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Results of the IEC 61508 Functional Safety Assessment

Project:
Pressure, Temperature and Vacuum Switches

Customer:
BETA B.V.
Rijswijk
The Netherlands

Contract No.: BETA 0804-32-C
Report No.: BETA 0804-32-C R004
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Peter Söderblom

Management summary

The Functional Safety Assessment of the BETA B.V., performed by *exida* Certification S.A. consisted of the following activities:

- *exida* Certification S.A. assessed the setup of the development process used by BETA B.V. for development projects against the relevant requirements of IEC 61508:2000 (hereafter called IEC 61508) parts 1 and 2.
Subject to this assessment were the Functional Safety Planning activities, the tailoring of the Verification and Validation activities and the realization of the technical safety aspects using the Pressure, Temperature and Vacuum Switches development project.
- *exida* Certification S.A. audited the development process by a detailed development audit which investigated the compliance with IEC 61508 of the processes, procedures and techniques as implemented for the BETA B.V. Pressure, Temperature and Vacuum Switches development. The investigation was executed using subsets of the IEC 61508 requirements tailored to the work scope of the development team.
- *exida* Certification S.A. assessed the Safety Case prepared by BETA B.V. against the technical requirements of IEC 61508.

The result of the Functional Safety Assessment can be summarized by the following statements:

The audited BETA B.V. development process tailored and implemented by the Pressure, Temperature and Vacuum Switches development project, complies with the relevant safety management requirements of IEC 61508 SIL2.

The assessment of the FMEDA, which was performed according to IEC 61508, has shown that the Pressure, Temperature and Vacuum Switches has a PFD_{AVG} within the allowed range for SIL2 (HFT = 0) according to table 2 of IEC 61508-1 and a Safe Failure Fraction (SFF) of more than 60%.

This means that the BETA B.V. Pressure, Temperature and Vacuum Switches are capable for use in SIL2 applications, when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual.

	
Assessor Peter Söderblom	Certifying Assessor Audun Opem

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1 Purpose and Scope

This document describes the results of the

Full Functional Safety Assessment according to IEC 61508:2000

of the product development processes according to the safety lifecycle phase 9 of IEC 61508-1. The purpose of the assessment was to investigate the compliance of:

- the Pressure, Temperature and Vacuum Switches with the technical IEC 61508-2 requirements for SIL2 and the derived product safety property requirements

and

- the Pressure, Temperature and Vacuum Switches development processes, procedures and techniques as implemented for the safety-related deliveries with the managerial IEC 61508-1 and -2 requirements for SIL2.

It was not the purpose to assess the fulfilment of the statement of conformance from BETA B.V. for the following European Directives;

- EMC Directive
- Pressure Directive
- Low Voltage Directive
- ATEX Directive

The correct execution of all activities that lead to the statement of Conformance to these European Directives is in the responsibility of BETA B.V. and builds a basis for the certification.

It was not the purpose of the assessment / audits to investigate Company quality management system versus ISO 9001 and ISO 9000-3 respectively.

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

1.1 Tools and Methods used for the assessment.

This assessment was carried by using the *exida* assessment backends for the Safety Case DB tool. The expectations for a positive judgment of the assessor are documented within this tool.

The assessment was based on a set of document templates.

2 Project Description

2.1 Description of the Functional Safety Management System

The functional safety management system is implemented in the BETA B.V. development process described in Product Development E&D [D2] by the use of the related planning documents, which describes the activities in detail. The development process defines an implementation of a safety life cycle model which adopts the V-model as described in IEC 61508.

This is a phase / gate model process for product development with specific deliverables, reviews and approvals at each gate. All new product development is managed through this process. The same process is used for larger modifications whilst a lighter version is available for minor product modifications.

The phases included in the main development process are:

- Design preparation
- Design
- Testing
- Design review
- Release for production
- Production drawing and document preparation
- Document distribution

These phases, the input and output documents, responsibilities are all described in more detail in the Product Development E&D [D2].

Evidence for the fulfilment of the detailed requirements has been collected in a FSM Safety Justification report, which was subject to the assessment.

2.2 Description of the Pressure, Temperature and Vacuum Switches

The Pressure, Temperature and Vacuum Switches are considered to be Type A subsystems with a hardware fault tolerance of 0.



Figure 1: C-Series

The weatherproof C-Series, in cast aluminium or 316SS enclosures. (Optional also Eex ia/b IIC T6). Pressure ranges starting from 2 mbar to 540 bar. Vacuum ranges / Differential ranges and Temperature ranges available. Several options and specials possible.



Figure 2: W-Series

The explosion proof (Eex-d IIC T6) W-series, in cast aluminium, SS316 or V5 series in cast iron enclosures. Pressure ranges starting from 2 mbar to 540 bar. Vacuum ranges / Differential ranges and Temperature ranges available. Several options and specials possible.



Figure 3: Z-Series

The explosion proof (Eex-ed IIC T6) Z-series, in cast aluminium or 316SS enclosures. Pressure ranges starting from 20 mbar to 540 bar. Vacuum- / Differential ranges and Temperature ranges available. Several options and specials possible.



Figure 4: B-Series

The OEM range the BETA MINI switch is anodized aluminium enclosure fixed Hirschmann connector. Pressure ranges starting from 0.3 bar to 540 bar. Fluid power (hydraulic) range up to 540 bar. Vacuum ranges and Temperature ranges available. Limited option and specials possible.



Figure 5: G-Series

The Differential Pressure Switch G-Series is an aluminum enclosure for low differential pressure. The differential range starting from 2 mbar to 15 mbar by a max. static pressure of 10 bar. The Low pressure side is for use of Air or INERT gas. Any fluid can be used on the High pressure side

3 Project management

3.1 Assessment of the development process

The development audit was closely driven by requirements subsets filtered from the IEC 61508 content of the *exida* SafetyCaseDB database. That means that the Functional Safety Management related requirements were grouped together according their related objectives. The detailed answers to the requirements, i.e. the justification report, were subject to the assessment. This assessment of the justification report was supplemented by the prior review of documents.

The assessment was planned by *exida* Certification S.A. and agreed with BETA B.V.

The following IEC 61508 objectives were subject to detailed auditing at BETA B.V.:

- FSM planning, including
 - Safety Life Cycle definition
 - Scope of the FSM activities
 - Documentation
 - Activities and Responsibilities (Training and competence)
 - Configuration management
 - Tools
- Safety Requirement Specification
- Change and modification management
- Hardware architecture design - process, techniques and documentation
- Hardware design / probabilistic
- Hardware and system related V&V activities including documentation, verification
 - Integration and fault insertion test strategy
- System Validation
- Hardware-related operation, installation and maintenance requirements

The project teams, not individuals were audited.

The development audit has been done in Rijswijk September 29th – 30th 2009.

3.2 Roles of the parties involved

BETA B.V.

Represents the designer of the safety related Pressure, Temperature and Vacuum Switches and the investigated organization. The following teams / responsible persons were audited:

- Managing Director Martin Van der Leden
- Project Management Arvid Bergström
 Safety Manager
 Hardware Development
 Test Team
- System Architect Marian Kokshoorn
 Hardware Development
 Test Team
- Production Test team Peter Van der Stap
- Quality Manager Kees van Tilburg

exida Certification S.A.

Set up and structure of the assessment and audit process, extracted the requirements for the assessment and audit from the IEC 61508 standard and guided through the audit.

The activities were done by *exida* Certification S.A. as an independent organization. The assessment was performed by the CEO, Peter Söderblom who was not involved in the execution of the audited activities.

4 Results of the Functional Safety Assessment

exida Certification S.A. assessed the development process used by BETA B.V. for this development project against the objectives of IEC 61508 parts 1 and 2. The results of the pre-assessment are documented in [R1].

All objectives have been successfully considered in the BETA B.V. development processes for the Pressure, Temperature and Vacuum Switches development.

exida Certification S.A. assessed the safety case prepared by BETA B.V., set of documents, against the functional safety management requirements of IEC 61508. This was done by a pre-review of the completeness of the related requirements and then a spot inspection of certain requirements, before the development audit.

The safety case demonstrated the fulfillment of the functional safety management requirements of IEC 61508-1 and 2.

The detailed development audit (see [R2]) investigated the compliance with IEC 61508 of the processes, procedures and techniques as implemented for the Company Pressure, Temperature and Vacuum Switches.

The investigation was executed using subsets of the IEC 61508 requirements tailored to the work scope of the development team. The result of the assessment can be summarized by the following observations:

The audited BETA B.V. development process tailored and implemented by the Pressure, Temperature and Vacuum Switches development project, complies with the relevant safety management requirements of IEC 61508 SIL2.

The assessment of the FMEDA, which was performed according to IEC 61508, has shown that the Pressure, Temperature and Vacuum Switches has a PFD_{AVG} within the allowed range for SIL2 (HFT = 0) according to table 2 of IEC 61508-1 and a Safe Failure Fraction (SFF) of more than 60%.

This means that the BETA B.V. Pressure, Temperature and Vacuum Switches are capable for use in SIL2 applications, when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual.

Some areas for improvement were nevertheless identified. However, because of the size of the project (limited number of people) and the low complexity / limited size of the products, BETA B.V. was able to demonstrate that the *objectives of the related areas have been successfully met*. More details can be found in the chapters below.

4.1 Technical aspects of the Pressure, Temperature and Vacuum Switches

The Pressure, Temperature and Vacuum Switches are considered to be Type A subsystems with a hardware fault tolerance of 0.

The safety function of the switches is that the micro switch will de-energize when the input pressure, or temperature, rises above, or falls below, the set-point within the stated safety accuracy

Details can be found in chapter 2.2 and in the document "Pressure and Temperature switches, General Bulletin" [D1].

4.2 Functional Safety Management

Objectives of the Functional Safety Management

The main objectives of the related IEC 61508 requirements are to:

- Structure, in a systematic manner, the phases in the overall safety lifecycle that shall be considered in order to achieve the required functional safety of the E/E/PE safety-related systems.
- Structure, in a systematic manner, the phases in the E/E/PES safety lifecycle that shall be considered in order to achieve the required functional safety of the E/E/PE safety-related systems.
- Specify the management and technical activities during the overall, E/E/PES and software safety lifecycle phases which are necessary for the achievement of the required functional safety of the E/E/PE safety-related systems.
- Specify the responsibilities of the persons, departments and organizations responsible for each overall, E/E/PES safety lifecycle phase or for activities within each phase.
- Specify the necessary information to be documented in order that the management of functional safety, verification and the functional safety assessment activities can be effectively performed.
- Document all information relevant to the functional safety of the E/E/PE safety-related systems throughout the E/E/PES safety lifecycle.
- Document key information relevant to the functional safety of the E/E/PE safety-related systems throughout the overall safety lifecycle.
- Specify the necessary information to be documented in order that all phases of the overall, E/E/PES safety lifecycle can be effectively performed.
- Select a suitable set of tools, for the required safety integrity level, over the whole safety lifecycle which assists verification, validation, assessment and modification.

4.2.1 Safety Life Cycle

The development process as described in Product Development E&D [D2] describes the phases in the development process. These phases fit to the relevant SLC in IEC 61508 for these types of devices.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system / development process.

4.2.2 FSM planning

The development process Product Development E&D [D2] describes the phases, input and output, control measures and responsibility for each phase. The main safety related phases of these are:

- Design preparation
- Design
- Testing
- Design review
- Release for production
- Production drawing and document preparation

The review points Requirement review, Design review and Implementation review verifies that the activities performed in each of these phases and the related documentation are correct.

All larger change projects are also performed according to the same process as the development of a new device. A short-cut version of the process is applied for minor changes as described in “Shortlist voor speciale opdrachten” [D3]

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.2.3 Documentation

For all main documents, templates exists which control a common layout of the documents together with consistent document quality attributes (name, number, version, date, author etc.)

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.2.4 Training and competence recording

The different training courses / seminars of each individual in the project are documented in addition to the official education in a personal profile kept at HR. Since the development department is so small (<5 persons), all projects always have access to the developers which have a long experience from similar projects at the BETA B.V.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.2.5 Configuration Management

The configuration management and document management procedures are described in “Toekennen tekeningnummer / onderdeelnummer” [D4]. These procedures are followed for all development work products. No tool is used for supporting the version management but given the small group and a limited number of work items for each project the manual procedure as defined is sufficient.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.2.6 Tools

The tools used for HW development have all been in use at BETA B.V. for an extensive period of time and for a number of different product development projects. The outputs from these tools are subject to extensive verifications and test activities. This together with the low complexity of the products is the argument why the selected tools are deemed as suitable.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.3 Safety Requirement Specification

Objectives of the Safety Requirement Specification

The main objectives of the related IEC 61508 requirements are to:

- Specify the requirements for each E/E/PE safety-related system, in terms of the required safety functions and the required safety integrity, in order to achieve the required functional safety.

4.3.1 Safety Requirement Specification and traceability into design

The Pressure, Temperature and Vacuum Switches have a very limited number of safety related product requirements. As these requirements are the same as the main functional requirements of the switch, no separate SRS was created. As all requirements are thoroughly verified and validated, this approach was considered to be appropriate, fulfilling the objectives of the standard.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.4 Change and modification management

Objectives of change and modification management

The main objectives of the related IEC 61508 requirements are to:

- Ensure that the required safety integrity is maintained after corrections, enhancements or adaptations to the E/E/PE safety-related systems.

4.4.1 Change and modification procedure

The modification procedure is defined in the BETA B.V. development process [D2]. Each modification which leads to a design change is treated as a new development project and thereby following the development process and procedures as described. The Short-cut process which is applied for minor modifications is also described therein.

All change requests to devices which are certified by an external company will be treated by the safety responsible and thereby enforcing the relevant strict handling.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.5 Hardware Design

Objectives of hardware design

The main objectives of the related IEC 61508 requirements are to:

- Create E/E/PE safety-related systems conforming to the specification for the E/E/PES safety requirements (comprising the specification for the E/E/PES safety functions requirements and the specification for the E/E/PES safety integrity requirements).
- Ensure that the design and implementation of the E/E/PE safety-related systems meets the specified safety functions and safety integrity requirements.

Objectives of hardware design / probabilistic properties

The main objectives of the related IEC 61508 requirements are to:

- Ensure that the design and implementation of the E/E/PE safety-related systems meets the specified safety functions and safety integrity requirements.

4.5.1 Hardware architecture design

The product architecture and design is described in the Design Output form [D8] and in Design drawings.

All components and special configurations are listed in the identification list, part list and BoM tool. The designer always starts by searching for a similar component, or solution, in these lists / tool before choosing the actual part. Only if this fails, a new part will be developed and produced.

The switches are built with a 10% safety factor at each end of their range.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.5.2 Hardware Design / Probabilistic properties

The detailed hardware design is described by mechanical drawings with related parts list [D11] and the other design artefacts (calculations etc.) as kept in the Design Cover Sheet [D6] for the product / project. As required by IEC 61508, an FMEDA [R4] with probabilistic calculations is carried out for the product.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.5.2.1 FMEDA - Pressure, Temperature and Vacuum Switches:

This section contains the summary of the FMEDA results performed for the BETA B.V. switches. Further details are found in the FMEDA report [R4].

[C1]	Pressure switches C.-P....- series with air-relay
[C2]	Pressure switches W.-P....- or C.-P.... - or Z.-P....- or B.-P....- series with micro-switch
[C3]	Temperature switches C.-T....- series with air-relay
[C4]	Temperature switches W.-T....- or C.-T....- or Z.-T....- or B.-T....- series with micro-switch
[C5]	Vacuum switches W.-V....- or C.-V....- or Z.-V....- or B.-V....- series
[C6]	Differential pressure switches W.-D....- or C.-D....- or G.-D.... - or Z.-D....- series

	Failure rates (in FIT), Profile 2 data			
	λ_{Safe}	$\lambda_{\text{Dangerous}}$	λ_{Total}	SFF ¹
[C1]	431	212	643	67%
[C2]	276	124	400	69%
[C3]	394	233	627	62%
[C4]	248	134	382	65%
[C5]	171	80	251	68%
[C6]	813	255	1068	76%

Table 1: Pressure, Temperature and Vacuum Switches – Failure rates

The analysis shows that design of the products can meet the hardware requirements of IEC 61508, SIL 2 depending on the complete final element design. The PFD_{AVG} and Safe Failure Fraction and architectural constraints requirements of the IEC 61508 must be verified for each specific design.

4.5.2.2 Impulse line clogging

The failure rates of the Pressure, Temperature and Vacuum Switches which are displayed in section 4.5.2.1 are failure rates that reflect the situation where the pressure switches are used in clean service. Clean service indicates that failure rates due to clogging of the impulse line are not accounted for. For applications other than clean service, the user must estimate the failure rate for the clogged impulse line and add this failure rate to the failure rates of the Pressure, Temperature and Vacuum Switches.

¹ The complete sensor subsystem will need to be evaluated to determine the overall Safe Failure Fraction. The number listed is for reference only.

4.5.2.3 PFD_{AVG} calculation for profile 2

An average Probability of Failure on Demand (PFD_{AVG}) calculation is performed for a single (1oo1) Pressure, Temperature and Vacuum Switches in the worst-case configuration. The failure rate data used in this calculation are displayed in section 4.5.2.1. The resulting PFD_{AVG} (for a variety of proof test intervals) values are displayed in Table 2.

A mission time of 10 years and a MTTR of 24 hours have been considered. It is assumed that proof testing is performed with a proof test coverage of 90%.

For SIL2 applications, the PFD_{AVG} value needs to be < 1.00E-02.

The Proof test procedure is described in the Safety Manual [D13].

Configuration	T[Proof] = 1 year	T[Proof] = 2 years	T[Proof] = 5 years
[C1]	PFD _{AVG} = 1.76E-03	PFD _{AVG} = 2.60E-03	PFD _{AVG} = 5.11E-03
[C2]	PFD _{AVG} = 1.03E-03	PFD _{AVG} = 1.52E-03	PFD _{AVG} = 2.99E-03
[C3]	PFD _{AVG} = 1.94E-03	PFD _{AVG} = 2.86E-03	PFD _{AVG} = 5.61E-03
[C4]	PFD _{AVG} = 1.12E-03	PFD _{AVG} = 1.64E-03	PFD _{AVG} = 3.23E-03
[C5]	PFD _{AVG} = 6.66E-04	PFD _{AVG} = 9.81E-04	PFD _{AVG} = 1.93E-03
[C6]	PFD _{AVG} = 2.02E-03	PFD _{AVG} = 2.97E-03	PFD _{AVG} = 5.83E-03

Table 2: Pressure, Temperature and Vacuum Switches – PFD_{AVG} values

Figure 6 shows PFD_{AVG} as a function of the proof test interval.

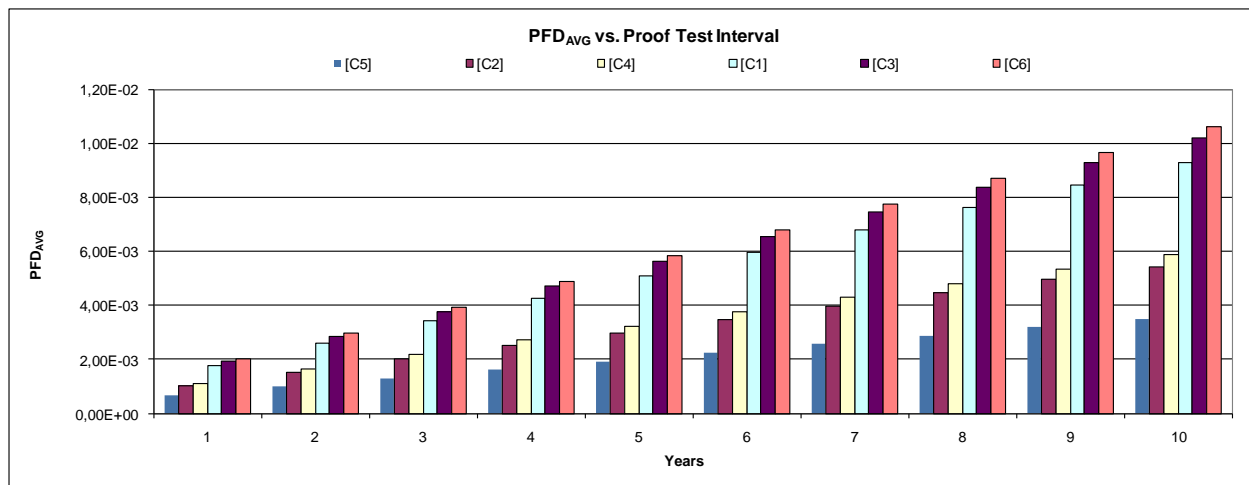


Figure 6: PFD_{AVG}(t)

4.6 Verification & Validation

Objectives of HW related verification & validation activities

The main objectives of the related IEC 61508 requirements are to:

- Demonstrate, for each phase of the overall, E/E/PES and software safety lifecycles (by review, analysis and/or tests), that the outputs meet in all respects the objectives and requirements specified for the phase.
- Test and evaluate the outputs of a given phase to ensure correctness and consistency with respect to the products and standards provided as input to that phase.
- Integrate and test the E/E/PE safety-related systems.
- Ensure that the design and implementation of the E/E/PE safety-related systems meets the specified safety functions and safety integrity requirements.
- Plan the validation of the safety of the E/E/PE safety-related systems.
- Validate that the E/E/PE safety-related systems meet, in all respects, the requirements for safety in terms of the required safety functions and the safety integrity.

4.6.1 HW related V&V activities

The development and the corresponding verification and validation activities are described in Product Development E&D [D2]. For each phase, the required input and output documents / work products are listed together with their corresponding verification activities.

At the end of each phase, the results of the different verification steps are being reviewed before moving on to the next phase. During the on-site audit, a selection of the different verification procedures and steps were presented to the assessor. The results of these activities are all tracked in the Design Cover Sheet [D6] and are all kept under the configuration management as described in section 4.2.5.

The Design test consists of a function test verifying the range of the switch and a lifetime test. The production test contains a full functional test of the switch and can therefore be used as validation evidence for the switch.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

4.7 Safety Manual

Objectives of the Safety Manual

The main objectives of the related IEC 61508 requirements are to:

- Develop procedures to ensure that the required functional safety of the E/E/PE safety-related systems is maintained during operation and maintenance.

4.7.1 Operation, installation and maintenance requirements

The responsibility of BETA B.V. is to provide the end-users with a Safety Manual [D13], with all necessary product information in order to enable a correct and safe engineering of the product in a safety instrumented function. The Safety Manual [D13] should be used together with the “Assembly, installation and adjustment manual” [D12] in which the general installation and maintenance procedures are described.

Additionally, the provided information enables the end-user to perform the required verification analysis steps of a safety instrumented function, e.g. SFF, PFD, proof test interval and procedure, etc.

Conclusion: The objectives of the standard are fulfilled by the BETA B.V. functional safety management system.

5 Agreement for future assessment

Areas of possible improvements have been identified during the assessment. However, these are not assessed to be in contradiction to an overall positive judgment of the subject.

Recommendations have been given by *exida* Certification S.A. to BETA B.V. as confidential information for the following lifecycle phases:

- Configuration management

6 Reference documents

The services delivered by *exida* Certification S.A. were performed based on the following standards.

- N1 IEC 61508-1:1998 Functional Safety of E/E/PES; General requirements
- N2 IEC 61508-2:2000 Functional Safety of E/E/PES; Hardware requirements

The assessment delivered by *exida* Certification S.A. was performed based on the audit of the following documents.

- D1 Pressure and Temperature switches, General Bulletin SP.210.I/08/05/4M
- D2 Product development E&D, 5.3.03, 9/9/2004
- D3 Shortlist voor speciale opdrachten, 5.3.02/22, 4/8/2005
- D4 Toekennen tekeningnummer / onderdeelnummer 5.3.03/01, 3/11/2004
- D5 E & D request form, 5.3.03/09, 9/11/2004
- D6 Drawing Cover Sheet, 5.3.03/10, 9/11/2004
- D7 Design input form, 5.3.03/11, 9/11/2004
- D8 Design output form, 5.3.03/12, 10/11/2004
- D9 Test report, 5.3.03/13, 9/09/2004
- D10 Indentlijst, 5.3.03/16, 10/09/2004
- D11 Parts file, 5.3.03/17, 10/09/2004
- D12 I.O. Manual SP 001 Rev. K, August 2008
- D13 Beta B.V. Pressure and Temperature switches Safety Manual, Rev. A, April 2010

The supporting services delivered by *exida* Certification S.A. were documented by the following documents / databases.

- R1 BETA FSM V1R0 - SafetyCaseDB back-end
- R2 BETA Tech V1R0 - SafetyCaseDB back-end
- R3 BETA 0804-32-C R004 V1R1 - Results of the IEC 61508 Functional Safety Assessment (this document)
- R4 BETA 0804-32-C R001 V1 R1 – FMEDA
- R5 FSM Justification report – BETA 0804-32-C R002 V1R0
- R6 Technical Justification report – BETA 0804-32-C R003 V1R0
- R7 BETA 0804-32-C R005 V1R1 - Results of the IEC 61508 Functional Safety Assessment Recommendations. V1R0, April 2010, Confidential Report

7 Status of the document

7.1 Releases

Version History: V0, R1: Initial Report March 29th, 2010
V0, R2: Updated after review by the certifying assessor.
March 30th, 2010
V1, R0: Updated after customer review, April 7th 2010
V1, R1 Updated clarifying air-relay / micro-switch and G housing
added.

Author: Peter Söderblom

Review: V0, R1 Audun Opem
V0, R2 Customer and Audun Opem.

Release status: Released.