

## 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: Air 350 Biaxial Upper Back

Models Numbers: 002035BP, 002035PP, 002035PS, 002035SP

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 EUROPE SP. Z O.O.

ul. Starodworska 1  
Gdańsk 80-137  
Polska

*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: 2020