ARMOCON TECHNOLOGY

Suzhou Armocon Technology Co., Ltd.

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EC Declaration of Conformity

In accordance with EN ISO 17050-1:2004

We: Suzhou Armocon Technology Co., Ltd.

of: 3-5/F No. 77 SuHong Middle Road SIP Jiangsu China 215027

in accordance with the following Directive(s)

2014/30/EU	The Electromagnetic Compatibility Directive (EMC)
2011/65/EU	Restriction of Hazardous Substances (RoHS)
2012/19/EU	Waste Electrical and Electronic Equipment Directive (WEEE)
2014/35/EU	The Low Voltage Directive (LVD)
93/42/EEC (Including 2007/47/EC)	Medical Devices Directive
ISO10993-5/10	Biological evaluation of medical device
IEC 60529	Degrees of protection provided by enclosures (IPX7)
UN38.3	Transportation testing for Lithium Batteries (Safe AIR transport)

hereby declare that:

Product description: Personal Pelvic Trainer
Branded: Intimina
Model No: Kegelsmart 2
Classification: Class I, Rule 5, transient use, Rule 12

Is in conformity with the applicable requirements of the above directives and the following documents

Ref. No.	Title	Edition/date
EN 55014-1	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Emission (EMC)	2021
EN 55014-2	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Immunity. Product family standard (EMC)	2021
EN 61000-3-2	Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	2019
EN 61000-3-3	Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection	2013
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
ISO 10993-10	Biological evaluation of medical devices - Part10: Test for irritation and skin	2002

	sensitization	
IEC 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	2020
IEC 60601-1-2:2015	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance	2020
IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2020
IEC 60601-1-11:2015	General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2020
IEC 60335-2-32	Safety of household and similar electrical appliances Part 2: Particular requirements for massage appliance	2003
EN IEC 63000:2018	Harmonized Standard to Demonstrate RoHS Compliance	2018
EN 50419	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)	2006
IEC 60529	Declaration to IPX7	2013
MSDS	Lithium Ion Battery	2016
UN38.3	Test procedure Test T.1 - Altitude Simulation Test T.2 - Thermal test Test T.3 - Vibration Test T.4 - Shock Test T.5 - External Short Circuit Test T.6 - Impact/Crush Test T.7 - Overcharge Test T.8 - Forced Discharge	2017

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directives.

Signed:

Name: Michael Duff

Position: Engineering Director

Date: 2025 -05- 15