

MANUFACTURER'S DECLARATION OF CONFORMITY

We: Keiser Corporation
2470 South Cherry Avenue
Fresno, CA 93706
United States

Declare under our own responsibility that the product(s) manufactured after the date below:

Product Name: M3i Series Total Body Trainer Bike
Models Number(s): 005510BBC, 005510XXC, 005512BBC, 005512XXC
Risk Classification: Class I (as defined by Annex VIII of MDR (EU) 2017/745)

to which the declaration refers, conform to the APPLICABLE EUROPEAN DIRECTIVES:

93/42/EEC: Medical Device Directive
2014/53/EU: Radio Equipment Directive
2014/30/EU: Electromagnetic Compatibility Directive
2001/95/EC: General Product Safety Directive
2011/65/E: Restriction of Hazardous Substances Directive

for those application areas where this marking is mandatory and according to the APPLICABLE STANDARDS:

EN 60601-1-2:2015: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests IEC 60601-1-2:2014
EN 60601-1: 2005 +A1:2013: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN ISO 20957-1:2013: Stationary training equipment – Part 1: General safety requirements and test methods
EN 957-10:2005: Stationary training equipment – Part 10: Exercise bicycles with a fixed wheel or without freewheel, additional specific safety requirements and test methods
EN 300.328 V2.1.1: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301.489-17 V3.2.0: Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 50581:2012: Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

EC Representative: Keiser UK Ltd.
Unit 3, Hampton Industrial Estate
Hampton St., Tetbury
Gloucestershire, GL8 8LD
United Kingdom

We have an internal production control system that ensures compliance between the manufactured product(s) and the technical documentation.

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directives and Standards.

Authorized Signature: _____

Dennis L. Keiser
President, Keiser Corporation
2470 South Cherry Avenue
Fresno, CA 93706
United States



Year in which CE marking was affixed: 2020