

EU DECLARATION OF CONFORMITY



**European Directive or Regulation:
MDR 2017/745**

Chiaro Technology Ltd, 63-66 Hatton Garden, London, EC1N 8LE United Kingdom, hereby declares under its sole responsibility that:

Product Name:	Chiaro, Elvie, Pelvic Trainer for Personal Use
Model Number(s):	EL01
UDI-DI	(01) 05060442520004
Classification (Annex VIII):	Class I, Rule 5
UMDNS Code/GMDN Code:	None

EU Authorised Representative:	AR Experts B.V, Amerlandseweg 7, 3621 ZC Breukelen, The Netherlands
Conformity Assessment Route:	Chiaro Technology Ltd uses the following procedures for the CE-Labeling of their products according to the Regulation MDR 2017/745: Class 1: Self-certification in addition to Maintenance of Technical Documentation according to Annex II & III.

This declaration of conformity is issued under the sole responsibility of Chiaro Technology Limited. We hereby declare that the medical device specified above meets the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

Hereby declare that:

Equipment: Chiaro, Elvie, Pelvic Trainer for Personal Use
is in conformity with the applicable requirements of the following documents:

Ref No.	Title	Edition/Date	Evidence
2014/30/EU	Directive 2014/30/EU on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 2004/108/EC	2016	See below
2011/65/EU	Directive 2011/65/EU on the restrictions of the use of hazardous substances in electrical and electronic equipment (recast)	2011	CX/2015/50129 / RPT-000865
2006/66/EC	EU Battery Directive	2006	CX/2015/50129 / RPT-000865
2012/19/EU	Directive 2012/19/EU on waste of electrical and electronic equipment (WEEE)	2012	CW/2015/50010 / RPT-000863
BS EN 60601-1	Medical Electrical Equipment Part 1: General Requirements of Safety	2006	TRA-057336-34-00A
ISO10993-5	Biological evaluation of medical device Part 5: Test in vitro cytotoxicity	ISO10993-5 2009	RPT-000964
ISO10993-10	Biological evaluation of medical device Part 10: Test for irritation and skin sensitization	ISO10993-10 2010	RPT-000965, RPT-000966
EN300328	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems	V2.2.2 / Jul 2019	ER332245-12 / RPT-000857
EN300330	SRDs; Technical characteristics and test methods for radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz.	EN300330-2 v1.5.1/Jul.23,2015 EN300330-1 v1.7.1/Jul.23,2015	ER552245-02 / RPT-000860

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Ref No.	Title	Edition/Date	Evidence
EN301489-1	Electromagnetic Compatibility And Radio Spectrum Matters (Erm) - Electromagnetic Compatibility (Emc) Standard For Radio equipment and services	V1.92, Jul.23, 2015	ER552245-09 / RPT 000859
EN301489-3	Electromagnetic Compatibility And Radio Spectrum Matters (Erm) - Electromagnetic Compatibility (Emc) Standard For Radio equipment and services. Specific conditions for Short-Range Devices (SRD)	V1.6.1/Jul.23, 2015	ER552245-09 / RPT 000859
EN301489-17	Electromagnetic Compatibility And Radio Spectrum Matters (Erm) - Electromagnetic Compatibility (Emc) Standard For Radio equipment and services. Specific conditions for Broadband Data Transmission Systems	V2.2.1/Jul.23, 2015	ER552245-09 / RPT 000859
IEC 62133:2012	Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	IEC62133B, #SZES150800277201 / Sep 06, 2015	FI-18853 / SZES150800277201
IEC60529	Protection provided by enclosures (IPX7)	IEC60529(2013)/Jan 27,2105	#SHIN1501003227MR / RPT-000873
EN55022/24	The measurement of the levels of spurious signals generated by the ITE	V.2010/Jul.23, 2015	EW552245-09 / RPT-000859
EN60950-1	Information technology equipment – Safety	V.A1/Jul.23, 2015	L552245L183 / RPT-000867
EN62311	Assessment Of Electronic And Electrical Equipment Related To Human Exposure Restrictions For Electromagnetic Fields	2008	EA552245-04 / RPT-001709
EN62479	Assessment of the compliance of low power electronic and electrical equipment	V2010/Jul.23, 2015	EA552245 / RPT-000874
EN301489	Electromagnetic compatibility and Radio spectrum Matters (ERM)	EN301489-1, EN301489-3, EN301489-17	EW552245 / RPT-000859
REACH.	SVHC of the REACH Regulation	V1907/2006(2014/12/17)_2015/5/29	CR/2015/50042 & CR/2015/50043 / RPT-000864

IDENTIFICATION CLASS I:

LEGAL MANUFACTURER:

Chiaro Technology Ltd
63-66 Hatton Garden, London, EC1N 8LE

Signed for and on behalf of:

Place of issue: London
 Date of issue: 19th April 2023
 Date of expiry: 18th April 2024
 Name: Alastair Traquair
 Position: Director of Quality and Regulatory Compliance
 Signature: *Alastair Traquair*