



2nd Floor, 63-66 Hatton Garden, London - EC1N 8LE
Tel: +44 (0) 203 745 5201

DECLARATION OF CONFORMITY
IN ACCORDANCE TO THE EU REGULATION SET OUT IN THE RADIO EQUIPMENT DIRECTIVE (2014/53/EU)

MANUFACTURER:	Chiaro Technology Ltd, 63-66 Hatton Garden, London, EC1N 8LE
MHRA Registration.	6905
Device Name:	Chiaro, Elvie, Powered Breast Pump
Model Number:	EP01
EC REP	AR Experts, P.O. Box 5047, 3620 AA Breukelen, The Netherlands

We, Chiaro Technology Ltd., hereby declare that the stated device meets the transposition IN ACCORDANCE TO THE EU REGULATION SET OUT IN THE RADIO EQUIPMENT DIRECTIVE (2014/53/EU)

Hereby declare that:

Equipment: Chiaro, Elvie, Powered Breast Pump

is in conformity with the applicable requirements of the following documents:

Ref No.	Title	Edition/Date
ISO10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	ISO10993-1:2009
ISO10993-5	Biological evaluation of medical device Part 5: Tests for in vitro cytotoxicity	ISO10993-5:2009
ISO10993-10	Biological evaluation of medical device Part 10: Test for irritation and skin sensitization	ISO10993-10:2010
IEC 60601-1	Medical electrical Equipment Part 1: General requirements for basic safety and essential performance	IEC 60601-1:2005, 06-07-2018
IEC 60601-1-11	Part 1-11: 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	IEC 60601-1-11:2015, 06-07-2018
IEC 60601-1-2	Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2:2014, 29-06-2018
IEC 62133	Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	IEC 62133:2012 (Second Edition)
IEC 60529	Protection provided by enclosures (IPX7)	IEC 60529:2013
RoHS	RoHS Directive (EU)	2015/863 amending 2011/65/EU
ISTA 3A	Packaging Performance Test	ISTA 3A: 2018
WEEE	WEEE Directive	WEEE 2nd Category
2017 No. 1206	Radio Equipment Regulations 2017	2017 No. 1206/ 2017

www.chiaro.co.uk

Registered company name - Chiaro Technology Ltd
Company No. 08502405 registered in England and Wales
VAT Reg. GB 172 6300 28

CHIARO

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IDENTIFICATION CLASS :  R.E.D

LEGAL MANUFACTURER : Chiaro Technology Ltd,
63-66 Hatton Garden, London, EC1N 8LE
MHRA Registration: 6905

Singed for and on behalf of: Chiaro Technology Ltd.

Place of Issue: London

Date of Issue: 20 Jul 2021

Name: Alastair Traquair

Position: Head of Quality

Signature: *Alastair Traquair*

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