



2nd Stage Audit

**INITIAL ASSESSMENT REPORT
NO. 6G250826.YATQ049
IEC 61508:2023 Parts 1-7**



CUSTOMER GENERAL DATA

Yuesheng Automation Technology
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Has been assessed per the relevant requirements of:
IEC 61508:2023 Parts 1-7, ISO 13849-1:2023, ISO 14119: 2020, IEC 61496:2023, IEC 62061:2023

Model(s):LT-3DYS-AI-ZDH6, LT-3D-Series

Corresponding NACE Code or Category	IEC 61508:2023
Number of employees in the certified area	20
Number of filials outside of the registered seat	2
Special processes	
The certified processes are ensured	by own employees without exception
Number of Shifts	1.00

CERTIFICATION DATA PROCESS

Certification standard applied	IEC 61508:2023 IEC 62061:2023
Audit date	10/08/2025 08:00:00 - 11/08/2025 09:30:00
Place(s) of Audit	headquarters
Audit Coordinator and Lead Auditor	Fen chensong(IEC 61508:2023 EC 62061:2023)
Other participants of the audit (and their position)	Company management representative, director of quality department, director of technology department, director of production department, director of purchasing department
Audit Plan Date	11. August 2024
Total Audit Days (on the spot)	1.50 (1.19)
Deviation from the audit plan	NO
Significant issues impacting on audit programme or client's MS	NO
Consultant involved in management system support	ISO 9001
Audit (Report) language	English

1. AUDIT SCOPE

Audit Criteria

The audit criteria are the requirements of the standard and the established processes as well as the documentation of the organization's management system. The purpose of the audit is to confirm the compliance of the client's management system with the audit criteria, to determine the ability of the management system to ensure that the organization meets the relevant legal and other requirements (but the audit is not an audit of compliance with the legislation). Furthermore, the objective is to determine whether the effectiveness of the management system makes it possible to achieve the objectives set and identify areas for potential improvement.

Description of the audited company and its activities

Corporation details, infrastructure, working places and branch offices, organizational chart description

Juyi Pin is a high-tech enterprise integrating independent research and development, production, sales, and service. It was registered by an influential team of industry veterans and experienced industry investors and was established in 2023. The company's headquarters is located in Shenzhen. Juyi Pin has a total of four domestic subsidiaries focused on investment, R&D, production, and marketing: one R&D-oriented in South China, one production-oriented in South China, one marketing-oriented in South China, and one marketing-oriented in East China.

Manufacturing equipment or services support activities

Infrastructure, human resource management, technology development, production management and procurement management, and product verification testing.

Description of the main product or services

3D Stereoscopic Safety Protection Sensor and Product Configuration Function of WINDOWS System Setup Software

Human resources

N/A

Scope of certification

IEC 61508:2023 IEC 62061:2023

Areas excluded from certification

N/A

Audit Objectives

The audit objectives can, in terms of methodology: 1) confirm whether the client's management system complies with the audit standards, 2) determine the management system's capability to ensure the organization can meet applicable legal, regulatory, and contractual requirements, 3) achieve specified objectives, as the management system can identify potential areas for improvement, including quality reviews and manufacturing audits-completed.

Certification procedure

Disclaimer

Auditing is based on a sampling process of the available information and consequently there will always be an element of uncertainty present in auditing evidence, which may be reflected in the audit findings. Those relying or acting upon the audit results and conclusions should take into account this uncertainty.

Opening and closing meeting participants

Company management representative, director of quality department, director of technology department, director of production department, director of purchasing department

Audit methods

Remote video review and sample testing verification

Volume of sales, products, orders, services, as applicable

Please refer to the attachment for details

Description of sampling and sampling statistics

The samples were used correctly, the software and device settings were correct, and after testing they met the IEC 61508 certification standards. The product complies with ISO 13849-1:2023 certification. Two prototype samples were randomly selected for testing, and both met the SIL3 standard.

Significant changes impacting the MS of the organization occurred since the previous audit and unresolved issues

No

Certification reference (use of CE mark)

is used by common way and is not misleading and is not inconsistent with business conditions

2. SYSTEM DESCRIPTION AND COMPLIANCE MATRIX - IEC 61508:2023

System description

Conformance to this standard, Documentation

IEC 61508(Parts 1-7):2023 Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems

Management of functional safety, Hazard and risk analysis

Hazard analysis, risk assessment, and determination of ASIL levels are used to determine the safety objectives of relevant items to avoid unreasonable risks. Therefore, based on the potential hazardous events in the relevant items, evaluate the relevant items. Determine safety objectives and the ASIL level assigned to them through a systematic assessment of hazardous events. The ASIL level is determined by estimating the impact factors: severity, exposure probability, and controllability. The determination of the impact factors is based on the functional behavior of the relevant items, so it is not necessary to know the design details of the relevant items, Scenario analysis and hazard identification, classification of hazardous events, determination of levels and safety objectives External events that should be considered in hazard and risk analysis should be identified Equipment and systems related to hazards and hazardous events should be identified The types of events that trigger accidents that need to be considered (such as component failures, program failures, human errors, and related failure mechanisms that can lead to hazardous events) should be determined. The required information and results should be archived

Objectives and requirements - general, Concept, Overall scope definition

The grading of SIL involves selecting the required SIL level for SIF, usually after risk assessment, and requires the definition of the required SIF. There are multiple recommended methods in IEC 61511 and IEC 61508 to determine SIL, including quantitative, semi quantitative, and qualitative forms. The most rigorous and complex method is fully quantitative analysis (refer to Appendix D of Part 5 of IEC 61508 and Appendix B of Part 3 of IEC 61511), such as quantitative risk assessment (QRA). However, this method is not widely used because the grading process is overly complex. Currently, the commonly used methods include LOPA, risk graph method, and risk matrix method. The mainstream methods in the petrochemical industry are LOPA and risk graph methods

Overall safety requirements, Overall safety requirements allocation

Be able to quickly and promptly avoid dangerous situations when they are discovered

Overall operation and maintenance planning, Overall safety validation planning

Verification of instrument calibration and inspection methods;
Verification of main equipment;
System validation;
Verification of cleaning of main facilities and equipment;
Product production process validation

Overall installation and commissioning planning

- 1.Installation
- 2.Debugging of relevant equipment and facilities,
- 3.Acceptance,
4. Employee training

E/E/PE system safety requirements specification

1. A description of all safety functions required to achieve the required functional safety, and a description of each safety function
2. Response time performance (i.e. safety functions must be completed within the required time).
3. E/E/PE safety related systems and operator interfaces necessary for achieving the required functional safety.
4. All functional safety related information that may have an impact on the design of E/E/PE safety related systems
5. The interfaces between E/E/PE safety related systems and other systems (internal or external to EUC) necessary to achieve the required functional safety.

All relevant operating modes of EUC, including:

Preparation for use includes setting and adjusting;
Start, teach, automatic, manual, semi-automatic, steady-state operation;

Non operational stable state, reset, shutdown, maintenance:

A reasonably foreseeable abnormal state.

Define the behavior patterns of all E/E/PE safety related systems. Especially the response to the failure behavior and failure event requirements of E/E/PE safety related systems (such as alarms, automatic parking, etc.).

E/E/PE safety-related systems - realisation

E/E/PE System Design Requirements Specification - E/E/PE System Safety Confirmation Plan - E/E/PE System Design and Development Scope including ASIC and Software - E/E/PE System Integration - E/E/PE System Installation Debugging, Operation and Maintenance Procedures

Other risk reduction measures - specification and realisation

Not Applicable

2. SYSTEM DESCRIPTION AND COMPLIANCE MATRIX - IEC 61508:2023

continuation ...

Overall installation and commissioning, Overall safety validation

The validation plan document specifies the steps (procedural and technical) used to validate all safety requirements and software safety requirements for the product. The methods used to validate that each safety function has been correctly implemented and the pass/fail criteria for each test are specified. For each safety requirement (including software safety requirements) shown in the requirements traceability document, there are one or more test cases or analysis files. Each test case includes a test procedure, as well as the pass/fail criteria for the test (inputs, outputs, and any other acceptance criteria). The validation test plan includes the procedures used to properly judge whether the validation test was successful. (Field experience or statistical testing recommendations are considered when creating the test plan.) In addition to static analysis/testing, dynamic testing is also used.

The product has been tested with fault injection as defined in the fault injection test plan. The results have been analyzed and the FMEDA has been adjusted based on these results. Diagnostics have been tested. Test results are documented, including reference test cases and the version of the test plan being executed. The EMC/environmental specifications tested are the same or more stringent than those reviewed and approved by the FMEDA analyst

Overall operation, maintenance and repair, Overall modification and retrofit

The organizational measures involved are to create conditions for the effective implementation of technical requirements, with the aim of fully realizing and maintaining the functional safety of E/E/PE safety related systems. The technical requirements required for maintaining functional safety will be specified as part of the information provided by suppliers of E/E/PE safety related systems and their components and components



















The functional safety requirements in maintenance and repair activities may differ from those in operation. Without checking the effectiveness and practicality of the testing procedures developed for initial installation and commissioning, it is not appropriate to assume that these procedures can be used when EUC is running online.

The requirement of 7.15 is for E/E/PE safety related systems. It is recommended to consider combining other risk reduction measures, especially assuming that other risk reduction measures that need to be managed throughout the entire lifecycle of the EUC have been considered. To achieve functional safety, it is necessary to propose similar requirements for other risk reduction measures.

Decommissioning or disposal, Verification, Functional safety assessment

It is designed for E/E/PE safety related systems. It is recommended to consider combining other risk reduction measures, especially assuming that other risk reduction measures that need to be managed throughout the entire lifecycle of the EUC have been considered. In order to achieve functional safety, it is necessary to propose similar requirements for other risk reduction measures

Compliance matrix - IEC 61508:2023

Standard element	Fulfillment degree	Next audit verification
1 Scope, 2 Normative references, 3 Definitions and abbreviations		YES
4 Conformance to this standard, 5 Documentation		YES
6 Management of functional safety, 7 Overall safety lifecycle requirements		YES
7.1 General, 7.1.1 Introduction, 7.1.2 Objectives and requirements - general		YES
7.2 Concept, 7.3 Overall scope definition		YES
7.4 Hazard and risk analysis, 7.5 Overall safety requirements		YES
7.6 Overall safety requirements allocation		YES
7.7 Overall operation and maintenance planning		YES
7.8 Overall safety validation planning		YES
7.9 Overall installation and commissioning planning		YES
7.10 E/E/PE system safety requirements specification		YES
7.11 E/E/PE safety-related systems - realisation		YES
7.12 Other risk reduction measures - specification and realisation		YES
7.13 Overall installation and commissioning		YES
7.14 Overall safety validation		YES
7.15 Overall operation, maintenance and repair		YES
7.16 Overall modification and retrofit, 7.17 Decommissioning or disposal		YES
7.18 Verification, 8 Functional safety assessment		YES



Standard requirements and own management dossier are properly met. Outstanding deficiencies are recognised and removed during the process



Standard requirements and own management dossier are properly met. Outstanding deficiencies are not always recognised/removed during the process; or fall under disclosure requirements of standard with no benefit for a company. Auditor can make exceptions



Standard requirements and own management dossier are not properly met. Auditor opts for exception or non-conformity according to the extent and its impact on system functionality

Overall safety lifecycle

The functional safety management plan defines the safety lifecycle for this project. This includes a definition of the safety activities and documents to be created for this project. This information is communicated via these documents to the entire development team so that everyone understands the safety plan. The Software Development Procedure identifies the phases of the software development lifecycle and the inputs/outputs associated with each phase. The manufacturer has a Quality Management System in place. The Manufacturer has been ISO 9001 certified. All sub-suppliers have been qualified through the Manufacturer Qualification procedure. All phases of the safety lifecycle have verification steps described in a verification checklist. The verification is carried out using this checklist

E/E/PE system safety lifecycle (in realisation phase), Software safety lifecycle (in realisation phase)

The implementation phase of E/E/PE safety related systems includes safety requirement specifications (safety functional requirement specifications and safety integrity requirement specifications), safety confirmation plans, design and development, integration, operation and maintenance procedures, and safety confirmation (IEC61508-2)

Relationship of overall safety lifecycle to the E/E/PE system and software safety lifecycles

The ability to adopt technologies and measures to ensure software security, in order to prevent safety accidents or minimize the degree of harm in the event of accidents, and avoid triggering personal injury and equipment damage accidents

Allocation of overall safety requirements to E/E/PE safety-related systems and other risk reduction measures

In IEC61508, there are detailed requirements for the integrity of hardware safety, including the content of structural constraints, in addition to the requirement of hazardous random hardware failure rate. The table reflects the integrity of hardware security and imposes structural constraints; Class B security mainly constrains the structure of subsystems. Safety integrity level: The target failure level D of the low demand mode and high demand mode SIL system structure design is shown as the structural constraints of the safety related subsystem. For example, a newly developed logic solver product (due to not being used on-site and lacking data support for on-site use)

Operations and maintenance activities model, Operation and maintenance management model, Modification procedure model

Performance of fault tree analysis (FTA) and Failure Mode and Effect Analysis (FMEA/FMEDA)

Structuring information into document sets for user groups

The document list typically includes the following information:

1. Drawing or document number;
2. Revision index;
3. Document naming code;
4. Title;
5. Revision date;
6. Data carrier

This list can appear in different forms, such as databases that can be classified by pattern, document number, or document naming code. The document naming code may contain reference names for the functions, locations, or products described in the document, making it an effective tool for information retrieval.

Additional audit findings - IEC 61508:2023

Terms and Definitions:

Fault tolerance: Ability of a functional unit to continue to perform a required function in the presence of faults or errors (IEC 61508-4, 3.6.3)

FIT: Failure In Time (1×10^{-9} failures per hour)

FMEDA: Failure Mode Effect and Diagnostic Analysis

HFT: Hardware Fault Tolerance

Low demand mode: Mode where the demand interval for operation made on a safety-related system is greater than twice the proof test interval.

High demand mode: Mode where the demand interval for operation made on a safety-related system is less than 100x the diagnostic detection/reaction interval. or where the safe state is part of normal operation.

PFDavg: Average Probability of Dangerous Failure on Demand

PFH: Average Frequency of Dangerous Failure per Hour

SFF: Safe Failure Fraction - Summarizes the fraction of failures which lead to a safe state and the fraction of failures which will be detected by diagnostic measures and lead to a defined safety action.

SIF: Safety Instrumented Function

SIL: Safety Integrity Level

SIS: Safety Instrumented System - Implementation of one or more Safety Instrumented Functions. A SIS is composed of any combination of sensor(s), logic solver(s), and final element(s).

Type A element: "Non-Complex" element (using discrete components); for details see 7.4.4.1.2 of IEC 61508-2

Type B element: "Complex" element (using complex components such as micro controllers or programmable logic); for details see 7.4.4.1.3 of IEC 61508-2

3. AUDIT OUTCOME SUMMARY

3.1. Strengths of the company

Has been assessed per the relevant requirements of:
IEC 61508:2023 Parts 1-7, ISO 13849-1:2023, ISO 14119: 2020, IEC 61496:2023, IEC 62061:2023

3.2. Nonconformities and Areas of improvement

Area for improvement 1

Regarding Improvement Item 3, it is necessary to strengthen the management of raw material suppliers. Specific measures include: 1. Establish a supplier evaluation mechanism and regularly assess suppliers; 2. Develop a supplier management standard mechanism.

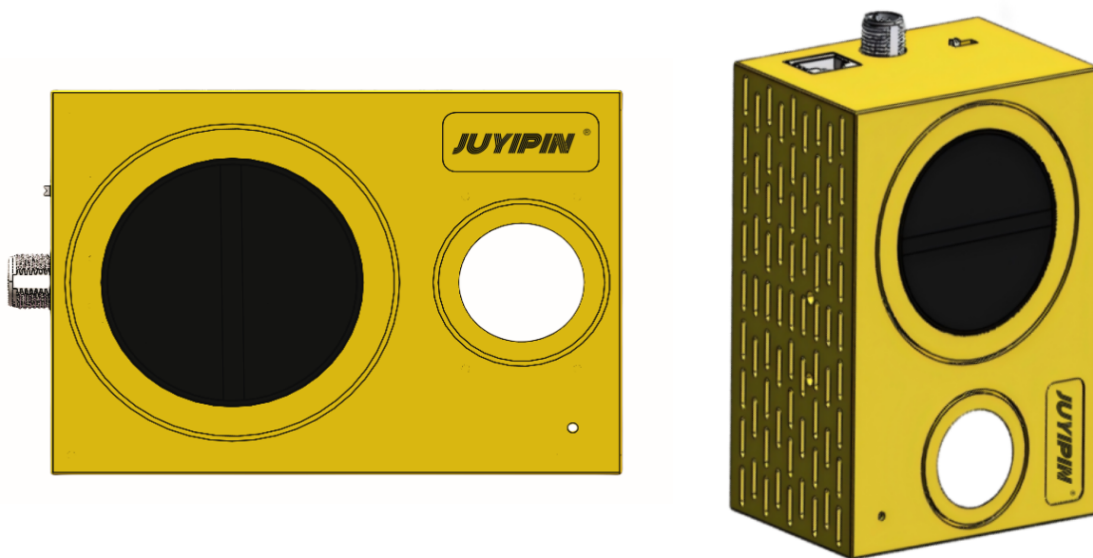
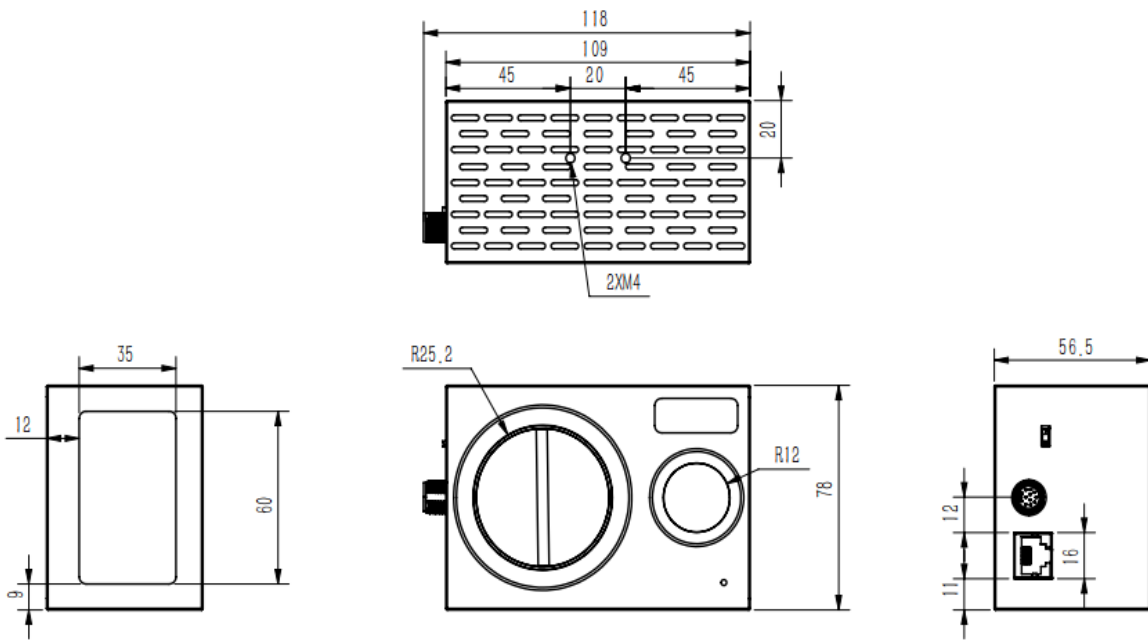
IEC 61508:2023, 7.12 Other risk reduction measures - specification and realisation

Summary of nonconformities and areas of improvements

Major nonconformity: 0
Minor nonconformity: 0
Area for improvement: 1

3.5. Obstacles encountered that could compromise reliability of the audit findings and conclusions

The Industries website was searched and no misleading or misuse of the certification or certification marks was found.



4. CONSECUTIVE ACTION, FINAL PROVISIONS AND RECOMMENDATION

Thanks to everyone involved in organizing, and also to those who participated in the audit. We are pleased that your company's quality management system audit went smoothly and that the atmosphere was friendly.

Expected Outcomes

The applicant for certification (certification company) has been informed about the applicability of accredited certification, namely: 'For the defined scope of certification, an organization or product with a certified management system, if it meets and appropriately applies the relevant management system certification requirements, can ensure the continuous provision of its services and/or products to meet customer requirements and relevant laws and regulations, thereby improving customer satisfaction.'

Use of the ECM logo

Upon obtaining a valid certificate, the client is entitled, for the duration of the certificate validity, to use an approved logo of the certification company or a private scheme. In case of system certification, process certification or technical documentation completeness assessment, this mark shall not be used on a product or product packaging seen by the consumer or in any other way that may be interpreted as denoting conformity of a specific product. The use and placement of the logo must not create confusion between the client and the certifying company, or convey a false impression that the certification applies to a specific product instead of the management system, unless it is clear from the certification scheme that it is not about assessment of a specific product, where its compliance with essential requirements is verified, which are given by a normative or other legal document.

Settlement of nonconformities, areas for improvement

The findings of the audit are given in a previous chapter, in the form of nonconformities and Areas for improvements. We kindly ask you to settle them as follows:

Major nonconformity

If it has been found, it shall be formulated in the Nonconformity Protocol, which is annexed to this report. Major Nonconformity is such insufficient fulfilment of the standard requirements that the certificate cannot be issued (or must be commenced its removal) unless is finished its settlement by the applicant for certification. When a major nonconformity is issued during an audit, the client must provide the CB with objective evidence of an investigation into causal factors and the risks they expose and their proposed corrective action plan (CAP). This shall be provided within 30 days after the audit. Settlement procedure must be formulated by the applicant on the same form (Nonconformity Protocol). The major nonconformity shall be closed within a further 30 days by implementing a corrective action (CA) and submitting evidence to the CB. When a satisfactory settlement of nonconformity is finished, audit can be completed with positive results. The CB provides the method of verifying of the nonconformity settlement.

Minor nonconformity

The Minor nonconformity is such insufficient fulfilment of the standard requirements that the certificate can be issued without finishing Minor Nonconformity settlement by the applicant. A root analysis and a proposed corrective action plan is required within 30 days after the audit. Certification body must be informed about the settlement or about the objection on its relevance within 12 months from the last day of the audit or during the next audit. The method for verifying the settlement of this minor nonconformity is subject to surveillance or recertification audit. In the case of insufficient settlement of the minor nonconformity, it should be reclassified as major nonconformity and threaten the validity of the certificate.

Area for improvement

The area for improvement is a comment for improving of the management system or the better and efficient fulfilment of standard certain requirements (notably the removal of formal fulfillment of the standard requirements of or optimization solutions) . According to the accreditation criteria the certified company need not respond actively to these findings, but when there are lots of areas for improvement and will be ignored, it can be considered during the subsequent audit as a reduced level of system performance.

Certification period and certificate validity

For the duration of the validity of the certificate of the product technical documentation completeness assessment, the applicant is required to maintain a functional management system and not to change the essential characteristics of the product set out in the product's technical documentation. During the validity of the certificate, the certification company may carry out a surveillance audit.

Before the termination of the certificate validity a contract with possible price advantage will be offered for the next certification period, if the client is interested in it (while the scope of certification will remain). To keep the price advantage, the recertification audit/ assessment shall be carried before the expiration of the original certificate. In severe cases, it is possible to request a postponement of surveillance audit, the approval of this exemption is solely on the certification body. In case of failure to cooperate in a surveillance audit we must begin the process of withdrawing of the certificate and we must publish that fact, according to the accreditation criteria.

Obligations of the certified company

The basic duties of certified company arise from the contract and business conditions that are part of it.

For the duration of the validity of the certificate of the product technical documentation completeness assessment, the applicant is required to maintain a functional management system and needs to inform the certification body of any changes made within the assessed process, product, presented technical documentation or the approved type.

Further the certified company is obliged to register and document all complaints by third parties relating to its management system and properly inform the certification body.

Obligation of the CB / NB 1280

The basic duties of certification body arise from the contract and business conditions that are part of it. Certification body shall maintain its accreditation status, conduct regular audits and surveillances according to the specified dates and time frames and provide objectivity in determining the operability of the management system. Further the certification body is obliged monitor changes in the requirements of the relevant standards and notifies the certified company accordingly in advance and process complaints and reservations raised by the client or a third party in a timely manner.

Appeal

Applicant for certification (certified company) is entitled to lodge any complaint against procedure of the certification body or individual auditors. Complaint of the applicant for certification (certified company) is to be sent in writing. Likewise applicant for certification (certified company) can comment this report. Severe appeal, as the claim against auditor impartiality or the decision of the certification company to refuse issuing or withdrawal of the certificate, are solved by the independent Appeal Committee within the period 30 days. Other comments and objections are dealt with operationally in an appropriate period of time.

Report provision to third parties

This report summarizes the results of the audit. The report is provided to the customer, one copy in electronic format is deposited with the E C M (Certification). The customer is entitled to present to any third party the full report only. The contents of this report and all audit records are considered confidential.

The contents of this report and all audit records are considered confidential. The reports may be presented to any third party only with the consent of the customer, without that authorization if the accreditation body and the owners of private schemes will request it.

Recommendation

The 1st stage of audit has been successfully completed. The 1st stage report has been drafted and released to the organization. Moreover, the audit plan and the audit team have been confirmed. Upon these processes the 2nd stage of audit has begun and resulted in the following. The overall audit target (as specified in the plan) was achieved. The documented system management conformity was measured through highly qualified process. Further, client's activity was compared with standard requirements. It was confirmed that the organization's MS is capable to meet the applicable requirements of the relevant standard(s) and achieve the expected outcomes for accredited Certification as stated in ISO-IAF Communiqué for Accredited Certification. The organization meets and appropriately implements the applicable MS requirements, and can ensure the continued provision of this service or products in conformity to customer requirements and relevant laws and regulations in order to increase customer satisfaction. This statement was made on the assessment of the individual standard's requirements fulfilment level, as evidenced in the compliance matrix of this report. The audit objectives as specified in Section 1 - Audit Scope were successfully met. Furthermore, the scope of certification has been assessed to be fully representative of the current activities of the audited organization.

I recommend, taking into account the audit results:

3D spatial protection sensor is equipped with AI algorithms and comes with the sensor's exclusive Windows debugging software. The product is suitable for safety-related parts of control systems (SRP/CS). It meets the safety integrity level (SIL3) requirements of the manufacturer's design process and complies with PLe and CAT4 standards, as well as ISO 13849 specifications.

Applicable product range: 3D Stereo Protection Sensor LT-3DYS-AI-ZDH6, LT-3D Series



Approver
EnteCertificazioneMacchine Legal Representative
Luca Bedonni

5. ADDITIONAL SPECIFICATIONS

Technical specifications

Product type & Assessment Report reference

Product type	Assessment Report reference
3D Stereo Protection Sensor	No.6G250826.YATQ049

Disclaimer

The use of the product must obey the required rules to conservation of SIL properties. These rules are recalled in the §6 of the Assessment Report reference.

Product version of hardware components used for validation and type tests

Component	Model
3D Stereo Protection Sensor	LT-3DYS-AI-ZDH6
3D Stereo Protection Sensor	LT-3D-Series

Environmental constraints

Document of reference	Remark
EN 50130-4:2011	These elements must be checked for each integration operation of the product

SIL - capable certified Safety Instrumented Function

Product	Safety Instrumented Function (1)	Safety Instrumented Function (2)	Safety Instrumented Function (3)
LT-3DYS-AI-ZDH6	SF1: protected control circuit	SF1: protected control circuit	N/A
LT-3D-Series	SF1: protected control circuit	SF1: protected control circuit	N/A

Calculation Hypothesis for architecture

Component architecture	SIL Capability	Demand frequency	PFD
1001	SIL2	Low	9.08E-04
1002	SIL3	Low	2.19E-05

Calculation Hypothesis for safety

Safety function	Failure rate	Undetected dangerous failure rate	Tests intervals	MTTR
LT-3DYS-AI-ZDH6	$\lambda_S=2.36E-07(/hr), \lambda_{DD}=4.72E-07(/hr)$	3.90E-08(/hr)	12 months	24h
LT-3D-Series	$\lambda_S=2.36E-07(/hr), \lambda_{DD}=4.72E-07(/hr)$	3.90E-08(/hr)	12 months	24h

Disclaimer

The Safety Integrated Level of the safety function using the product shall be calculated taking into account the characteristics of the whole system