Conformity Risk Assessment
To Comply With RE Directive 2014/53/EU

Product name:
Model:

(1) The following requirements are mentioned in Annex Ⅲ of RE (Radio Equipment) Directive 2014/53/EU.

ANNEXⅢ

CONFORMITY ASSESSMENT MODULES B AND C

EU-TYPE EXAMINATION AND CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

When reference is made to this Annex, the conformity assessment procedure shall follow Modules B (EU-type examination) and C (Conformity to type based on internal production control) of this Annex.

Module B
EU-type examination

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.

2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice. The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive 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 radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;

(d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the radio equipment.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive that apply to the radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type. The EU-type examination certificate may have one or more annexes attached. The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control. Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued. Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the *Official Journal of the European Union* have not been applied or not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for

10 years after the radio equipment has been placed on the market. 10.The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

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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/MF/RE 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		
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 RE (Radio Equipment) Directive (AnnexⅢ) 2014/53/EU.

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Date; Day Month, Year

Prepared by; _____

(Responsible person)
(Title)
Engineering Dept.

(Company)

(Address)

http://fujisafety.jp/