEVICES ARE THESE PARTS OR SERVICES ASSOCIATED WITH? (INDICATE 'NOT KNOWN' IF YOUR CUSTOMERS DO NOT PROVIDE THIS INFORMATION)

FINISHED MEDICAL DEVICE CATEGORY	DETAILS OF EACH DEVICE
NON-ACTIVE MEDICAL DEVICES	
ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES	
ACTIVE IMPLANTABLE MEDICAL DEVICES	
IN VITRO DIAGNOSTIC MEDICAL DEVICES	
STERILISATION SERVICES	
CALIBRATION SERVICES	ACCREDITATION TO ISO 17025 IS MANDATORY

ARE YOU PROVIDING A SUPPORT SERVICE SUCH AS CALIBRATION ETC. (Y/N)	YES❑ NO❑	

BASED ON THE DECLARED SCOPE OF BUSINESS AND NUMBER OF EMPLOYEES, PLEASE COMPLETE BELOW

PROCESSES INVOLVED	EMPLOYEE NUMBERS

PLEASE PROVIDE DETAIL OF ANY OUTSOURCED PROCESSES/SUB PROCESSS *Enter on the right the number of companies or freelancers generally used*	NUMBER OF OUTSOURCERS /SUB CONTRACTORS (companies) USED/INVOLVED

IF YOUR COMPANY CARRIES OUT WORK AT CUSTOMER SITES (SUCH AS INSTALATION AND COMMISSIONING), PLEASE PROVIDE DETAILS BELOW OF THE WORK CARRIED OUT BY YOUR COMPANY	TYPICAL NUMBER OF SITES OPERATING AT ANY TIME	

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SECTION 5 – MANAGEMENT SYSTEM DETAILS

WAS THE MDMS DEVELOPED/UPDATED WITH THE SUPPORT OF A CONSULTANT? *If yes, please provide the Consultant Company name and the Consultant name* ARE INTERNAL AUDITS PERFORMED BY EXTERNAL PERSONNEL? *if yes, please provide the name*
PLEASE NOTE THAT IT IS POSSIBLE THAT THE EXTERNAL PROFESSIONAL/CONSULTANT YOU NOMINATE, MAY HAVE A BUSINESS RELATIONSHIP WITH OUR ORGANISATION (EVEN A REMUNERATED ONE). SUCH A RELATIONSHIP DOES NOT PUT YOUR COMPANY IN AN ADVANTAGEOUS POSITION AND WILL NOT AFFECT THE CERTIFICATION PROCESS.

PLEASE INDICATE ANY PERMISSABLE 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?														YES ❑						NO ❑					

IS YOUR COMPANY ALREADY CERTIFIED BY AN ACCREDITED 3RD PARTY CERTIFICATION BODY IN ANY OF THE STANDARDS BELOW?											
14001	❑	45001	❑	27001	❑	22000	❑	9001	❑	others	❑
IF "YES" PLEASE PROVIDE THE NAME OF THE CERTIFICATION BODY INVOLVED							❑				

SECTION 6 – CONTACT INFORMATION

PRIVACY

BY SIGNING THIS FORM, YOU DECLARE THAT THE INFORMATION PROVIDED IS CORRECT AND COMPLETE.
YOU ALSO DECLARE THAT YOU HAVE READ THE A CUBE TIC LTD INFORMATION NOTICE PUBLISHED ON THE COMPANY'S WEBSITE, THAT YOU HAVE READ THE INFORMATION CONTAINED THEREIN AND THAT YOU GIVE YOUR FREE AND INFORMED CONSENT TO THE FOLLOWING TYPES OF PROCESSING:

A. PROCESSING OF PERSONAL DATA FOR MARKETING, DIRECT SALES AND MARKET RESEARCH PURPOSES

I CONSENT ☐ I REFUSE CONSENT

B. COMMUNICATION OF PERSONAL DATA TO OTHER COMPANIES IN THE A CUBE TIC LTD GROUP

I GIVE CONSENT ☐ I REFUSE CONSENT

NAME		SIGNATURE	
POSITION		DATE OF COMPLETION	
EMAIL ADDRESS		PHONE NUMBER	

We inform you that, as a data subject, you have the right to withdraw your consent for one or more processing purposes at any time. This revocation, however, in no way affects the lawfulness of the processing carried out by us on the basis of the consent you have previously granted us.

PLEASE RETURN COMPLETED QUESTIONNAIRE TO A CUBE TIC Limited
OR TO YOUR LOCAL A CUBE TIC LIMITED's OFFICE

A CUBE TIC LIMITED: Unit 5, Middle Bridge Business Park, Bristol Road, Portishead, BS 20 6PN, UK
Tel: +44 - 01275 397423; E-mail: K.Bashar@acubetic.com

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SECTION 7 – AUDITOR CONFIRMATION (*A CUBE TIC LIMITED USES ONLY*)

TO BE COMPLETED BY THE APPOINTED A CUBE TIC LIMITED LEAD AUDITOR AT TIME OF THE STAGE 1 OR RECERTIFICATION/EXTENSION AUDIT ARISING FROM ENQUIRY AND PRESENTED WITHIN THE RELEVANT PACKAGE
I CONFIRM THAT THE INFORMATION AND DATA SHOWN ON THE COMPLETED QUESTIONNAIRE IS VALID AND ACCURATE TO THE COMPANY CIRCUMSTANCES SEEN AT THE TIME OF THE STAGE 1 AUDIT/RECERTIFICATION - *(Note – if any significant discrepancies between the information and data shown on the Questionnaire and those observed during the Stage 1 audit/ recertification are identified these must be brought to the attention of the company and to the attention of the A Cube TIC Limited's office Accreditation Review Officers immediately as these may impact the validity of the original proposal and contract as well as the adequacy of audit planning)*

Name		Signature		Date	

SECTION 8 - MULTISITES ONLY

SITE ADDRESS	ACTIVITIES INVOLVED (SCOPE)	TOTAL EMPLOYEE	SHIFT WORK YES/NO	START AND END TIME OF EACH SHIFT