Conformity Risk Assessment
To Comply With Low Voltage Directive 2014/35/EU

Product:
Model:

(1) The following requirements are mentioned in Annex Ⅲ of Low Voltage Directive 2014/35/EU

MODULE A
Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the electrical equipment concerned satisfy the requirements of this Directive that apply to it.
2. Technical documentation
   The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the electrical equipment's conformity to the relevant requirements, and ***shall include an adequate analysis and assessment of the risk(s)***. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the electrical equipment. The technical documentation shall, where applicable, contain at least the following elements:

Manufacturer has implemented risk analysis and assessment according to the method of R-Map specified by manufacturer's standard.

The following list indicates the dominant contents of risk assessment performed by manufacturer about FSS PRODUCT.
Regarding Risk number (#) in the list, it corresponds to risk analysis identified by risk meeting. Contents of safety countermeasure have been verified with engineering considerations and described in technical documentation. In details, please see the R-Map of risk assessment report for safety design

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(2) Method of Risk Assessment
The followings are basic concept to perform Risk Assessment at manufacturer's place.

Assess the scale of risk by filling out the levels of safety countermeasure, the contents of safety countermeasure and reduction level (effectiveness) of corresponding safety countermeasure.
If the scale of risk does not result in C area after performing corresponding safety measure, fill out the "Severity of harm" and "Occurrence frequency" after performing corresponding safety measure in the underneath the specified column, and verify another safety countermeasure. Finally, if the scale of risk does not result in C area, fill out the reason in the Risk Assessment Sheet.

製品残存リスク： Remaining risk in the target product	A3	×		個 pieces	本領域にリスクが残留する場合、現状での製品化をしてはならない。 追加で安全対策を施し、他のリスク領域までリスクを低減しなければならない。 If any risk remains in these areas, we need to stop product planning.
	A2	×		個 pieces	
	A1	×		個 pieces	
	B3	×		個 pieces	本領域にリスクが残留する場合、製品仕様の見直しを十分に検討しなければならない。 B3、B2領域に残留するリスクがある場合、A領域のリスクに発展する可能性があるため、追加の安全対策を施すべきである。 If any risk remains in these areas, we need to reconsider product specification very well. If any risk remains in B3 or B2 areas, we should add safety countermeasure to avoid getting it worse risk in A areas.
	B2	×		個 pieces	
	B1	×		個 pieces	
	C	×		個 pieces	

R-Map

			危害の程度				
			なし	製品発煙	製品発火 製品損傷	火災	火災 (建物損傷)
			なし	軽傷	通院加療	重傷 入院治療	死亡
			無傷	軽微	中程度	重大	致命的
			0	1	2	3	4
発生頻度	頻発する	5	C	B3	A1	A2	A3
	しばしば発生する	4	C	B2	B3	A1	A2
	時々発生する	3	C	B1	B2	B3	A1
	起こりそうに無い	2	C	C	B1	B2	B3
	まず起こり得ない	1	C	C	C	B1	B2
	考えられない	0	C	C	C	C	C

A	許容できないリスク領域
B	最小限のリスクまで低減すべき領域
C	社会的に受入可能なリスク領域

判定結果：
（該当するものに○をつける）
Judgement result:
(Add circle to applicable one, Yes or No.)

問題なし　・　問題あり（出荷不可）
No problem　Have problems (Fail to ship)

問題点／対策／フォロー方法 等：
Problems/countermeasure/follow-up method, etc.:

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(3) Risk Assessment Report (Summary of Risk Assessment implemented by manufacturer)

The following list indicates the dominant contents of risk assessment of the product performed by manufacturer. Regarding Risk number (#) in the list, it corresponds to risk analysis identified by risk meeting. Contents of safety countermeasure have been verified with engineering considerations and described in technical documentation. In details, please see the Risk Assessment Sheet according to safety design.

Item No.	DESCRIPTION	HOW RISK APPLIES TO THE PRODUCT UNDER CONSIDERATION	STANDARD THAT APPLIES
1.	■PRODUCT SAFETY As the product in using, it could occur malfunction to the product, and make bad influence to human and property due to not enough for safety measures.		
2.	■EMC Electro-magnetic wave from the product interferes other equipment, and it could become in malfunction. And the product may receive interference from other equipment, and it could become in malfunction.		
3.	■TRANSPOTATION 1. Packing 2. Carrying		

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4.	■INSTALLATION 1. Unpacking 2. Installation 3. Setting (Input power) 4. Environment (Recycle)		
5.	■OPERATION 1. Trouble Shooting 2. Continuous Working 3. Connection (Interface) 4. Mal-function 5. Providing Supplies 6. Intentional Act 7. Unintentional Act.		
6.	■MAINTENANCE 1. Checking before working 2. Cleaning 3. Maintenance 4. Repair		
Remarks; The above Risks#x to #xx are including hazardous events such as Mechanical, Electrical, Thermal, Fire and so on. Risk analysis has been performed by representative persons of the manufacturer.			

*This document is prepared by the manufacturer to meet Low Voltage Directive (AnnexⅢ) 2014/35/EU.

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Date; Day Month, Year

Prepared by; _____

(Responsible person)
(Title)
Engineering Dept.

(Company)

(Address)

http://fujisafety.jp/