





# **EU – TYPE EXAMINATION CERTIFICATE RADIO EQUIPMENT DIRECTIVE 2014/53/EU Annex III Module B**

#### MANUFACTURER

MINOTICIONER	
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#### PRODUCT DESCRIPTION

Trademark/Trade Name :	Olive Healthcare Health to the thirt Tameron
Model Number :	MT715-BTWT, MT715-BTGY
Product Description :	Fitto

#### NOTIFIED BODY

Certificate issued by	Notified Body 1	177, TIMCO Engineer	ring, Inc.	
Certificate number	E1177-221586			
Name and Signature	Bruno Clavier	Bruno Clavier	Date:	February 4, 2022

The device shall be marked as follows:



Based on the evidence presented in the Technical Documentation, TIMCO Engineering, Inc., as appointed Notified Body, has issued this EU-Type Examination Certificate in accordance with Annex III Module B. The product described appears to be in conformity with the essential requirements Article 3.1(a), 3.1(b), and 3.2 of RED 2014/53/EU. This certificate relates only to the documents as provided to Timco Engineering, Inc. and is valid up to (1) the date of cessation of presumption of conformity of any of the superseded standards which were used for testing this product and assessed by Notified Body or (2) the date of modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of this Directive or the conditions for validity of that certificate, whichever comes first.

TIMCO Engineering, Inc.	This Certificate is issued under the provision that TIMCO Engineering, Inc. nor its
849 NW State Road 45	subsidiary companies accept any liability concerning the contents of this document other
Newberry, FL 32669	than forced by law. Reproduction of the Certificate (with Annex) in full is allowed.
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(Certificate No. 0955.02)	







# EU – TYPE EXAMINATION CERTIFICATE E1177-221586

Date: February 4, 2022

## PRODUCT SPECIFICATIONS

Intended Use / Category		Non – Specific Short Range Devices (Bluetooth LE)
RF output power	V	5.00 dBm (EIRP)
Frequency range (MHz)	3	2402 – 2480
Modulation		GFSK
Antenna type		Internal antenna

According to the Technical Documentation compiled by the Manufacturer, the following standards were used:

## ESSENTIAL REQUIREMENTS

<b>Essential Requirement</b>	Standard Number & Version
Radio (Article 3.2) :	EN 300 328 V2.2.2
EMC (Article 3.1b) :	EN 55032:2015+A11:2020
	EN 55035:2017+A11:2020
	EN 55035:2017
	EN IEC 61000-3-2:2019
	EN 61000-3-3:2013/A1:2019
	EN 301 489-1 V2.2.3
	EN 301 489-17 V3.2.4
Health (Article 3.1a) :	EN 62479:2010
Safety (Article 3.1a) :	EN IEC 62368-1:2020+A11:2020
	EN 62368-1:2014+A11:2017

#### TECHNICAL DOCUMENTATION

Item	Exhibit Description	
1.	Copy of the Declaration of Conformity (Draft acceptable)	V
2.	RED 10(10): Pictogram exhibit of the packaging or a Letter of Attestation and/or exhibits explaining compliance with Article 10(10). A draft pictogram is acceptable.	
3.	Operational Description and Circuit Description of the product/device, where applicable.	
4.	External Photos of the device	$\square$
5.	Internal Photos of the device	☑
6.	User manual and information and installation instructions	Ø
7.	Schematic drawings	V
8.	Block Diagrams	V
9.	Risk Assessment. RED Annex III module B - Analysis and assessment of the risk(s) (See TGN 30 for guidance)	☑
10.	If Applicable: Modification/Standard Update/Applicant or Manufacturer info change letter explaining the changes to the existing version of the product along with supporting exhibits (e.g., photos, schematics, new applicant details, etc.) Applicable for Product Modifications, Applicant Name Change, Add Model, and Standard Update.	

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Item		Exhibit Description (Cont.	.)		
11.	If Applicable: Previous Copy of the EU/UK-type examination certificate and annexes as delivered by other notified bodies involved in the conformity assessment (e.g., original certificates in case of product modifications, modules certificates, etc.) Where applicable.				
12.	Test Reports			$\square$	
	Radio / EMC / Health / Safety	Test Report Number	Issue Date/ Rev. No		
	Radio	DRTKCET2112-0520	Dec. 16, 2021 / 00		
	Radio	ETLT180307.0035	Apr. 06, 2018 / 00		
	Radio	ICRT-TR-E210586-0A	Mar. 15, 2021 / 00		
	Health	DRTKCET2112-0521	Dec. 16, 2021 / 00		
	EMC	DREKCEE2112-0705	Dec. 13, 2021 / 00		
	EMC	DREKCEE2112-0704(1)	Jan. 27, 2022 / 01		
	Safety	DRSCEL2201-0005	Jan. 18, 2022 / 00		

This certificate is issued under the following additional and non-exhaustive list of provisions of the Radio Equipment Directive (2014/53/EU) of the European Parliament and the Council of the European Union: 1. Article 10(1): When placing their radio equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the essential requirements set out in Article 3. 2. Article 10(2): Manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum. 3. Article 10(4): Manufacturers 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 apparatus has been placed on the market. 4. Article 10(5): Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in radio equipment design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of radio equipment is declared shall be adequately taken into account. When deemed appropriate with regard to the risks presented by radio equipment, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of nonconforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring. 5. Article 10(6): Manufacturers shall ensure that radio equipment which they have placed on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the radio equipment does not allow it, that the required information is provided on the packaging, or in a document accompanying the radio equipment. Article 10(7): Manufacturers shall indicate on the radio equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where the size or nature of radio equipment does not allow it, on its packaging, or in a document accompanying the radio equipment. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities. Excerpts from Blue Guide: If the manufacturer (declaring himself as a manufacturer by putting his name and address on the product) is **outside the EU** and the products are placed on the Union market by an importer, the product will bear two addresses; the one of the manufacturer and the one of the importer. Indicate the following three elements: his (1) name, (2) registered trade name or registered trade mark and (3) a single contact postal address at which they can be contacted on the product or when not possible because of the size or physical characteristics of the products, on its packaging and/or on the accompanying documentation. The single contact point may not necessarily be located in the Member State where the product is made available on the market. (Notes: However, if the importer acts as the manufacturer's Authorised Representative, then only the importer's address is required on the product.) If the original manufacturer is outside the EU and the importer places the product on the market under his own name or trademark or modifies the product already placed on the market (in such a way that compliance with the applicable requirements may be affected), the importer is considered the manufacturer. The only address that in this case will figure on the product (or packaging or accompanying document) is the address of the importer who is considered as the manufacturer. If the manufacturer is within the EU, the product will bear only one (manufacturer's) address as there is no importer involved. If the manufacturer is within the EU (a company located in the EU declaring itself to be a manufacturer by putting its name and address on the product) although the products are manufactured outside the EU, that company is considered to be the manufacturer who places the product on the Union market, even if actual importation is done by another company. In this case there is no importer in the meaning of the importer's definition and it is sufficient to put only the manufacturer's address.

7. Article 10(8): Manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The following information shall also be included in the case of radio equipment intentionally emitting radio waves:

(a) frequency band(s) in which the radio equipment operates;

(b) maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

8. Article 10(9): Manufacturers shall ensure that each item of radio equipment is accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity. Where a simplified EU declaration of conformity is provided, it shall contain the exact internet address where the full text of the EU declaration of conformity can be obtained. The simplified EU declaration of conformity is to be placed in the user's manual:

Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:xxxxx

- 9. Article 10(10): In cases of restrictions on putting into service or of requirements for authorisation of use, information available on the packaging shall allow the identification of the Member States or the geographical area within a Member State where restrictions on putting into service or requirements for authorisation of use exist. Such information shall be completed in the instructions accompanying the radio equipment. The Commission may adopt implementing acts specifying how to present that information. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 45(2).
- 10. Article 10(11): Manufacturers who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the radio equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market to that effect, giving details, in particular, of the non-compliance, of any corrective measures taken and of the results thereof.
- 11. **Article 10(12):** Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the radio equipment with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have placed on the market.
- 12. **Article 19(2):** On account of the nature of radio equipment, the height of the CE marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.
- 13. **Article 20(1):** The CE marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the nature of radio equipment. The CE marking shall also be affixed visibly and legibly to the packaging.
- 14. **Annex III Module B, Point 7, Declaration of Conformity:** 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.
- 15. **Annex VI Declaration of Conformity, Point 8:** Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity
- 16. **Product Specifications:** The antenna gain and any other data is provided by the applicant.