



IEC 61508 Functional Safety Assessment

Project:

DIE ERSTE 2 & 3-Way Ball Valves

Customer:

DIE ERSTE INDUSTRY CO., LTD.

Taichung, Taiwan

R.O.C.

Contract Number: Q23/05-184

Report No.: DIE 15/10-104 R005

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Management Summary

This report summarizes the results of the functional safety assessment according to IEC 61508 carried out on the DIE ERSTE 2 & 3-Way Ball Valves.

- 2 & 3-way Floating Ball Valve, see Product Description for model covered by this assessment
- 2 & 3-way Trunnion Ball Valve, see Product Description for model covered by this assessment

The functional safety assessment performed by *exida* consisted of the following activities:

- *exida* assessed the development process used by DIE ERSTE INDUSTRY CO., LTD. through an audit and review of a detailed safety case against the *exida* certification scheme which includes the relevant requirements of IEC 61508. The investigation was executed using subsets of the IEC 61508 requirements tailored to the work scope of the development team.
- *exida* performed a detailed Failure Modes, Effects, and Diagnostic Analysis (FMEDA) of the devices to document the hardware architecture and failure behavior.
- *exida* reviewed field failure data to verify the accuracy of the FMEDA analysis.
- *exida* reviewed the manufacturing quality system in use at DIE ERSTE.

The functional safety assessment was performed to the requirements of IEC 61508: ed2, 2010, SIL 3 for mechanical components. A full IEC 61508 Safety Case was prepared using the *exida* Safety Case tool as the primary audit tool. Hardware process requirements and all associated documentation were reviewed. Environmental test reports were reviewed. Also the user documentation (safety manual) was reviewed.

The results of the Functional Safety Assessment can be summarized as:

The audited development process as tailored and implemented by the DIE ERSTE INDUSTRY CO., LTD. DIE ERSTE 2 & 3-Way Ball Valves development project, complies with the relevant safety management requirements of IEC 61508 SIL 3, **SC 3 (SIL 3 Capable)**.

The assessment of the FMEDA, done to the requirements of IEC 61508, has shown that the DIE ERSTE 2 & 3-Way Ball Valves can be used in a low demand safety related system in a manner where the PFD_{avg} is within the allowed range for up to SIL 2 according to table 2 of IEC 61508-1.

The assessment of the FMEDA also shows that the DIE ERSTE 2 & 3-Way Ball Valves meets the requirements for architectural constraints of an element such that it can be used to implement a SIL 2 safety function (with HFT = 0) or a SIL 3 safety function (with HFT = 1).

This means that the DIE ERSTE 2 & 3-Way Ball Valves is capable for use in SIL 3 applications in Low DEMAND mode, when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual and when using the versions specified in section 3.1 of this document.

The manufacturer will be entitled to use the Functional Safety Logo.





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1 Purpose and Scope

This document shall describe the results of the IEC 61508 functional safety assessment of the DIE ERSTE INDUSTRY CO., LTD.:

- 2 & 3-way Floating Ball Valve, see Product Description for model covered by this assessment
- 2 & 3-way Trunnion Ball Valve, see Product Description for model covered by this assessment

by *exida* according to accredited *exida* certification scheme which includes the requirements of IEC 61508: ed2, 2010.

The assessment has been carried out based on the quality procedures and scope definitions of *exida*.

The results of this provides the safety instrumentation engineer with the required failure data as per IEC 61508 / IEC 61511 and confidence that sufficient attention has been given to systematic failures during the development process of the device.

1.1 Tools and Methods used for the assessment

This assessment was carried out by using the *exida* Safety Case tool. The Safety Case tool contains the *exida* scheme which includes all the relevant requirements of IEC 61508.

For the fulfillment of the objectives, expectations are defined which builds the acceptance level for the assessment. The expectations are reviewed to verify that each single requirement is covered. Because of this methodology, comparable assessments in multiple projects with different assessors are achieved. The arguments for the positive judgment of the assessor are documented within this tool and summarized within this report.

The assessment was planned by *exida* agreed with DIE ERSTE INDUSTRY CO., LTD..

All assessment steps were continuously documented by *exida* (see [R1] to [R5]).



2 Project Management

2.1 *exida*

exida is one of the world's leading accredited Certification Bodies and knowledge companies, specializing in automation system safety and availability with over 500 years of cumulative experience in functional safety. Founded by several of the world's top reliability and safety experts from assessment organizations and manufacturers, *exida* is a global company with offices around the world. *exida* offers training, coaching, project oriented system consulting services, safety lifecycle engineering tools, detailed product assurance, cyber-security and functional safety certification, and a collection of on-line safety and reliability resources. *exida* maintains a comprehensive failure rate and failure mode database on process equipment based on 350 billion hours of field failure data.

2.2 Roles of the parties involved

DIE ERSTE INDUSTRY CO., LTD. Manufacturer of the DIE ERSTE 2 & 3-Way Ball Valves

exida Performed the hardware assessment

exida Performed the IEC 61508 Functional Safety Assessment per the accredited *exida* scheme.

DIE ERSTE contracted *exida* in January 2016 for the IEC 61508 Functional Safety Assessment of the above-mentioned devices.

2.3 Standards and literature used

The services delivered by *exida* were performed based on the following standards / literature.

[N1]	IEC 61508 (Parts 1 - 7): 2010	Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems
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2.4 Reference documents

2.4.1 Documentation provided by DIE ERSTE INDUSTRY CO., LTD.

Doc ID	Generic Document Name	Project Document Name and Link	Version
D001	Quality Manual	QM-01.pdf	Rev 10
D003	Overall Development Process	QP-07! 新產品開發管理程序	Rev 2
D004	Configuration Management Process	QP-10.pdf	Rev 4
D006	Field Return Procedure	QP-19 客訴處理、矯正措施及改善管理程序	Rev 8
D007	Manufacturer Qualification Procedure	QP-08 協力廠商評選管理程序	Rev 6
D008	Part Selection Procedure	QP-09! 採購作業管理程序	Rev 7



Doc ID	Generic Document Name	Project Document Name and Link	Version
D010	Quality Management System (QMS) Documentation Change Procedure	QP-02 文件要求管制記錄程序	Rev 6
D010b	Quality Management System (QMS) Documentation Change Procedure	QP-06 圖面管理管制程序	Rev 9
D012	Non-Conformance Reporting procedure	QP-18 不合格產品管理程序	Rev 4
D013	Corrective Action Procedure	QP-19 客訴處理、矯正措施及改善管理程序	Rev 8
D016	Action Item List Tracking Procedure	Action Item Track	NA
D018	Test Equipment Calibration Procedure	D018 Calibration Record_QC-319 (Shell Test).pdf	NA
D018b	Test Equipment Calibration Procedure	D018b Photos of Test Bench & Gauge Calibration (Shell Test).pdf	NA
D018c	Test Equipment Calibration Procedure	D018c Calibration Record_QC302 (low-pressure closure).pdf	NA
D018d	Test Equipment Calibration Procedure	D018d Photos of Test Bench & Gauge Calibration (low-pressure closure).pdf	NA
D019	Customer Notification Procedure	QP-22 設計變更管理程序.pdf	Rev 3
D023	Modification Procedure	QP-22! 設計變更管理程序	Rev 2
D023b	Impact Analysis Template	D023b_Impact Analysis Template v1.0.pdf	Ver 1.0
D026	FSM Plan or Development Plan	2 way 3 way Floating Document Records	NA
D026b	FSM Plan or Development Plan	2 way trunnion Document Record	NA
D026c	FSM Plan or Development Plan	2 way 3 way Floating Document Records	NA
D026d	FSM Plan or Development Plan	M4-HP DN50.pdf	NA
D026e	FSM Plan or Development Plan	Medium Vacuum – SRS.pdf	Rev 1
D026f	FSM Plan or Development Plan	D2.1 Functional Safety ManagementPlan_v1.3.pdf	v1,3
D029	Verification Plan	★WI-002閥門檢驗程序.docx	NA
D030	Shipment Records	★ Die Erste 2020-2022 Shipment & Return Records_SIL 3 R1.1.xls	R1.1
D031	Field Returns Records	★ Die Erste 2020-2022 Shipment & Return Records_SIL 3 R1.1.xls	R1.1
D032	Job Descriptions and Competency Levels	QP-04 資源管理程序	NA
D033	Training Record	D033 – EM Training Record.pdf	NA
D034	Skills Matrix	QP-04 資源管理程序	



Doc ID	Generic Document Name	Project Document Name and Link	Version
D036	ISO 900x Cert or equivalent	★ ISO 9001-QMS-ENGUS-UKAS-DIE ERSTE INDUSTRY CO., LTD. - I.A..pdf	10303870
D040	Safety Requirements Specification	2 way 3 way Floating Document Records	NA
D040b	Safety Requirements Specification	2 way trunnion Document Record	NA
D040c	Safety Requirements Specification	2 way 3 way Floating Document Records	NA
D040d	Safety Requirements Specification	M4-HP DN50.pdf	NA
D040e	Safety Requirements Specification	Medium Vacuum – SRS.pdf	Rev 1
D041	Safety Requirements Review	2 way 3 way Floating Document Records	NA
D041b	Safety Requirements Review	2 way trunnion Document Record	NA
D041c	Safety Requirements Review	M4F DN200.pdf	NA
D041d	Safety Requirements Review	2 way 3 way Floating Document Records	NA
D041e	Safety Requirements Review	Medium Vacuum – SRS.pdf	Rev 1
D054	Verification Results	2 way 3 way Floating Document Records	NA
D054b	Verification Results	2 way trunnion Document Record	NA
D054c	Verification Results	2 way 3 way Floating Document Records	NA
D054d	Verification Results	M4-HP DN50.pdf	NA
D054e	Verification Results	Safety Validation Test Report 1.pdf	Rev 1
D069	Validation Test Plan	2 way 3 way Floating Document Records	NA
D069b	Validation Test Plan	2 way trunnion Document Record	NA
D069c	Validation Test Plan	2 way 3 way Floating Document Records	NA
D069d	Validation Test Plan	M4-HP DN50.pdf	NA
D069e	Validation Test Plan	Safety Validation Test Specification.pdf	Rev 1
D069f	Validation Test Plan	D069f FSB-26 Validation test plan and Results.pdf	NA
D069g	Validation Test Plan	D069g FSB-22 Validation test plan and Results.pdf	NA
D070	Validation Test Plan Review Record	Safety Validation Test Specification.pdf	Rev 1
D071	Environmental Test Plan	Environmental test cert	NA
D074	Validation Test Results	2 way 3 way Floating Document Records	NA
D074b	Validation Test Results	2 way trunnion Document Record	NA
D074c	Validation Test Results	2 way 3 way Floating Document Records	NA
D074d	Validation Test Results	Validation Result – M4HP	NA



Doc ID	Generic Document Name	Project Document Name and Link	Version
D074e	Validation Test Results	Safety Validation Test Report 2.pdf	NA
D074f	Validation Test Results	D069f FSB-26 Validation test plan andResults.pdf	NA
D074g	Validation Test Results	D069g FSB-22 Validation test plan and Results.pdf	NA
D075	Environmental Test Results	Environmental test cert	NA
D078	Operation / Maintenance Manual	D078 IOM	NA
D079	Safety Manual	D079 D11.1 Safety Manual_v1.5.pdf	Rev 1.5
D081	Engineering Change Documentation	D081 ECR 2018001.pdf	NA
D081b	Engineering Change Documentation	D081b FSB-26 Impact Analysis.pdf	NA
D081c	Engineering Change Documentation	D081c FSB-22 Impact Analysis.pdf	NA
D088	Impact Analysis Record	D081 ECR 2018001.pdf	NA
D088b	Impact Analysis Record	D081b FSB-26 Impact Analysis.pdf	NA
D088c	Impact Analysis Record	D081c FSB-22 Impact Analysis.pdf	NA

Note: Documents highlighted in blue were revised since the initial assessment. The changes were reviewed as part of the 2023 surveillance audit. See Section 6.

2.4.2 Documentation generated by *exida*

[R1]	DIE 15-10-104 R001 V1R1 FMEDA 2-Way 3-Way Trunnion Ball Valve.pdf, August 12, 2016	FMEDA report, 2-Way & 3-Way Trunnion Ball Valves
[R2]	DIE 18-03-103 R001 V2R1 FMEDA FBV 2-Way.pdf, March 5, 2020	FMEDA report, 2-Way Floating Ball Valves
[R3]	DIE 15-10-104 R003 V1R1 FMEDA 3-Way Floating Ball Valve.pdf, August 12, 2016	FMEDA report, 3-Way Floating Ball Valves
[R4]	DIE 15-10-104 V3R1 Safety Case.xlsm, September 22, 2023	IEC 61508 SafetyCase for DIE ERSTE 2 & 3-Way Ball Valves (internal document)
[R5]	DIE 15-10-104 R005 V3R1 Assessment Report, September 22, 2023	IEC 61508 Functional Safety Assessment, DIE ERSTE INDUSTRY CO., LTD. DIE ERSTE 2 & 3-Way Ball Valves (this report)



2.5 Assessment Approach

The certification audit was closely driven by requirements of the *exida* scheme which includes subsets filtered from IEC 61508.

The assessment was planned by *exida* and agreed upon by DIE ERSTE INDUSTRY CO., LTD..

The following IEC 61508 objectives were subject to detailed auditing at DIE ERSTE INDUSTRY CO., LTD.:

- FSM planning, including
 - Safety Life Cycle definition
 - Scope of the FSM activities
 - Documentation
 - Activities and Responsibilities (Training and competence)
 - Configuration management
 - Tools and languages
- Safety Requirement Specification
- Change and modification management
- Hardware architecture design - process, techniques and documentation
- Hardware design / probabilistic modeling
- Hardware and system related V&V activities including documentation, verification

3 Product Descriptions

DIE ERSTE 2 & 3-Way Ball Valves are ¼ turn ball valves used to control process fluids. The valves are available from ¼” to 12” and are designed to meet international standards for pressure and temperature ratings, shell thickness, and bore diameters. The ball valves provide ISO 5211 mounting for simple actuator mounting. The ball valves include multiple body-gasket sealing and stem seals.

3.1 Hardware Version Numbers

This assessment is applicable to the following hardware versions of DIE ERSTE 2 & 3-Way Ball Valves:

2-Way & 3-Way Trunnion Ball Valve

Model	Type	Body Type (Pieces)	End Connection	Size Range	Pressure Rating
M4-HP / KHD-M4-HP	3-Way Trunnion	6	THREADED	1/4" - 2"	3000PSI
M4F-HP / KHD-M4F-HP	3-Way Trunnion	6	FLANGE	1/4" - 2"	ANSI #600 / ANSI #900 / ANSI #1500
T2 / KHD-T2	2-Way Trunnion	2	FLANGE	2" – 4"	Class 150LB / 300LB
T2 / KHD-T2	2-Way Trunnion	3	FLANGE	2" – 4"	Class 600LB
T2 / KHD-T2	2-Way Trunnion	3	FLANGE	6" – 12"	Class 150LB / 300LB / 600LB

2-way Ball Valve



3-way Ball Valve



Figure 1 Typical 2-Way & 3-Way Trunnion Ball Valve

2-Way Floating Ball Valve

Model	Body Type (Pieces)	End Connection	Size Range	Pressure Rating
FSB 1D / KHD-FSB1D	1	WAFER	1/2" - 6"	ANSI#150/PN16/PN40
FSB 2D / KHD-FSB2D	2	FLANGE	1/2" - 8"	ANSI#150/ANSI#300/PN16/PN40
Series 2F / KHD-2F	2	FLANGE	1/2" - 12"	ANSI#150/ANSI#300/PN16/PN40
FSAB 2-WAY / KHD-FSAB 2WAY	3	THREAD / SOCKET / BUTTWELD	1/4" - 4"	PN63
FSB 35 / KHD-FSB35	3	THREAD / SOCKET / BUTTWELD	1/4" - 1" 1-1/4"-2" 2-1/2"-4"	PN125 PN100 PN63
AC-35 / KHD-AC35	3	THREAD / SOCKET / BUTTWELD	1/4" - 4"	PN63
SERIES 35 / KHD-35	3	THREAD / SOCKET / BUTTWELD	1/4" - 4"	PN63
SERIES 35S	3	THREAD / SOCKET / BUTTWELD / EXTENDED BUTTWELD FLANGE	1/4" - 4" 1/2"-4"	PN63 PN40
SERIES 32 / KHD-32	3	THREAD / SOCKET / BUTTWELD	1/4" - 2" 2-1/2"-4"	PN63 PN50
SERIES 25 / KHD-25	2	THREADED	1/4" - 3"	PN63
SERIES 1T / KHD-1T	2	THREAD / SOCKET / BUTTWELD	1/2" - 4"	800PSI
SERIES 1TF / KHD-1TF	2	FLANGE	1/2" - 4"	ANSI#150/ANSI#300
FSB 26 / KHD-FSB26	2	THREAD	1/4" - 2"	6000PSI/Class2500
FSB 22 / KHD-FSB22	2	THREAD	1/4" - 4"	2000PSI/Class900



Figure 2 Typical 2-Way Floating Ball Valve

3-Way Floating Ball Valve

Model	Body Type (Pieces)	End Connection	Size Range	Pressure Rating
M5 / KHD-M5	3	THREADED	1/2" - 2"	800PSI 1000PSI
M4 / KHD-M4	5	TH/SW/BW	1/4" - 2" 2-1/2" - 4"	800PSI
M4F / KHD-M4F	5	FLANGED	1/2" - 2" 2-1/2" - 8"	ANSI#150/ANSI#300/PN16/PN40
FSAB 3-WAY / KHD-FSAB 3WAY	5	TH/SW/BW	1/4" - 2" 2-1/2"-4"	PN63 PN50



Figure 3 Typical 3-Way Floating Ball Valve

4 IEC 61508 Functional Safety Assessment Scheme

exida assessed the development process used by DIE ERSTE INDUSTRY CO., LTD. for this development project against the objectives of the *exida* certification scheme which includes subsets of IEC 61508 -1 to 3. The results of the assessment are documented in [R3].

4.1 Methodology

The full functional safety assessment includes an assessment of all fault avoidance and fault control measures during hardware development and demonstrates full compliance with IEC 61508 to the end-user. The assessment considers all requirements of IEC 61508. Any requirements that have been deemed not applicable have been marked as such in the full Safety Case report, e.g. software development requirements for a product with no software. The assessment also includes a review of existing manufacturing quality procedures to ensure compliance to the quality requirements of IEC 61508.

As part of the IEC 61508 functional safety assessment the following aspects have been reviewed:

- Development process, including:
 - Functional Safety Management, including training and competence recording, FSM planning, and configuration management
 - Specification process, techniques and documentation
 - Design process, techniques and documentation, including tools used
 - Validation activities, including development test procedures, test plans and reports, production test procedures and documentation
 - Verification activities and documentation
 - Modification process and documentation
 - Installation, operation, and maintenance requirements, including user documentation
 - Manufacturing Quality System
- Product design
 - Hardware architecture and failure behavior, documented in a FMEDA

The review of the development procedures is described in section 5. The review of the product design is described in section 5.2.

4.2 Assessment level

The DIE ERSTE 2 & 3-Way Ball Valves have been assessed per IEC 61508 to the following levels:

- SIL 3 capability

The development procedures have been assessed as suitable for use in applications with a maximum Safety Integrity Level of 3 (SIL 3) according to IEC 61508.



5 Results of the IEC 61508 Functional Safety Assessment

exida assessed the development process used by DIE ERSTE INDUSTRY CO., LTD. for these products against the objectives of the *exida* certification scheme which includes IEC 61508 parts 1, 2, & 3 see [N1]. The development of the DIE ERSTE 2 & 3-Way Ball Valves was done per this IEC 61508 SIL 3 compliant development process. The Safety Case was updated with project specific design documents.

5.1 Lifecycle Activities and Fault Avoidance Measures

DIE ERSTE INDUSTRY CO., LTD. has a defined product lifecycle process in place. This is documented in the Quality Management System Manual [D001] and various Quality Procedures [D003-23]. A documented modification process is also covered in the Quality Manual. No software is part of the design and therefore any requirements specific from IEC 61508 to software and software development do not apply.

The assessment investigated the compliance with IEC 61508 of the processes, procedures and techniques as implemented for product design and development. The investigation was executed using the *exida* certification scheme which includes subsets of IEC 61508 requirements tailored to the SIL 3 work scope of the development team. The result of the assessment can be summarized by the following observations:

The audited DIE ERSTE INDUSTRY CO., LTD. design and development process complies with the relevant managerial requirements of IEC 61508 SIL 3 .

5.1.1 Functional Safety Management

The valves manufactured by DIE ERSTE are not built for inventory. These valves are built-to-order. The basic designs are standardized, but each order can have trim and materials variations or specific customer requested proof tests. Due to the specialized nature of each valve, documentation that defines all of the requirements is generated for every order as part of the process.

FSM Planning

DIE ERSTE INDUSTRY CO., LTD. has a defined process in place for product design and development. Required activities are specified along with review and approval requirements. This is primarily documented in section 8.3 of their Quality Manual [D001] and in greater detail in procedures QP-07 [D003]. Templates and sample documents were reviewed and found to be sufficient. The modification process is covered by QP-22 [D023]. This process and the procedures referenced therein fulfill the requirements of IEC 61508 with respect to functional safety management for a product with simple complexity and well defined safety functionality.

Version Control

QP-02 [D010] requires that all documents be under document control. Use of this to control revisions was evident during the audit.

Training, Competency recording

Quality Manual [D001] requires the Human Resource department to maintain training records of education, experience, training and qualifications for all personnel. Department heads are responsible for identifying and providing the training needs for their department as well as proficiency evaluations. The procedures and records were examined and found up-to-date and sufficient. DIE ERSTE hired *exida* to be the independent assessor per IEC 61508 and to provide specific IEC 61508 knowledge.

5.1.2 Safety Requirements Specification and Architecture Design

For the DIE ERSTE 2 & 3-Way Ball Valves, the simple primary functionality of the valve is the same as the safety functionality of the product (Valve changes position, Close / Open). Therefore, no special Safety Requirements Specification was needed. The normal functional requirements were sufficient. As the DIE ERSTE 2 & 3-Way Ball Valves designs are simple and are based upon standard designs with extensive field history, no semi-formal methods are needed. General Design and testing methodology is documented and required as part of the design process. This meets SIL 3.

5.1.3 Hardware Design

The design process is documented in section 8.3 of their Quality Manual [D001] and in procedures QP-07 [D003]. Items from **IEC 61508-2, Table B.2** include observance of guidelines and standards, (API, PED) project management, documentation (design outputs are documented per quality procedures), structured design, modularization, use of well-tried components / materials, and computer-aided design tools. This meets SIL 3.

5.1.4 Validation

Validation Testing is documented on form [D069] to [D070] and [D074] which is created for each order. The test plan includes testing per all standard and customer performance requirements. As the DIE ERSTE 2 & 3-Way Ball Valves are purely mechanical devices with a simple safety function, there is no separate integration testing necessary. The DIE ERSTE 2 & 3-Way Ball Valves perform only 1 Safety Function, which is extensively tested under various conditions during validation testing.

Items from **IEC 61508-2, Table B.3** include functional testing, project management, documentation, and black-box testing (for the considered devices this is similar to functional testing). Field experience and statistical testing via regression testing are not applicable. This meets SIL 3.

Items from **IEC 61508-2, Table B.5** included functional testing and functional testing under environmental conditions, project management, documentation, failure analysis (analysis on products that failed), expanded functional testing, black-box testing, and fault insertion testing. This meets SIL 3.

5.1.5 Verification

The development and verification activities are defined in 8.3 of their Quality Manual [D001] and in procedures QP-07 [D003]. For each design phase the objectives are stated, required input and output documents and review activities. This meets SIL 3.

5.1.6 Proven In Use

In addition to the Design Fault avoidance techniques listed above, a Proven in Use evaluation was carried out on the DIE ERSTE 2 & 3-Way Ball Valves. Shipment records were used to determine that the DIE ERSTE 2 & 3-Way Ball Valves have >30 million hours in use and they have demonstrated a field failure rate less than the failure rates indicated in the FMEDA reports. This meets the requirements for Proven In Use for SIL 3.

5.1.7 Modifications

Modifications are initiated per section 8.5.6 of QP-22 [D023] Design Change procedure. All changes are first reviewed and analyzed for impact before being approved. Measures to verify and validate the change are developed following the normal design process.



The modification process has been successfully assessed and audited, so DIE ERSTE INDUSTRY CO., LTD. may make modifications to this product as needed.

- As part of the *exida* scheme a surveillance audit is conducted every 3 years. The modification documentation listed below is submitted as part of the surveillance audit. *exida* will review the decisions made by the competent person in respect to the modifications made.
 - List of all anomalies reported
 - List of all modifications completed
 - Safety impact analysis which shall indicate with respect to the modification:
 - The initiating problem (e.g. results of root cause analysis)
 - The effect on the product / system
 - The elements/components that are subject to the modification
 - The extent of any re-testing
 - List of modified documentation
 - Regression test plans

This meets SIL 3.

5.1.8 User documentation

DIE ERSTE INDUSTRY CO., LTD. creates the following user documentation: product catalogs and a Safety Manual. The Safety Manual [D079] was found to contain all of the required information given the simplicity of the products. The Safety Manual references the FMEDA reports which are available and contain the required failure rates, failure modes, useful life, and suggested proof test information.

Items from IEC **61508-2, Table B.4** include operation and maintenance instructions, user friendliness, maintenance friendliness, project management, documentation, limited operation possibilities (DIE ERSTE 2 & 3-Way Ball Valves perform well-defined actions) and operation only by skilled operators (operators familiar with type of valve, although this is partly the responsibility of the end-user). This meets SIL 3.

5.2 Hardware Assessment

To evaluate the hardware design of the DIE ERSTE 2 & 3-Way Ball Valves Failure Modes, Effects, and Diagnostic Analysis's were performed by *exida*. These are documented in [R1] to [R3].

A Failure Modes and Effects Analysis (FMEA) is a systematic way to identify and evaluate the effects of different component failure modes, to determine what could eliminate or reduce the chance of failure, and to document the system in consideration. An FMEDA (Failure Mode Effect and Diagnostic Analysis) is an FMEA extension. It combines standard FMEA techniques with extension to identify online diagnostics techniques and the failure modes relevant to safety instrumented system design.

From the FMEDA, failure rates are derived for each important failure category. All failure rate analysis results and useful life limitations are listed in the FMEDA report [R1] to [R3]. Tables in the FMEDA report list these failure rates for the DIE ERSTE 2 & 3-Way Ball Valves under a variety of applications. The failure rates listed are valid for the useful life of the devices.



According to IEC 61508 the architectural constraints of an element must be determined. This can be done by following the 1_H approach according to 7.4.4.2 of IEC 61508-2 or the 2_H approach according to 7.4.4.3 of IEC 61508-2.

The 1_H approach involves calculating the Safe Failure Fraction for the entire element.

The 2_H approach involves assessment of the reliability data for the entire element according to 7.4.4.3.3 of IEC 61508-2.

The failure rate data used for this analysis meets the *exida* criteria for Route 2_H . Therefore, the DIE ERSTE 2 & 3-Way Ball Valves can be classified as a 2_H device. When 2_H data is used for all of the devices in an element, the element meets the hardware architectural constraints up to SIL 2 at HFT=0 (or SIL 3 @ HFT=1) per Route 2_H .

If Route 2_H is not applicable for the entire final element, the architectural constraints will need to be evaluated per Route 1_H .

Note, as the DIE ERSTE 2 & 3-Way Ball Valves are only one part of a (sub)system, the SFF should be calculated for the entire final element combination.

These results must be considered in combination with PFD_{avg} values of other devices of a Safety Instrumented Function (SIF) in order to determine suitability for a specific Safety Integrity Level (SIL). The architectural constraints requirements of IEC 61508-2, Table 2 also need to be evaluated for each final element application. It is the end user's responsibility to confirm this for each particular application and to include all components of the final element in the calculations.

The analysis shows that the design of the DIE ERSTE 2 & 3-Way Ball Valves can meet the hardware requirements of IEC 61508, SIL 3 and SIL 2 for the DIE ERSTE 2 & 3-Way Ball Valves depending on the complete final element design. The Hardware Fault Tolerance and PFD_{avg} requirements of IEC 61508 must be verified for each specific design.



6 2023 IEC 61508 Functional Safety Surveillance Audit

6.1 Roles of the parties involved

DIE ERSTE INDUSTRY CO., LTD. Manufacturer of the DIE ERSTE 2 & 3-Way Ball Valves

exida Performed the hardware assessment review

exida Performed the IEC 61508 Functional Safety Surveillance Audit per the accredited *exida* scheme.

DIE ERSTE INDUSTRY CO., LTD. contracted *exida* in Sep 2023 to perform the surveillance audit for the above DIE ERSTE 2 & 3-Way Ball Valves. The surveillance audit was conducted onsite at the DIE ERSTE INDUSTRY CO., LTD.'s facility in Taichung, Taiwan on Sep 6, 2023.

6.2 Surveillance Methodology

As part of the IEC 61508 functional safety surveillance audit the following aspects have been reviewed:

- Procedure Changes – Changes to relevant procedures since the last audit are reviewed to determine that the modified procedures meet the requirements of the *exida* certification scheme.
- Engineering Changes – The engineering change list is reviewed to determine if any of the changes could affect the safety function of the DIE ERSTE 2 & 3-Way Ball Valves.
- Impact Analysis – If changes were made to the product design, the impact analysis associated with the change will be reviewed to see that the functional safety requirements for an impact analysis have been met.
- Field History – Shipping and field returns during the certification period will be reviewed to determine if any systematic failures have occurred. If systematic failures have occurred during the certification period, the corrective action that was taken to eliminate the systematic failure(s) will be reviewed to determine that said action followed the approved processes and was effective.
- Safety Manual – The latest version of the safety manual will be reviewed to determine that it meets the IEC 61508 requirements for a safety manual.
- FMEDA Update – If required or requested the FMEDA will be updated. This is typically done if there are changes to the IEC 61508 standard and/or changes to the *exida* failure rate database.
- Evaluate use of the certificate and/or certification mark - Conduct a search of the applicant's web site and document any misuse of the certificate and/or certification mark. Report any misuse of the certificate and/or certification mark to the *exida* Managing Director.
- Recommendations from Previous Audits – If there are recommendations from the previous audit, these are reviewed to see if the recommendations have been implemented properly.



6.3 Surveillance Results

6.3.1 Procedure Changes

There were no changes to the procedures during the previous certification period.

6.3.2 Engineering Changes

There were no design changes to these products during the previous certification period.

6.3.3 Impact Analysis

There were no safety-related design changes during the previous certification period.

6.3.4 Field History

Shipping and field return data [D030] and [D031] were reviewed. The field histories of these products were analyzed and found to be consistent with the failure rates predicted by the FMEDA.

6.3.5 Safety Manual

There were no changes to the safety manual during the previous certification period.

6.3.6 FMEDA Update

There was no change in the FMEDA report since the last assessment.

6.3.7 Evaluate use of certificate and/or certification mark

The DIE ERSTE INDUSTRY CO., LTD. website was searched and no misleading or misuse of the certification or certification marks was found.

6.3.8 Previous Recommendations

There were no previous recommendations to be assessed at this audit.

6.4 Surveillance Audit Conclusion

The result of the Surveillance Audit Assessment can be summarized by the following observations:
The DIE ERSTE INDUSTRY CO., LTD. DIE ERSTE 2 & 3-Way Ball Valves continues to meet the relevant requirements of IEC 61508:2010 for SIL 3 in low demand applications based on the initial assessment and considering the above surveillance results.

This conclusion is supported by the updated SafetyCase and certification documents.

7 Terms and Definitions

Architectural Constraint	The SIL limit imposed by the combination of SFF and HFT for Route 1 _H or by the HFT and Diagnostic Coverage (DC applies to Type B only) for Route 2 _H
<i>exida</i> criteria	A conservative approach to arriving at failure rates suitable for use in hardware evaluations utilizing the 2 _H Route in IEC 61508-2.
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.
PFD _{avg}	Average Probability of Failure on Demand
PVST	Partial Valve Stroke Test It is assumed that the Partial Stroke Testing, when performed, is automatically performed at least an order of magnitude more frequent than the proof test, therefore the test can be assumed an automatic diagnostic. Because of the automatic diagnostic assumption, the Partial Valve Stroke Testing also has an impact on the Safe Failure Fraction.
Random Capability	The SIL limit imposed by the PFD _{avg} for each element.
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).
Systematic Capability	The SIL limit imposed by the capability of the products manufacturer.
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



8 Status of the Document

8.1 Liability

exida prepares reports based on methods advocated in International standards. *exida* accepts no liability whatsoever for the use of this report or for the correctness of the standards on which the general calculation methods are based.

8.2 Version History

Contract Number	Report Number	Revision Notes
Q23/05-184	DIE 15/10-104 R005 V3, R1	Updated for recertification; September 27, 2023; Jack Gao
Q19/09-128	DIE 15/10-104 R005 V2, R2	Released; updated for recertification; September 7, 2020; Desmond Lee
Q19/09-128	DIE 15/10-104 R005 V2, R1	Draft, updated for recertification; May 13, 2020; Desmond Lee
Q18/03-103	DIE 15/10-104 R005 V1, R2	Released; December 5, 2018; Desmond Lee
Q15/10-104	DIE 15/10-104 R005 V1, R1	Released; January 23, 2017; Desmond Lee
Q15/10-104	DIE 15/10-104 R005 V0, R1	Draft; January 17, 2017; Desmond Lee

Reviewer: Desmond Lee, *exida*, September 22, 2023

Status: Released, September 27, 2023

8.3 Future Enhancements

At request of client.

8.4 Release Signatures

Jack Gao, CFSE, Senior Engineer

Desmond Lee, CFSE, Senior Engineer