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Risk Assessment according 2014/53(RED)

Purpose:

The risk analysis that are most relevant for the development of products and applications compliance to the European Union RED 2014/53/EU directive. It focuses among others on health, safety, spectrum and environmental risks.

Objectives:

The objectives of product risk management are to increase the probability and impact of the positive events, and decrease the probability and impact of the negative events.

Risk analysis is an essential part of product risk management which includes the processes of conducting risk management planning, identification, analysis, response planning and monitoring and control.

Overview of product risk management processes:

- 1- Planning: The process of defining how to conduct risk management activities for a product.
- 2- Identification: The process of determining which risks may affect the product and documenting their characteristics. The outcome is a list of potential risks.
- 3- Analysis: The process of prioritizing risks for further analysis or action by assessing and combining their probability of occurrence and impact, and analyzing the effect of identified risks. Categorize the risk (e.g. low, medium, high (or any other rating scale based on severity and probability)).
- 4- Responses: The process of developing options and actions to enhance opportunities and to reduce threats to the product.
- 5- Monitor & Control: The process of implementing risk response plans based on risk categorization, and define and implementing needed control measures.

Identification of Equipment	
Model Name	Hand Free Module
Brand Name	Continental
Model NO.	HFM4C01

Identification of Equipment

Target environmental for radio application

Automotive, additional requirements requested to RED defined in ECE 10 Directive & OEM
Requirements
Îndustry
Consumer
Medical, additional requirements requested to RED defined in 93/42/EU
Airborne, additional requirements requested to RED defined in OEM Requirements
Ship, additional requirements requested to RED defined in OEM Requirements or 96/98/EU&
2014/90/EU
ARTEX 93/15/EU & 2014/28/EU
Other

Identification of hazards / risks.	Analysis	Evaluation (Low,medi	Control measures
11a2a1 US / 115885.	~	um, high)	
Electric shock	Connecting to device with improperly grounded equipment can result in an electric shock to the device and may permanently damage the device.	Low	Device has been tested in accordance with the adequate standards (ETSI EN 62368-1) and meets the essential requirement. Clear safety instructions are provided in the user instruction to avoid the undesirable operating condition such as connecting device to poor grounding devices which would easier to cause electric shock.
Extreme heat, fire	High temperature environment or intensive sunlight could raise the heat of the device and may result in fire.	Low	Device has been tested in accordance with the adequate standards ETSI EN 62368-1 and meets the essential requirement. Clear safety instructions are provided in the user instruction to avoid the undesirable operating environment such as hot area or direct sunlight which would easier to cause extreme heat or fire.
Power supply	Using incorrect type of power supply, charger, may result in Safety/EMC issues.	Low	The power supply has been tested in accordance with the adequate standards (ETSI EN 301 489-1, ETSI EN 301 489-3 and ETSI EN 62368-1), andmeets the essential requirement. Instruction of choosing the tested AC adapter is provided in the user instruction. User has been warned that they should not use incorrect power supply.
Causing interference or damage to other electronic devices such as TV, medical equipment, and aircraft.	Some equipment is vulnerable to interference causing by this device.	Low	Device has been tested in accordance with the adequate standards (ETSI EN 301 489-1 and ETSI EN 301 489-3) and meets the essential requirement. Clear instruction of restriction in operating this device in hospital and aircraft are provided in the user instruction in a language that easily understand by end users.
Radiation to human/animals	Wireless devices could generate radiation. Other electronic devices, microwave ovens, may also generate the radiation to user and causing higher level of RF exposure.	Low	Device has been tested in accordance with (ETSI EN 62311) and meetsthe essential requirement. Clear instructions regarding the protection to RF exposure are provided in the user instruction in a language that easily understand by end users.
Transmission Power	Essential requirement of the use of radio spectrum efficiency as requested by Radio Equipment Directive.	Low	Device has been tested in accordance with the adequate RF standards (ETSI EN 300 330, ETSI EN 300 220) and meets the essential requirement.
Radio Spurious Emission	Essential requirement of the use of radio spectrum efficiency as	Low	Device has been tested in accordance with the adequate RF standards (ETSI EN 300 330, ETSI EN 300 220) and meets the essential

requested by Radio	requirement.
Equipment Directive.	

Conclusion

All relevant risks of the«Continental», Hand Free Module, model HFM4C01

(the name of the product)

according to the essential requirements of the RED are considered and evaluated by application of the identified standards.



__Claudia Ioana Vlasin_

_____ (Signature & Stamp)

Continental Automotive Technologies GmbH