

	n			
Name of Organisation	VISAT ENGINEERING COLLEG	E		
Name of corporate group (in case of multi site organization only)				
Street	Vijnan Nagar, Nelloorupara, Muth District	Vijnan Nagar, Nelloorupara, Mutholapuram Post, Elanji, Ernakulam District		
Postcode / Town / Country	686665 / Kerala / India	686665 / Kerala / India		
Contact	Ms.Divya Nair (MR), Dr.Anoop K (Director – Administrator)	Ms.Divya Nair (MR), Dr.Anoop K. J (Ptincipal), Mr.Pramod Nair (Director – Administrator)		
E-Mail	asst-prof-divya@visat.ac.in, princdirector-admin@visat.ac.in	asst-prof-divya@visat.ac.in, principal@visat.ac.in, director-admin@visat.ac.in		
Phone	9496266228, 887027177, 80545	89500		
Multi-site organisation	All sites are listed in: ☐ Audit reference data sheet ☐ Separate listing ☐ Audit program/ATEA (calculation)			
Shift operation				
System documentation: (Revision / Issue)	VISAT/EOMS/MDI/2022, Issue N	lo: 01, Rev: 00, Dated: 07.02.2022		
Language	English			
Audit profile ?				
Contract ID (ZE):	Q 12381			
Standards under contract / Audit type	ISO 21001 : 2018 Certification Audit (Stage 2) Transition audit (Partly) Remote ICMED 13485 Issue 2 Transition audit (Partly) Remote	ISO 13485:2016 □ Transition audit □ (Partly) Remote ICMED 9000 Issue 2 □ Transition audit □ (Partly) Remote		
Surveillance mode		•		
Audit team leader	Sathish Kumar R (SR)			
Audit team	Nil			
Technical expert	Nil			
Technical expert Trainee	Nil Nil			



Audited Standards				
ISO 21001 : 2018		Certification Audit		
Certificate ID (TP):	NA since Initial Audit	Valid until: NA		
Scope: Providing Educational S	gree in Engineering & Technology.			
Industry / Sector (EA, TB,)				
Non-applicability of chapters:				
No. of considered persons: 42		No. of sites (incl. HQ): 1		
Lead auditor:	Sathish Kumar R	Audit ID (ZA): Q 12381/2023		
ISO 13485 : 2016				
Certificate ID (TP):		Valid until:		
Scope:				
Industry / Sector (EA, TB,)				
Non-applicability of chapters:				
No. of considered persons:		No. of sites (incl. HQ):		
Lead auditor:		Audit ID (ZA):		
ICMED 13485 Issue 2				
Certificate ID (TP):		Valid until:		
Scope:				
Industry / Sector (EA, TB,)				
Non-applicability of chapters				
No. of considered persons:		No. of sites (incl. HQ):		
Lead auditor:		Audit ID (ZA):		
ICMED 9000 Issue 2				
Certificate ID (TP):		Valid until:		
Scope:				
Industry / Sector (EA, TB,)				
Non-applicability of chapters:				
No. of considered persons:		No. of sites (incl. HQ):		
Lead auditor:		Audit ID (ZA):		

Audit Details					
Sites	VISAT ENGINEERING COLLEGE Vijnan Nagar, Nelloorupara, Mutholapuram Post, Elanji Ernakulam District – 686665, Kerala, India.				
Audit date	04.04.2023 - 05.04.2022				
Audit duration	2,00 person days on site (incl. remote locations as applicable) inclusive 1,00 person days on site for audit stage 1 (separate report)				
Remote Auditing (ICT) tools used, if	□ Skype □ MS Teams □ Webex □ Zoom □ Google Meet				
any	☐ Others : Please specify				

Organisation: VISAT ENGINEERING COLLEGE

Audits (ZA): Q 12381/2023



Distribution/Confidentiality/Rights of ownership/Limitations/Responsibilities

This report is sent to the certification body or bodies, the members of the audit team and the audit representative of the organisation. All documents (such as this report) regarding the certification procedure are treated confidentially by the audit team and the certification body. This audit report remains the property of the certification body.

An audit is a procedure based on the principle of random sampling and cannot cover each detail of the management system. Therefore nonconformities of weaknesses may still exist which were not expressly mentioned by the auditors in the final meeting or in the audit report.

The responsibility for continuous effective operation of the management system always rests solely with the audited and certified organisation.

Salvo clause:

The audit report will be left to the organisation at the end of the audit - subject to approval by the certification body. The independent veto process may cause modifications or additions. In these cases a modified revision will be sent to the audited organisation.

Houried Tevision will be some to the dualted organisation.			
Annex/Enclosures			
Annex/ corresponding audit documentation	☐ Questionaire(s) / Checklist(s)		
	☐ Additional annexes, number		

Audits (ZA): Q 12381/2023



ISO 2	1001:201	18	ISO 13	3485:201	16	ICEMD	9000 Iss	ue 2	ICMED 13	8485 Iss	485 Issue 2	
Clause	Audit ed	Resul ts*	Clause	Audit ed	Resul ts*	Clause	Audit ed	Resul ts*	Clause	Audit ed	Resul ts*	
4.1	\boxtimes	1	4.1			4.1			4.1			
4.2	\boxtimes	1	4.2			4.2			4.2			
4.3	\boxtimes	1	5.1			4.3			4.3			
4.4	\boxtimes	1	5.2			5			5			
5.1	\boxtimes	1	5.3			6.1			6.1			
5.2	\boxtimes	1	5.4			6.2			6.2			
5.3	\boxtimes	1	5.5			6.3			6.3			
6.1	\boxtimes	1	5.6			7.1			7.1			
6.2	\boxtimes	1	6.1			7.2			7.2			
6.3	\boxtimes	1	6.2			7.3			7.3			
7.1	\boxtimes	1	6.3			7.4			7.4			
7.2	\boxtimes	1	6.4			7.5			7.5			
7.3	\boxtimes	1	7.1			8.1			8.1			
7.4	\boxtimes	1	7.2			8.2			8.2			
7.5	\boxtimes	1	7.3			8.3			8.3			
8.1	\boxtimes	1	7.4			8.4			8.4			
8.2	\boxtimes	1	7.5									
8.3			7.6									
8.4	\boxtimes	1	8.1									
8.5	\boxtimes	1	8.2									
8.6	\boxtimes	1	8.3									
8.7	\boxtimes	1	8.4									
9.1	\boxtimes	1	8.5									
9.2	\boxtimes	1										
9.3	\boxtimes	1										
10.1	\boxtimes	1										
10.2	\boxtimes	1										
10.3	\boxtimes	1										
Additional r	equiremer	nts in ac	cordance to I	SO 1702	1:2015							
			management							\boxtimes	1	
b) re	eview of a	ctions ta	ken on nonco	onformitie	s identi	fied in previo	ous audit			\boxtimes	1	
			complaints							\boxtimes	1	
			managemer					ectives		\boxtimes	1	
e) p	rogress of	planne	d activities air	ned at co	ntinual	improvemen	<u>ıt</u>			\boxtimes	1	
•		manage	ement system	ability an	id its pe	rtormance re	egarding m	eeting o	ot applicable	\boxtimes	1	
requireme			of the alleady								1	
			of the client's			t avatam da	numontati-				1	
			ges including								1	
<u>i) u</u>	se oi mari	ks and/d	r any other re	erence t	o certific	cation – Sind	<i>j</i> e muai Au	uit		\boxtimes	NA	

Mandatory elements from A00VA02

Temporary Sites

Audits (ZA): Q 12381/2023



a) Are temporary sites (i.e installation available?	on sites, project locations etc.)	□ Yes	⊠ No
b) If yes: which one are visited?	NA		
Objective evidences			

or the assessment of conformity the audit team has reviewed the following objective evidences.

s required (but at least in initial/recertification or extension audits) these objective evidences are attached adequately to the audit file and uploaded into the release workflow.

itle/Content	Edition	Attached
Entry in professional or commercial register (or comparable evidence) - if applicable	ICTE Approval: F:No: Southwest/1-10975921249/2022/EOA, Dated: 20.07.2022, for Academic Year 2022-2023. PT Abdul Kalam Technological University No: KTU/A/456/2015, Dated: 30.08.2022.	
Organization chart/evidence of organization	Organization Chart in VISAT/MDI/24, Rev:00, Dated: 07.02.2022	
Company policy for audited management systems	olicy in VISAT/MDI/22, Issue No: 01, Rev:00, Dated: 07.02.2022, Approved by Director Mr.Pramod Nair, Prepared by Deputy Co-Ordinator	
Overview of management system documentation (e.g. table of	rocess Map and Interactions VISAT/MDI/20, Issue No: 01, Rev:00, Dated: 07.02.2022	
contents or presentation of the structure of the management system documentation, process	rocedure for Control of Documented Information: VISAT/MDI/60, Issue No: 01, Rev:00, Dated: 07.02.2022	
map)	evel I: Manual, Level II: Procedure, Level III: Documents, Syllabus, Instruction, Level IV: Retained Doumented Information	
	laster List of Documented Information: VISAT/EOM/CCO/101.	
cover sheet or table of contents	rocedure for Management Review Meeting: VISAT/MDI/65	
with date and signature)	requency of MRM: Once in 6 Months. ast MRM dated: 05.01.2023.	
Current annual planning of internal	rocedure for Internal Audit: VISAT/MDI/61,	\boxtimes
audits and evidence of audit	requency of Internal Audit: Once in 6 Months	
report(s) (e.g.: cover sheet with date and signature)	ast IA dated: 11.11.2022 to 17.11.2022	
adio and oignaturo)	chedule dated: 04.11.2022.	
Standard-specific evidence, as applicable – (Medical manufacturing Licence, Regulatory	ICTE Approval: F:No: Southwest/1-10975921249/2022/EOA, Dated: 20.07.2022, for Academic Year 2022-2023.	
certificate etc.)	PT Abdul Kalam Technological University No: KTU/A/456/2015, Dated: 30.08.2022	
		ا بلم ماما مما

Confidential information in the attached evidences may be blacked.

Organisation: VISAT ENGINEERING COLLEGE

Audits (ZA): Q 12381/2023



Standard specific results

Additional standard specific audit results and/or information are recorded in corresponding "Supplemental audit reports" (e.g. for ICMED 9000 or ICMED 13485 Checklist).

Organisations profile

- •
- •
- •
- •
- •
- •

COMPANIES PROFILE CONTAINING FOLLOWING INFORMATION:

Established with the goal of uplifting talented young youth by delivering high standards of education, VISAT is an active initiative of the Vijnan Foundation, a charitable, educational trust. This organization is registered under the Indian Trust Act and comprises of a variety of like minded people in the pursuit of a common goal, including philanthropists, academicians and other professionals who value their social commitment of equipping the youth with the knowledge and skills that would enable them to be successful leaders of tomorrow.

Institution focus on holistic education and introduce international aspects to our curriculum while laying focus on research based studies so as to advance the knowledge of our students to a global scale, rendering them as career-ready professionals, who are skilled at 'smart' work as opposed to 'hard' work which is a prevailing corporate demand. Furthermore, we ensure that the knowledge we cater to the students is absorbed at a conceptual level as much as on a practical scale by providing numerous opportunities and assignments to gather hands on experience

Affiliated to the APJ Abdul Kalam Technological University, Thiruvananthapuram and approved by the All India Council for Technical Education (AICTE), New Delhi, VISAT is an educational venture of the Vijnan Foundation. This institution was established in 2011 and the campus is located in the scenic parts of the district, along the Western Ghats, offering spectacular views of the mighty hill ranges. At Vijnan, we are focused towards delivering excellent standards of education by implementing innovative teaching methodologies, imparted by an esteemed and highly experienced faculty. We cover all disciplines of engineering including CE, CSE, ECE, EEE and ME through the courses offered for undergraduates.

Social Responsability: Corona Virus (Covid-19) Pandemic Precaution, Safety, and Treatment support

during the Pandameic Time. Vaccination centre for the Near by Village. **Accessibility and equity**: Institution is Co-Education College with Male Students – 40%, Female Students – 60% of Total Strength.

Organisation: VISAT ENGINEERING COLLEGE

Audits (ZA): Q 12381/2023



Student are Accessible from Ernakulam by college Buses for Day Scholar.

Hostel Facility for Female Students are available.

Ethical Conduct in Education: Teaching of Yoga included in academica with other extra ciricular activity by center for human Resources.

Adherance to 100% requirments of Interseted Paties has been verified.

Proper Procedure for all Process has been derived and Acknowledged by the Staff to provide Ethical Conduct of Education.

Data Security and Protection: Institution has separate cloud ERP including Lesson Plan and monitoring, Result analysis, student Attendance Marking & Monitoring, Library Activity, Admission related Activity even though for Admission Hard copy is also maintained and Student History card is maintained to see the progress of Student from entry till exit of Institution.

The ERP is taken back up in defined frequency from server with External Hard disk for data protection that too in 2 device.

INFORMATION IF MULTI-SITE SCHEME IS APPLIED: NA

IF YES, LIST OF AUDITED SITES (E.G. IN AUDIT PROGRAM): NA
AND LIST OF CERTIFIED SITES BY THIS AUDIT AS ENCLOSURES

NUMBER OF EMPLOYEES: 42

Range of products: UG education in Mechanical Engineering, Civil Engineering, Computer Science Engineering, Electrical and Electronics Engineering, Electrical and Communication Engineering.

Clients / top clients / major clients : Students in and around Ernakulam District.

Important processes / products / services : Admission, Teaching, Internal Examination

Applicable Regulatory requirement & National and International Standards:

Legally required representatives (MR/ PRRC):

AICTE Approval: F:No: Southwest/1-10975921249/2022/EOA, Dated: 20.07.2022, for Academic Year 2022-2023.

APT Abdul Kalam Technological University No: KTU/A/456/2015, Dated: 30.08.2022.

Certified since? : NA since initial Certification

- _
- •
- •
- •

Summary of Results

Organisation: VISAT ENGINEERING COLLEGE

Audits (ZA): Q 12381/2023



SUMMARY:

ISO 21001 / ISO 13485/ ICMED 9000

requirements (Ref Checklist) were assessed in this audit.

- STATEMENT ON THE IMPLEMENTATION OF THE STANDARD REQUIREMENTS
 - O STRATEGICALLY DIRECTION OF THE ORGANISATION (CONTEXT, STAKEHOLDER ANALYSIS):
 Defined in VISAT/MDI/05, Rev: 00, Dated: 07.02.2022.

Internal and External Issue: VISAT/EOMS/CCO/116, Last Review Dated: 07.02.2022. Academic plan and strategy are reviewed, OK. External / Internal issues, Opportunities, Risks assessment and its action plan documents with respect to QMS, EMS & OH&SMS are reviewed, OK.

- **Ex 1:** Type of Issue: External Admission on time of Students.
- Ex 2: Type of Issue: Internal Coverage of Syllabus on time.
- O RISK-BASED APPROACH (ANALYSIS OF RISKS AND OPPORTUNITIES) / RISK ASSESSMENT PRODUCT REALIZATION REF STANDARD ISO 14971:

Risk and Opportunities are identified process wise and dynamically analysed and taken the control measures, considering Admission strategy. – Risk Management Addressed in Procedure for Risk and Opportunity Analysis VISAT/MDI/27, Rev:00, Dated: 07.02.2022, Last Review: 07.02.2022 & in MRM, for determining Risks and Opportunities, External / Internal issues, Opportunities, Risks assessment and its action plan documents with respect to EOMS. Process wise Risk and Opportunity: VISAT/ISO/CCO/018

- **Ex 1:** Function Admission, Intended Result Adherence to University Norms, Issue: Loss of Seats, External Issue, Category Culture, Type Negative, SWOT Analysis Threat, Risk Customer Input Data not Received on time, Risk Assessment, Likelihood 1, Consequence 2, Rating 2, Category Low
- O CONTROL OF EXTERNALLY PROVIDED PROCESSES: Guest Faculty with validation and assessment by on class verification by the Principal and also meeting the requirement of university norms.
- O SYSTEMATICALLY KNOWLEDGE MANAGEMENT (ORGANISATIONAL KNOWLEDGE):

Organisation: VISAT ENGINEERING COLLEGE

Audits (ZA): Q 12381/2023



Organisational knowledge is maintained through Manual, Standards, Procedures, Lesson Plan, Process documents, Syllabus, Admission register, CA reports, Competency / Skill developments, Training Manual etc., - Evidenced, OK

- O LEGAL AND OTHER OBLIGATIONS/ APPLICABLE REGULATORY REQUIREMENT:
 Anna University Affiliation 02/AFFLN/CAI/TVL/AU/2021-2022/9537, Dated: 10.08.2021
 DOTE Approval for Students AAA/DOTE/LE/2021-22/1813, Dated: 16.12.2021
- O MEASUREMENT AND CONTINUAL IMPROVEMENT: INSTITUTION WITH GRADE A IN NAAC ACCREDITATION AND AWARD OF PRICES IN DIFFERENT EVENTS AND PAPER PRESENTATION.
- For ICMED 13485 Statement on the implementation of the scheme requirements: NA
 - O SITE MASTER FILE -
 - O DEVICE MASTER FILE -
 - O ESSENTIAL PRINCIPLES FOR MANUFACTURING MEDICAL DEVICES -

Conclusion

Taking into account the size and structure of the organisation, the objectives, the scope of the management system, the processes and the outcome, the organisation has demonstrated, that it operates its management system in order to ensure fulfilment of its own requirements, the requirements of its customers and the relevant legal requirements as well as the applicable requirements of the management system standards.

This includes in particular:

- the objective evidences already mentioned,
- the policies and objectives and their implementation in the organisation,
- the processes existing in the management system and their interactions,
- the resource management,
- the measuring and analysis (incl. sample of indicators).
- the continual improvement process as well as
- the recording system (p.r.n. including standard specific objective evidences).

The implementation and the effectiveness of the management system and the processes for providing services/product realisation or to realize the objectives were assessed by the audit team by means of on-site inspection and examination of documents on a random sample basis.

Nonconformities are recorded in corresponding reports, other findings (as e.g. opportunities for improvement) are described in the section for "Detailed Results".



Notes	Notes for the detailed results				
The eva	The evaluation of the audit results basically follows the scheme shown below:				
Stage	Classification	Meaning			
NC A	Major Nonconformity (Nonconformity A)	 Nonconformities could be classified as major in the following circumstances: if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements, a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity. 			
NC B	Minor Nonconformity (Nonconformity B)	Nonconformities could be classified as minor, if these do not affect the capability of the management system to achieve the intended results.			
OFI	Opportunity for improvement	Items which would allow optimisation of the management system in relation to the requirements of the relevant standard. It is recommended that the company implements these items.			
GP	Positive aspects / Good Practice	Positive aspects of the management system worthy of special mention (see also point 4.3 if applicable).			
СМ	Comments	Special situation and information to be traced in next audit.			

Detailed results				
Summary for nonconformities				
Any identified nonconformity is recorded in	n an individual NC re	eport.		
In this audit From prevoius au				
Standard	Number NC A	Number NC B	Number NC	
ISO 21001 : 2018	0	1	0	
	0	0	0	
	0	0	0	
	0	0	0	
Total	0	1	0	
☐ During this audit the implementation of a audit was verified. The records are attack			nonformities of previous	

No	OFI (Opportunity for Improvement)	Area / Process	Standard:clause
110	con (opportunity for improvement)	7.11.00.7.7.7.00.000	
1.	Process of Reduction of Documents related to	Admission	ISO 21001:2018 -
1.	Students Property instead of having a separate	Admission	8.5.3
	Checklist and Register for Issue and Retrun / Special		0.0.0
	Reguest can be included in Check list for better		
	control		



2.	Process of Substitution of class in case of Faculty absent or due to Unavoidable circumstence evidenced and Verified. However the substitution class and Compensation hours of faculty can be recorded in the register either Course Diary / File for better control.	Teaching	ISO 21001:2018 – 10.2
4.	Procedure for Verification of Purchased Books & Equipments evidenced and verified, Whereas the Verification of same may be done by the concern requester to have Better control.	Purchase	ISO 21001:2018 – 8.4.2

No	GP (Good Practice)	Area / Process	Standard:clause
1.	Management Commitment towards implementation of system and Accreditation, Mission and Vission Appreciable	Top Management	ISO 21001:2018 – 5.1
2.	Competency Level of Faculty both Process and System wise Appreciable.	Training	ISO 21001:2018 – 7.2
No	CM (Comment)	Area / Process	Standard:clause
		•	
1.	Stability Certificate and Firs License to be verified in the next year Audit.	Administration	ISO 21001:2018 – 4.1

Total Results						
Results	ISO 21001:2018	ISO 13485:2016	ICMED 9000 Issue 2	ICMED 13485 Issue 2		
Fulfilled						
Open nonconformities	\boxtimes					
Not fulfilled						
Follow up actions						
None						
Action plan	\boxtimes					
Document review						
Follow up audit						



Next audit						
Recommendations						
Grant*/-Extension*/ Renewing*	\boxtimes					
Maintenance*						
Suspension						
Restoring						
Refuse						
Withdrawal						
^{*)} Grant / Extension / Renewing / Maintenance in the case of open nonconformities assumes that the nonconformities will be cleared as agreed						
Explanation of the terms:						
Renewing: New issue of the certificate for the re-certification.						
Restoring: End of the temporary invalidity of certificate after the suspension or after delayed re-certification.						
Comments for next audit						
If applicable, the final evidence of effectiveness and implementation of corrections and corrective actions for the nonconformities from this audit will be verified in the next audit.						
The comments and opportunities for improvement will be taken up again.						
The next audit is preliminarily scheduled for: 01st March 2023						
Responsible for content						
Name: R.Sathish Kumar	Dat	te: 05 th April 2023				
Signature audit team leader						