



MANUFACTURER'S DECLARATION OF CONFORMITY

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

Declare under our own responsibility that the products manufactured below:

Product Name: Functional Trainer
Models Numbers: 003020BP, 003020XA, 003020XP, 003020XS
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
2014/30/EU: Electromagnetic Compatibility Directive
2011/65/EU: Restriction of Hazardous Substances Directive

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

EN 60601-1: 2005 +A1:2013: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
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
(Group 1, Class B)
EN / ISO 20957-1:2013: Stationary training equipment – Part 1: General safety requirements and test methods
EN 957-2:2003 Rev. 01:2015: Stationary training equipment – Part 2: Strength training equipment, additional specific safety requirements and
test methods
EN / ISO 14971:2009: Medical devices – Application of risk management to medical devices
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 products 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 & CEO, Keiser Corporation
2470 South Cherry Avenue
Fresno, CA 93706
United States



Year in which CE Mark was
affixed: 2016