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

Product name:
Model:

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

ANNEXⅡ

CONFORMITY ASSESSMENT 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 of this Annex, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements set out in Article 3.

2. Technical documentation
   The manufacturer shall establish the technical documentation in accordance with Article 21.

3. Manufacturing
   The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ***ensure compliance of the manufactured radio equipment with the technical documentation referred to in point 2 of this Annex and with the relevant essential requirements set out in *Article 3.***

Article 3: **Essential requirements (RE Directive 2014/53/EU)**

1.Radio equipment shall be constructed so as to ensure:

(a) the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying;

(b) an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.

2.Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.

3.Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:

(a) radio equipment interworks with accessories, in particular with common chargers;

(b) radio equipment interworks via networks with other radio equipment;

(c) radio equipment can be connected to interfaces of the appropriate type throughout the Union;

(d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;

(e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;

(f) radio equipment supports certain features ensuring protection from fraud;

(g) radio equipment supports certain features ensuring access to emergency services;

(h) radio equipment supports certain features in order to facilitate its use by users with a disability;

(i)radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated. The Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories or classes of radio equipment are concerned by each of the requirements set out in points (a) to (i) of the first subparagraph of this paragraph.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it 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. The EU declaration of conformity shall identify the radio equipment for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, 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 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 (Annex Ⅱ) 2014/53/EU.

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Date; Day Month, Year

Prepared by; _____

(Responsible person)
(Title)
Engineering Dept.

(Company)

(Address)

http://fujisafety.jp/