

exida Certification S.A. 2 Ch. de Champ-Poury CH-1272 Genolier Switzerland

Tel.: +41 22 364 14 34 email: info@exidaCert.ch

Results of the IEC 61508 Functional Safety Assessment

Project: HiC2851, HiC2853 and HiC2853R2

> Customer: Pepperl+Fuchs GmbH Mannheim Germany

Contract No.: 08/03-32R1-C Report No.: 0803-32R1-C R003 Version 2, Revision 1, November 2011

Peter Müller, Peter Söderblom



Management summary

The Functional Safety Assessment of the Pepperl+Fuchs GmbH, HiC2851, HiC2853 and HiC2853R2 performed by exida Certification S.A. consisted of the following activities:

exida Certification S.A. assessed the setup of the development process used by Pepperl+Fuchs GmbH for development projects against the relevant requirements of IEC 61508:2000 parts 1 to 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 HiC2851, HiC2853 and HiC2853R2 development project.

- exida Certification S.A. audited the development process by a detailed development audit which investigated the compliance with IEC 61508:2000 of the processes, procedures and techniques as implemented for the Pepperl+Fuchs GmbH HiC2851, HiC2853 and HiC2853R2 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 Pepperl+Fuchs GmbH against the technical requirements of IEC 61508:2000.

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

The audited Pepperl+Fuchs GmbH development process tailored and implemented by the HiC2851, HiC2853 and HiC2853R2 Hardware development project, complies with the relevant safety management requirements of IEC 61508:2000 SIL3.

The assessment of the FMEDA, which was performed according to IEC 61508:2000, has shown that the HiC2851, HiC2853 and HiC2853R2 has a PFD_{AVG} / PFH within the allowed range for SIL3 (HFT = 0) according to table 2 and 3 of IEC 61508-1 and a Safe Failure Fraction (SFF) of > 99%.

This means that the HiC2851 with Hardware version 05-4361B; HiC2853 and HiC2853R2 both with HW version 05-6498, are capable for use in SIL3 applications in low or high demand mode, when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual.

Assessor Dipl-Ing. (FH) Peter Müller | Peter Söderblom

Assessor

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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 HiC2851, HiC2853 and HiC2853R2 with the technical IEC 61508-2 requirements for SIL3 and the derived product safety property requirements

and

- the HiC2851, HiC2853 and HiC2853R2 development processes, procedures and techniques as implemented for the safety-related deliveries with the managerial IEC 61508-1and -2 requirements for SIL3.

It was not the purpose to assess the fulfilment of the statement of conformance from Pepperl+Fuchs GmbH 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 Pepperl+Fuchs GmbH 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* Certification assessment documents, templates and checklists which are derived from 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, e.g. for the document review & assessment comments and the assessment plan.



2 **Project Description**

2.1 Description of the Functional Safety Management System

The functional safety management system is implemented by the use of the functional safety management plan, included in the Development process for HiC2851 document [D19], and the related planning documents, which describes the activities in detail. The functional safety management plan shows the implementation of a safety life cycle model which adopts the V-model as described in IEC 61508.

The related planning documents are mainly the verification and validation plan and a set of guidelines.

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

2.2 Description of the System

The HiC2851, HiC2853 and HiC2853R2 shall provide the following Type A safety function for the low and high demand mode of operation:

The HiC2851, HiC2853 and HiC2853R2 shall transfer discrete signals from a hazardous area to a safe area.

The binary input signal controls directly the electronic output and the resistive output for use in safety applications.

The error output, which indicates short circuit or open circuit of the loop is not intended to be used in a safety function.

2.2.1 Description of the variant HiC2851

Output I is connected to 11+ and 14- and designed to deliver 20V @ 15mA (24VDC nominal).

Output II emulates a Namur-sensor to connect the HiC2851 to fail safe NAMUR inputs. Between the connectors 12+ and 15- several resistance levels will be set depending on the device's status at the input



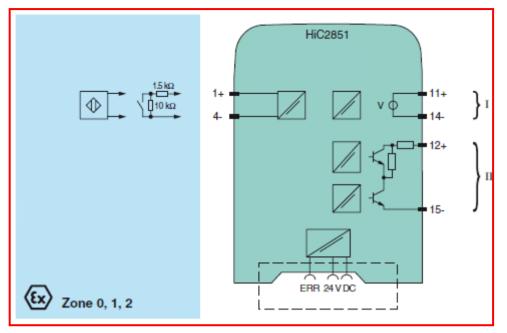


Figure 1 HiC2851

2.2.2 Description of the variant HiC2853

Output I emulate a Namur-sensor to connect the HiC2853 to fail safe NAMUR inputs. Between the connectors 11+ and 14- several resistance levels will be set depending on the device's status at the input.

The output II is connected to 12+ and 15- and designed to deliver 20V @ 15mA (24VDC nominal).

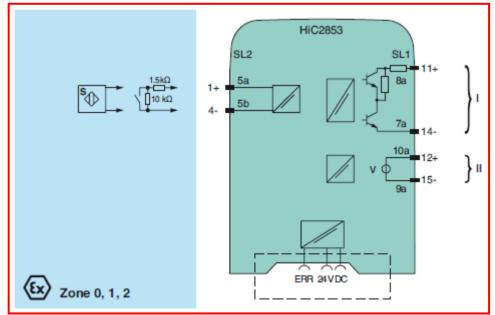


Figure 2 HiC2853



2.2.3 Description of the variant HiC2853R2

Output I of the HiC2853R2 has modified output impedances for the compatibility with the digital input of the RUSIO-3224 module from Honeywell. Between the connectors 11+ and 14- several resistance levels will be set depending on the device's status at the input. This output is built to be externally supplied with 24V (Ri = 250 Ohm).

The output II is connected to 12+ and 15- and designed to deliver 20V @ 15mA (24VDC nominal).

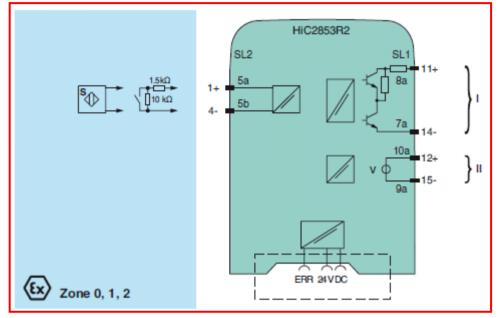


Figure 3 HiC2853R2

3 **Project management**

3.1 Assessment of the development process

The development audit was closely driven by subsets of the IEC 61508 requirements. 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 Pepperl+Fuchs GmbH.

The following IEC 61508 objectives were subject to detailed auditing at Pepperl+Fuchs GmbH:

- FSM planning, including
 - Safety Life Cycle definition
 - Scope of the FSM activities
 - o Documentation



- Activities and Responsibilities (Training and competence)
- Configuration management
- 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 related V&V activities including documentation, verification
- System Validation
- Hardware-related operation, installation and maintenance requirements

The project teams, not individuals were audited.

The development audit has been done in Mannheim, 14.08.2008 and 23.09.2008

For the update related to HiC2853 and HiC2853R2, the review was done offline in October 2011.

3.2 Roles of the parties involved

Pepperl+Fuchs GmbH

Represents the designer of the safety related HiC2851, HiC2853 and HiC2853R2 and the investigated organization. The following teams / responsible persons were audited:

- Project Manager, Safety Manager
- System Architect / HW Entwicklung
- Test team / Qualitätssicherung

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 Peter Söderblom and Peter Müller, who were 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 Pepperl+Fuchs GmbH for this development project against the objectives of IEC 61508 parts 1 to 2. The results of the pre-assessment are documented in [R1].

All objectives have been successfully considered in the Pepperl+Fuchs GmbH development processes for the HiC2851, HiC2853 and HiC2853R2 development.

exida Certification S.A. assessed the safety case prepared by Pepperl+Fuchs GmbH, including a 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 Pepperl+Fuchs GmbH HiC2851, HiC2853 and HiC2853R2 development projects.

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 shows that the HiC2851 with Hardware version 05-4361B; HiC2853 and HiC2853R2 both with HW version 05-6498, are capable for use in SIL3 applications in low or high demand mode, when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual.

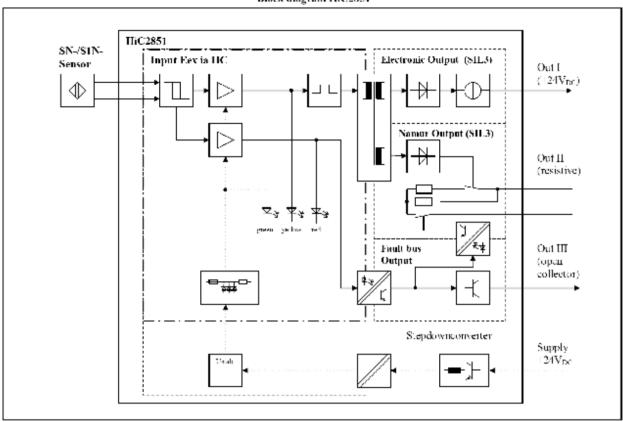
Some areas of improvement were nevertheless identified. The recommended improvements given are generally required to formally show the compliance to IEC 61508. However, Pepperl+Fuchs GmbH were able to demonstrate with respect to the size of the project (limited number of people) and the specific complexity of the product that the objectives of the related areas have been successfully met. More details can be found in the chapter below.

4.1 Technical aspects of the HiC2851, HiC2853 and HiC2853R2

The HiC2851, HiC2853 and HiC2853R2 are single channel Type A (HFT=0) devices with low complexity and with a systematic capability of SIL 3.

The HiC2851, HiC2853 and HiC2853R2 are galvanic isolated intrinsic safety barriers with a built in amplifier which transfer discrete signals (SN/S1N-Proximity sensors and approved mechanical contacts) from a hazardous area (Ex-Area) to a safe area. These barriers are provided with additional protective circuitry to maintain a reliable safety function.





Block diagram HiC2851

Figure 4 Block diagram HiC2851

The possibility to use the devices with the electronic output and the resistive output is considered to be compliant to IEC 61508 without a read back / diagnostic functionality, as the SFF is successfully met.

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 and software 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 and software safety lifecycles 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 is structured so all relevant phases of the overall Safety Life Cycle are identified and that different phases are defined with necessary activities, inputs and outputs.

Conclusion: The objectives of the standard are fulfilled by the Pepperl+Fuchs GmbH functional safety management system.

4.2.2 FSM planning

The standard quality process for Pepperl+Fuchs GmbH has been modified and extended in order to comply with the Functional Safety Management requirements in IEC 61508. This is documented and described in the document: P+F development process for HiC2851 [D19]. In this document the different phases together with the corresponding work items and their required input and output is defined. It also contains references to other planning documents where the verification and validation activities and methods are defined. The roles and responsibilities are also defined herein.

The modification process is also described in this document.

Conclusion: The objectives of the standard are fulfilled by the Pepperl+Fuchs GmbH functional safety management system.

4.2.3 Documentation

A set of templates and guidelines which controls the common layout of documents together with basic properties as document name or number, revision and approval identification exists and is part of the normal quality system of Pepperl+Fuchs GmbH.



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 project specific contact list. Also the applicable project experiences were, in some cases, used as reasoning behind the competence evaluation for the members of the project.

In addition safety coaches with extended safety experience were used throughout the project.

Conclusion: The objectives of the standard are fulfilled by the Pepperl+Fuchs GmbH functional safety management system.

4.2.5 Configuration Management

The handling of configurations is described in P+F development process for HiC2851 [D19]. This includes responsibilities for the activities, the items to be under version control and the defined tools / methods for this.

Conclusion: The objectives of the standard are fulfilled by the Pepperl+Fuchs GmbH 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 Safety Requirement Specification [D3] contains the safety functions and the safety integrity requirements for the HiC2851.

The requirements for the HiC2853 and HiC2853R2 are addressed as being the same as for the HiC2851 [D3] with the additions / modifications as specified in the Impact Analysis [D23].

The SRS provides a basis for simple tracking off the fulfillment of the requirements.



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

A modification procedure is defined in P+F development process for HiC2851 [D19]. This is implemented for product changes starting with formal validation tests for the HiC2851 project. The defined modification procedure, containing a procedure for Impact Analysis, in combination with the generic development model fulfils the objectives of IEC 61508.

The HiC2853 and HiC2853R2 project was performed as a modification project of HiC2851 and based on an impact analysis[D23] which fulfils the requirements of IEC 61508.

Conclusion: The objectives of the standard are fulfilled by the Pepperl+Fuchs GmbH 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 HW architecture is described by the Functional Description HIC2851. The hardware design follows the rules of modularization, the use of well-known components and de-rating.



4.5.2 Hardware Design / Probabilistic properties

The detailed hardware design is described by the Functional Description HIC2851 and supplemented by Circuit Diagrams, layout drawings and a related parts list. As required by IEC 61508, an FMEDA with probabilistic calculations and the related fault insertion tests has been carried out for the HIC2851.

To comply with the SIL3 requirements, the off-line Proof test Procedure need to be carried out at least every 5 years for the resistive output. For the electronic output the proof test needs to be carried out at least every 10 years.

Conclusion: The objectives of the standard are fulfilled by the Pepperl+Fuchs GmbH functional safety management system.

4.5.2.1 FMEDA - HiC2851, HiC2853 and HiC2853R2 Electronic Output:

The Safe Failure Fraction was confirmed additionally by the Fault insertion tests. The PFH and PFD_{AVG} listed below shows SIL 3 capability.

Table 1 Failure rates according to IEC 61508 – Electronic Output

λ_{sd}	λ_{su}^{1}	$\lambda_{ m dd}$	λ_{du}	SFF
0 FIT	332 FIT	0 FIT	1,91 FIT	99,43%

Table 2 PFH / PFD_{AVG} values – Electronic Output

T[Proof] = 1 year		T[Proof] = 2 years	T[Proof] = 5 years
PFH = 1,91E-9 /h PFD _{AVG} = 8,37E-06		PFD _{AVG} = 1,67E-05	PFD _{AVG} =4,18E-05

4.5.2.2 FMEDA - HiC2851, HiC2853 and HiC2853R2 Resistive Output:

The Safe Failure Fraction was confirmed additionally by the Fault insertion tests. The PFH and PFD_{AVG} listed below shows SIL 3 capability.

Table 3 Failure rates according to IEC 61508 – Resistive Output

λ _{sd}	λ_{su}^{1}	λ_{dd}	λ_{du}	SFF
0 FIT	334 FIT	0 FIT	2,99 FIT	99,11%

Table 4 PFH / PFD_{AVG} values – Resistive Output

	T[Proof] = 1 year	T[Proof] = 2 years	T[Proof] = 5 years
PFH = 2,99E-9 /h	PFD _{AVG} = 1,31E-05	PFD _{AVG} = 2,62E-05	PFD _{AVG} =6,55E-05

¹ Note that the SU category includes failures that do not cause a spurious trip



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 P+F development process for HiC2851 [D19] defines the required verification activities related to hardware and system including documentation, verification planning, test strategy and requirements tracking to validation test.

All applicable analysis steps as e.g. FMEDA, de-rating analysis and common cause failure analysis were planned and verified to be successful. All relevant practical tests as e.g. fault insertion test and validation tests were planned and successfully executed.

All specified safety requirements were tracked and successfully validated. The test specification contains the required description of the test, acceptance criteria and the documented result. Other applicable aspects as the used configuration, version and use of calibrated tools as required is documented in order to enable a re-test of the product at a later stage.

Conclusion: The objectives of the standard are fulfilled by the Pepperl+Fuchs GmbH 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 P+F is to provide the end-users with Safety Manuals for HiC2851 [D17] and HiC2853 and HiC2853(R2) [D27], with all necessary product information in order to enable a correct and safe engineering of the product in a safety instrumented function. Additionally, the provided information enables the end-user to perform the required verification analysis steps of a safety instrumented function, e.g. SFF, PFD/PFH, proof test interval and procedure, etc. The Safety Manual partly also refers the data sheets which are available of the official web-site for details regarding environmental conditions and other approvals of the product.

The Manuals describes the off-line Proof test Procedure which need to be carried out at least every 5 years for the resistive output. For the electronic output the proof test needs to be carried out at least every 10 years. The description in the manuals has been subject to validation activities at Pepperl+Fuchs GmbH.



5 Agreement for future assessment

Areas of possible improvements have been identified during the assessment of the HiC2851 development project. 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 Pepperl+Fuchs GmbH as confidential information for the following lifecycle phases / sub-phases:

- Documentation
- Training and competence recording
- Safety Requirement Specification

In the HiC2853 and HiC2853R2 project, the following recommendations from the initial HiC2851 project were closed:

- FSM planning
- Change and modification procedure
- Operation, installation and maintenance requirements



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
N3	IEC 61508-3:1998	Functional Safety of E/E/PES; Software requirements

The assessment delivered by *exida* Certification S.A. was performed based on the review of the following documents as provided by Pepperl+Fuchs GmbH.

D1	Safety Requirement Specification	FS-0005EA-28B
D2	Functional Description	FS-0005EA-31B
D3	FMEDA	FS-0005EA-20B
D4	FMEDA Safety output 1	FS-0005EA-26A.xls, 2008-Sep-22
D5	FMEDA Safety output 2	FS-0005EA-26A4.xls, 2008-Sep-22
D6	Critical components	FS-0005EA-xx, 2008-Jun-20
D7	Circuit Diagram	01-7080C , 2008-Apr-16
D8	Technical Justification Report Technical Solutions based on HIC2851 Type A IEC61508 Tech V0R1.efm	V0R1, with comments
D9	FSM Justification Report FSM Solutions based on HIC2851 Type A IEC61508 FSM V0R1.efm	V1R0, with comments
D10	Safety Validation Plan HiC2851	FS0005EA-29B
D11	Safety Validation Results HiC2851 (Prototypes)	FS0005EA-30A
D12	Safety Validation Results HiC2851 (Pilot Run Phase)	FS0005EA-30A2
D13	Validation of Proof Test	FS0005EA-26A6
D14	Safety Validation of User Information	FS0005EA-35A
D15	Data Sheet	FS0005EA-33 FS0005EA-33A3
D16	Safety Case	FS-0005EA-24A
D17	Safety Manual HiC2851	212351 DOCT-1594 01/2009 212351 DOCT-1594C 01/2011
D18	De-rating analysis for critical components HiC2851	FS-0005EA-26A7



D19	Development process for HiC2851	FS0005EA-23B
D20	QM-Plan	FS0005EA-23B2
D21	V&V Plan	FS0005EA-22
D22	Impact analysis checklist	FTM028
D23	Impact Analysis for changes to SIL devices – HiC2853, HiC2853R2	FS-0005EA-25A dated 16-Aug-2011
D24	Functional Safety Documents – HiC2851, HiC2853, HiC2853R2	FS-0005EAB dated 15-Aug-2011
D25	Data sheet Switch Amplifier HiC2853	FS-0005EA-33A dated 29-Jul-2011
D26	Data sheet Switch Amplifier HiC2853R2	FS-0005EA-33A2 dated 29-Jul-2011
D27	Safety manual HiC2853(R2)	DOCT-2418 dated 04/2011

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

- R1 Assessment & Document Review Comments Version 1 Revision 4, April 2009 Confidential Report
- R2 P+F 0803-32R1C R003 Results of the IEC 61508 Functional Safety Assessment (this document)
- R3 P+F 0803-32R1C R001 Assessment Plan V0R1
- R4 P+F 0803-32R1C R004 Recommendations caused by the IEC 61508 Functional Safety Assessment V1R1 September 2010, Confidential Report
- R5 P+F 1109-098-C R020 Assessment and review comments HiC2853(R2) V1R0, October 2011 Confidential Report



7 Status of the document

7.1 Releases

Version History:	V0R1:	Initial Report 04-May-2009
	V0R2	Updated after review by Certifying Assessor 06-May-2009
	V1R0	Released version
	V1R1	Report harmonized for Pepperl+Fuchs 29-Sep-2010
	V2R0	Updated with HiC2853 and HiC2853R2, 20-Oct-2011 and 04-Nov-2011
	V2R1	Updated after review by Pepperl+Fuchs 25-Nov-2011
Author: Peter Müller, Peter Söderblom		Peter Söderblom
Review:	V0R1	Audun Opem, Certifying Assessor 05-May-2009
	V0R2	Pepperl+Fuchs GmbH 8-May-2009
	V2R0	Pepperl+Fuchs GmbH 25-Oct-2011

Release status: Released