

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 250 Lower Back

Models Numbers: 002821BP, 002821PP, 002821PS, 002821SP

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